The Secretary Ministry of Health & Family Welfare, Govt. of India, Nirman Bhawan, New Delhi-110011.

<u>Subject</u>: Submission of report by Expert Committee in respect of FDCs categorized under category 'a' for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Sir,

This has reference to Ministry of Health and Family Welfare order No. X11035/53/2014-DFQC dated: 16.09.2014 whereby the Ministry has constituted the Committee under the Chairmanship of Prof. C.K. Kokate, VC, KLE University, Belgaum with the approval of Hon'ble Minister of Health and Family Welfare, Government of India.

As desired in meeting held in the Ministry on 04.03.2015, the evaluation of 963 FDCs categorized under **category** 'a' was deliberated by the Expert Committee in series of meetings and elaborative reasons were mentioned for each FDC.

The detailed report is enclosed, alongwith, Minutes of the Meetings as Annexures.

We acknowledge with thanks the support received from Dr. G.N. Singh, DCG (I) and his colleagues at CDSCO.

(Prof. C.K. Kokate)

Vice-Chancellor, KLE University,

Belgaum, Karnataka.

# REPORT OF EXPERT COMMITTEE

## ON

Applications of Fixed Dose Combinations (FDCs) received by CDSCO for proving safety and efficacy categorized under category 'a'

# CENTRAL DRUGS STANDARD CONTROL ORGANIZATION DIRECTORATE GENERAL OF HEALTH SERVICES MINISTRY OF HEALTH & FAMILY WELFARE GOVT. OF INDIA

Date: 16th April, 2015

### **PREFACE**

The meeting of Expert Committee on Fixed Dose Combinations was aimed to screen the drug combinations based on rationality, safety and efficacy. For this, Ministry of Health and Family Welfare vide order no X11035/53//2014-DQC dated: 16.09.2014 constituted an Expert Committee under the chairmanship of Prof. C.K.Kokate,Vice-Chancellor, KLE University,Belgaum, Karnataka with the following members:

- Prof. (Dr.) Chandrakant Kokate (Chairman)
- Prof. C.L. Kaul, Ex-Director, NIPER (Mohali)
- Dr. C.D Tripathi Safdarjung Hospital
- Dr. Bikash Medhi,PGI Chandigarh
- Dr. Sanjeev Sinha, AIIMS
- Prof. Sanjay Singh, BHU
- Dr. R.K. Khar, Frmer Dean and Head, Jamia Hamdard, New Delhi

All the members are experts of their respective fields and from esteemed Institutes. The Committee has done an extensive work related to work assigned and tried to take decision on the basis of published literature and the evidence based search as follow:

- Pubmed, EMBASE, Cochrane and other libraries, different jurnals and website has been searched for references.
- Disscusion with clinician and expert of the respective field
- National and international standerd treatment guidelines have been considered for the same.

Total 6220 application were received by CDSCO. Out of 6220 applications, 702 applications (11.29%) were not evaluated by the committee due to the reasons as under:

- 40 applications belonged to Single drug formulations,
- 294 applications fall under 294 category,
- 73 applications were Veterinary products
- 295 applications were already discussed by 10 Expert Committees

The remaining applications were examined by the Committee which were categorized as "category "a, b, c and d" based on the evidence and scientific rational. The break up of these applications of FDCs as recommended by the Committee is as under:

- 963 applications considered as category "a" i.e. FDCs considered Irrational (15.48%)
- 1629 applications considered as category "b" i.e. FDCs considered for further deliberation with Expert Committees (26.18%)
- 2617 applications considered as category "c" i.e. FDCs considered as Rational (42.07%)
- 309 applications considered as category 'd' i.e. FDCs needs further generation of Data (4.96%)

As per directions of Ministry of Health and Family Welfare, 963 applications (15.48%) of FDCs categorized under category 'a' were discussed again by the Committee and elaborative reasons with justification were given against each FDC. The minutes of the meetings conducted by the Committee on 7.4.2015 to 8.4.2015 and 16.4.2015 as well as detailed recommendations are annexed as **Annexure A**. List of Standard Text Books referred by the committee for completion of the assigned task is annexed as **Annexure B** and brief details with respect to the members of the Expert Committee are annexed as **Annexure C**.

**Chairman and Members of Expert Committee** 

Minutes of the Meeting of Expert Committee held on 7.4.2015 to 8.4.2015 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

### Members present:

- 1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
- 2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard - Member
- 3. Dr. C. D. Tripathi, Director-Professor & HOD (Pharmacology), VMMC and Safdarjung Hospital, New Delhi - Member
- 4. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
- 5. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi Member
- 6. Dr. Sanjeev Sinha, Addl. Prof. (Deptt. of Medicine), AIIMS, New Delhi Member
- 7. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi Member

The Chairman welcomed the members of Expert Committee for its seventh meeting organized to advise DCG(I) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I).

The Chairman briefed the members regarding the meeting held with the Secretary (Health) on 4.3.2015. He informed that Secretary (Health) in the said meeting requested the Committee to further discuss FDCs of category 'a' and give more elaborative reasons.

All the FDCs under category "a" were discussed thoroughly one by one in detail and elaborated reasons were mentioned against each FDC.

The Committee adopted the blinding procedure for evaluation of FDCs and members signed the "No Conflict of Interest undertaking.

The Committee prepared the detailed report in respect of the FDCs categorized under category "a" for further submission to the Ministry of Health and Family Welfare which is annexed herewith.

The meeting ended with the vote of thanks to the chair.

(Dr. C. D. Tripathi)

(Prof. C.K. Kokate) (Dr. C. L. Kaul) (Dr. C. D. Tripathi)

(Dr. Bikash Medhi) (Prof. Sanjay Singh) (Dr. Sanjeev Sinha) (Dr. R.K. Khar)

Minutes of the Meeting of Sub-Group of Expert Committee held on 16.04.2015 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

### Members present:

- 1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
- 2. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
- 3. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh-Member
- 4. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi Member

As desired by the Dr. C.K. Kokate, Chairman of the Expert Committee, a meeting of the sub-group was conducted for examining the proposals categorized under category "a" for compiling, reviewing and further corrections, if any.

The group reviewed again each proposal in respect of elaborative reasons, its correctness etc. and made necessary corrections wherever required. The Committee used various standard text books, Medical and Pharmaceutical journals, National and International, Guidelines, CIMS/MIMS etc., as well as, their knowledge in present scenario for doing this exercise. The sub-group also arranged and compiled the whole report for onward submission to the Ministry.

The sub-group adopted the blinding procedure as per SOP for reviewing the FDCs. The Committee members also signed no Conflict of Interest.

The meeting ended with the vote of thanks to the Chair.

(Prof. C.K. Kokate) (Dr. C. D. Tripathi) (Dr. Bikash Medhi)

|    |   | proving safe         | ety and efficac          | spect of applications of FDCs received by the O/O DCG(I) for y categorized under <i>category "a"</i>   |
|----|---|----------------------|--------------------------|--|
| 0. | Name of FDC   | Strength             | Dosage Form              | Categorization of the FDC by the Experts Committee as per Terms of references  |
| 1  | Nimesulide BP + Tizanidine HCL IP Eq. to Tizanidine           | 100                  | Dispersible<br>tablets   | a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule.  Rayasam SP et al., Int J Basic Clin Pharmacol. 2013 Aug; 2(4): 452-457.  |
| 10 | Aceclofenac<br>IP+Paracetamol<br>IP+Rabeprazole<br>Sodium IP  | 100mg+325<br>mg+10mg | Enteric Coated tablets   | <ul> <li>a,</li> <li>1. There is pharmacokinetics incompatibility among the three drugs, as the dosing intervals are BD for aceclofenac, OD for rabeprazole and TDS/QID for paracetamol.</li> <li>2. The FDC is not approved anywhere in the world</li> <li>3. The literature regarding safety and efficacy of this combination is not available in Pubmed &amp; Google scholar</li> </ul>   |
| 11 | 2 Nimesulide BP + Diclofenac Sodium II                        |                      | Soft Gelatin<br>Capsules | a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. No additional advantage but hepatotoxic potential of nimesulide and adverse effects add up. 3. Pharmacodynamically irrationale FDC as both have same mechanism of action (both drugs acting on the same enzyme). Thus, combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 795–796.  Kasarla Raju, A. Elumalai2, Eddla Srid, IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2  2013   52-56.  |
|    | 13 Nimesulide BP + Cetirizine HCL IP+Caffeine IP              | 100mg+5m<br>+30mg    | ng Tablets               | <ul><li>a,</li><li>1. Nimesulide in combination has potential of misuse in indications for allergic conditions.</li><li>2. Nimesulide has documented safety concern.</li></ul>   |
|    | 16 Nimesulide<br>+Tizanidine                                  | 100mg+2n             | ng Tablets               | <ul> <li>a,</li> <li>1. Nimesulide in combination form has potential of misuse.</li> <li>2. The FDC is pharmacokinetically incompatible as both have different dosing schedule.</li> <li>3. Safety concern with Nimesulide</li> </ul>  |
|    | 24 Paracetamol + cetrizine hydrochloride + caffeine (anhydrou | 500mg+ 5<br>mg+ 15 m |                          | <ul> <li>a,</li> <li>1. Pharmacokinetic incompatibility, as dosing interval for paracetamol in TDS/QID and for cetrizine it is OD/BD.</li> <li>2. No trial could be found in PUBMED and google scholar.</li> <li>3. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they common contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.</li> <li>Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Disease.</li> <li>4, 73-82.</li> </ul> |

| 29 | Cetirizine Hyrochloride IP+ Nimesulide BP+ Paracetamol+ Phenylephrine hydrochloride+ Caffeine | 5 mg+ 100<br>mg+ 325<br>mg+ 10 mg+<br>25 mg | Tablets                          | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Nimesulide-safety concern.  |
|----|---|---|----------------------------------|---|
|    | 2 °   |   |                                  |   |
| 39 | Paracetamol<br>IP+Caffeine<br>IP+Phenylepherine<br>HCl  | 500mg+32m<br>g+10mg                         | Tablets                          | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of   |
|    |   |   | 5 *                              | Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 42 | Diclofenac Sodium IP<br>+ Tramadol HCL BP<br>+ Chlorzoxazone USP                              | 50mg+37.5<br>mg+250mg                       | film coated<br>tablets           | a, 1. Tramadol is an opoid analgesic with abuse liability. 2. The combination will lead to additive sedation.   |
|    |   |   |                                  | http://reference.medscape.com/drug-interactionchecker.  |
| 43 | Dicyclomine HCl<br>IP+Paracetamol<br>IP+Domperidone BP  | 20mg+500m<br>g+10mg                         | Uncoated<br>Bilayered<br>Tablets | a,  1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity.  2. Combining can result in dangerous elevation of the body temperature.  |
|    |   |   |                                  | Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
| 44 | Paracetamol IP+Domperidone Maleate BP Eq. to  | 500mg+10m<br>g+10mg                         | Uncoated<br>Tablets              | a,  1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity.  2. Combining can result in dangerous elevation of the body temperature.  |
|    | Domperidone+Diclom ine HCL IP   | -   |                                  | Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796 Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| ,  |   |   |                                  |   |
| 49 | Diclofenac Sodium IP+Paracetamol IP+Magnesium Trisilicate IP+Chlorpheniramine Maleate IP      | 50mg+325m<br>g+100mg+4<br>mg                | Uncoate Tablets                  | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal).  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.   |
|    |   |   | (*)                              |   |

| Nimesulide<br>BP+Paracetamol IP                                      | 100mg/100<br>mg+500mg/<br>325mg  | Dispersible<br>tablets/Uncoate<br>d tablets  | a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. There are safety concerns with nimesuilide FDC with paracetamol. 2. Dose of paracetamol 500mg not approved in FDC with NSAIDs  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796  |
|--|--|--|--|
| Aceclofenac+<br>Paracetamol+<br>Rabeprazole                          | 100mg+<br>325mg+<br>10mg   | Capsules   | a, 1. There is pharmacokinetics incompatibility among the three drugs, as the dosing intervals are BD for aceclofenac, OD for rabeprazole and TDS/QID for paracetamol. 2. The FDC is not approved anywhere in the world 3. The literature regarding safety and efficacy of this combination is not available in Pubmed & Google scholar  |
| Nimesulide+<br>Serratiopeptidase                                     | 100mg/100<br>mg+10mg/1<br>5mg  | Tablets  | a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  |
| Diclofenac sodium+<br>Paracetamol+<br>Chlorpheniramine+<br>Magnesium | 50mg+<br>500mg+<br>4mg+<br>100mg   | Tablets  | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). 2. dose of paracetamol is high. Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.   |
| Paracetamol + Phenylephrine HCl + Caffeine                           | 500mg<br>+10mg +<br>32mg   | Oral Tablets   | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.  |
| Acetaminophen + Nimeusulide + Chlorzoxazone USP                      | 325mg+100<br>mg+250mg  | Uncoated<br>Tablets  | a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. Pharmacodynamically irrationale FDC as two ingredients have same mechanism of action.   |
| 4 Diclofenac<br>Sodium+Tramadol<br>HCL+Paracetamol IP                | 50mg+37.5<br>mg+325mg  | Film Coated<br>Tablets   | a, 1.Tramadol is itself a potent opoid analgesic. FDC is not rational as addition of Paracetamol and Diclofenac will not provide any additional benefit.   |
|  | Aceclofenac+ Paracetamol+ Paracetamol+ Rabeprazole  Nimesulide+ Serratiopeptidase  Paracetamol+ Chlorpheniramine+ Magnesium  Phenylephrine HCl + Caffeine  Acetaminophen + Nimeusulide + Chlorzoxazone USP | Aceclofenac+ Paracetamol IP  Aceclofenac+ Paracetamol+ Rabeprazole  Diclofenac sodium+ Serratiopeptidase  Diclofenac sodium+ Serratiopeptidase  Diclofenac sodium+ Paracetamol+ Chlorpheniramine+ Magnesium  Diclofenac sodium+ Serratiopeptidase  Somg+ Som | Aceclofenac+ Paracetamol P  Aceclofenac+ Paracetamol+ Rabeprazole  Nimesulide+ Serratiopeptidase  Diclofenac sodium+ Paracetamol+ Chlorpheniramine+ Magnesium  Diclofenac sodium+ Paracetamol+ Chlorpheniramine+ Magnesium  Somg+ Somg+ Somg+ Hoomg  Tablets  Tablets  Tablets  Oral Tablets  Acetaminophen + Nimeusulide + Chlorzoxazone USP  Diclofenac Sodium+Tramadol  Diclofenac Sodium+Tramadol  Somg+ |

| 77  | Acetaminophen<br>IP+Nimeusulide<br>BP+Chlorzoxazone<br>USP                 | 325mg+100<br>mg+250mg   | Uncoated<br>Tablets   | a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. Pharmacodynamically irrationale FDC as two ingredients have same mechanism of action.   |
|-----|--|---|-----------------------|--|
| 82  | Diclofenac<br>potassium+<br>paracetamol +<br>chlorzoxazone +<br>famotidine | 50 mg+ 325<br>mg+ 250<br>mg+ 20 mg  | tablets               | <ul><li>a,</li><li>1. Pharmacodynamic irrelevant as each ingredient has different dosing shedule/dosing requirement.</li><li>2. FDC will lead to misuse and toxicity.</li></ul>  |
| 85  | Serratiopeptidase + nimesulide   | 15 mg+ 100<br>mg  | Tablets               | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide   |
| 91  | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Caffeine IP                      | 500mg/325<br>mg+10mg/5<br>mg+32mg/3<br>0mg  | Tablets               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 98  | Paracetamol IP + DL-<br>Methionine BP                                      | 500mg/650<br>mg/1000mg/<br>125mg/250<br>mg/100mg+<br>50mg/50mg/<br>100mg/12.5<br>mg/25mg/10<br>mg | Tablets               | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.   |
| 116 | Serratiopeptidase + nimesulide   | 10 mg+<br>100mg   | tablets               | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796. |
| 123 | Nimesulide +<br>serratiopeptidase  | 100mg+ 15<br>mg   | film coated<br>tablet | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796. |

| 133 | Paracetamol<br>IP+Diclofenac<br>Potassium<br>BP+Famotidine IP         | 500mg+50m<br>g+20mg                     | Film Coated<br>Tablets | a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse. 2. Paracetamol dose is high 3. Both diclofenac and paracetamol hepatotoxic 4. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
|-----|---|---|------------------------|--|
| 166 | Paracetamol<br>IP+Caffeine<br>IP+Codeine<br>Phosphate IP              | 325mg+15m<br>g+5mg                      | Uncoated<br>Tablets    | a, Pharmacodynamically irrelevant.  1. Close Monitoring is required as codeine increases and caffeine decreases sedation.  2. Effect of interaction is not clear, Potential for drug-drug interaction.  3. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  http://reference.medscape.com/drug-interactionchecker.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
| 173 | B Paracetamol IP+Diclofenac Potassium BP+Famotidine IP                | 500mg+50m<br>g+20mg                     | Tablets                | a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse. 2. Paracetamol dose is high 3. Both diclofenac and paracetamol hepatotoxic 4. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 18  | 7 Nimesulide + Pitofenone HCL+ Fenpiverinium bromide + benzyl alcohol | 100mg +<br>2mg +<br>0.02mg +<br>4.0%v/v | Injection              | a, 1.There are no evidences on safety and efficacy of the FDC. 2. Safety concern with nimesulide   |

| 199 | Omeprazole Magnesium USP eq. to Omeprazole + Paracetamol IP+ Diclofenac Potassium                             | 10mg+<br>500mg<br>+50mg            |                          | a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse. 2. Paracetamol dose is high 3. Both diclofenac and paracetamol hepatotoxic 4. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
|-----|---|------------------------------------|--------------------------|---|
| 202 | Nimesulide BP +<br>Paracetamol IP   | 30mg+195m<br>g                     |                          | a, 1.There are safety concerns with nimesuilide 2. Both ingredients are hepatotoxic   |
| 203 | Paracetamol IP+Phenylephirine HCl IP+ Caffeine IP+Chlorpheniramine Maleate IP                                 | 500mg+5mg<br>+30mg+4mg             | Tablets                  | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 213 | Tamsulosin<br>hydrochloride +<br>diclofenac sodium  | 0.4 mg+ 50<br>mg                   | hard gelatin<br>capsules | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.   |
| 220 | Paracetamol IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Caffeine IP                                  | 325mg+10m<br>g+2mg+30m<br>g        |                          | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 225 | Paracetamol IP+Phenylephirine HCl Ip+Chlorpheniramine Maleate IP+Dextromethorphan Hydrobromide IP+Caffeine IP | 650mg+10m<br>g+4mg+15m<br>g+30mg   | Uncoated<br>Tablets      | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 232 | Diclofenac Potassium<br>BP+Zinc Carnosine   | 50mg+75mg                          | Film Coated<br>Tablets   | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.   |
| 242 | Dextromethorphan<br>HBr + paracetamol+<br>phenyl phrine +<br>chlorpheniramine<br>maleate                      | 15 mg + 650<br>mg+ 10 mg<br>+ 4 mg | uncoated tablet          | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |

|     | dextromethorphân +<br>paracetamol+<br>phenylphrine+<br>chlorpheniramine<br>maleate             | 1 4 6                    | suspension<br>Form | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|-----|--|--------------------------|--------------------|---|
| 249 | Diclofenac sodium +<br>paracetamol+<br>chlorpheniramine<br>maleate + magnesium<br>trisillicate | mg+ 4 mg+<br>100 mg      | tablets            | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal).  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.   |
| 250 | Paracetamol + pseudoephdrine + cetrizine dihydrochloride                                       | 325 mg + 30<br>mg+ 10 mg | film coated tablet | a, 1. Pharmacokinetic incompatibility, as dosing interval for paracetamol is TDS/QID and for cetrizine it is OD/BD. 2. No trial could be found in PUBMED and google scholar. 3. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
| 2   | Phenylbutazone+So<br>um Salicylate   | di 200mg+20mg            | n Injection        | a, 1. Safety not established and FDC has high risk of toxicity 2. There is no synergism when two drugs acting on the same enzyme are combined. Thus combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects 3. Already prohibited in the country for use in human.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  |
|     | 270 Prochlorperazine<br>Maleate+Paracetan  |                          | ng Tablets         | a, Pharmacodynamically irrelevant and overdose dose of Paracetamol.   |
| 40  | 281 Nimesulide+Serra eptidase  | tiop 100mg+1             | 5m Tablets         | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:3795–796.   |

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|                  |   | 00mg+10m F          | ilm Coated                | a,   |
|------------------|---|---------------------|---------------------------|--|
| 288 N<br>B<br>II | 3P+Serratiopeptidase  | g T                 |                           | 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.     |
| 294 5            | - I   |                     | Enteric Coated<br>Tablets | a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected  |
| 3                |   |                     |                           | peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  |
|                  | Nimesulide BP + Pitfenone HCl IP + Fenpiverinium Bromide IP                                   | 100mg+3mg<br>+375mg | Injection                 | a, 1. There are no evidences on safety and efficacy of the FDC. 2. Safety concern with nimesulide  |
|                  | Nimesulide BP+ Serratiopeptidase IP   | 100mg+15m<br>g      | Uncoated<br>Tablets       | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796. |
| 310              | Paracetamol IP + Diclofenac Potassium BP + Chlorpheniramine Maleate IP + Magnesium Trisilicat | mg                  | Uncoated<br>Tablets       | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal).  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
|                  |   |                     |                           |  |

|     | Dicyclomine HCl IP  |   | ablets                 | a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Combining can result in elevation of the body temperature.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
|-----|---|---|------------------------|---|
| 326 | Methionine  | mg/250mg/1 S<br>25mg/250m<br>g/125mg+50<br>mg/50mg/25<br>mg/12.5mg/<br>25mg/12.5m<br>g per 5 ml                 | Suspension             | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.  |
| 339 | Heparin Sodium<br>IP+Diclofenac<br>Sodium IP  | IU+10mg<br>per gm.  | Gel                    | a, Pharmacodynamically irrelevant- Topical use of heparin is irrelevant.  |
| 34: | 2 Glucosamine Sulphate Potassium USP+Methyl Sulfonyl Methane+Vitamin D3 IP+Manganese Sulphate USP eq. to elemental Manganese+Sodium Borate BP eq. to elementaol Boron+Copper Sulpahte USP eq. to elemental Copper+Zinc Sulphat Monohydrate USP eq to elemental Zinc | mg+200<br>IU+9.3mg<br>eq. to<br>3mg+4.4mg<br>eq. to<br>0.5mg+2.0m<br>g eq. to<br>0.5mg+8.24<br>mg eq. to<br>3mg | Film Coated<br>Tablets | a, 1. Pharmacodynamic irrelevant as each ingredient has different therapeutic use. 2. therapeutic efficacy of FDC not established and will lead to misuse.  |
| 3.  | A6 Nimesulide<br>BP+Serratiopeptidase<br>IP   |   | Film Coated<br>Tablets | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  |

| 350 Se |  | 10mg+100m F     | Tablets 1 2 a 3 g p    | Safety concern with nimesulide No evidence to support that Serratiopeptidase offer any particular dvantage over Nimesulide. On the other hand, the patient is exposed to greater risk of astrointestinal (GI) irritation and serious bleeding from unsuspected eptic ulceration.   |
|--------|--|-----------------|------------------------|--|
|        |  |                 | (                      | Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations<br>FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 /<br>195–796.   |
|        | erratiopeptidase<br>P+Nimesulide BP                            | 15mg+100m<br>g  | Tablets                | 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5795–796.   |
|        | Nimesulide<br>BP+Serratiopeptidase<br>IP                       | 100mg+10m<br>g  | Tablets                | a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:2795–796. |
| 386    | Tranexamic Acid BP<br>+ Proanthocyanidin                       | 250mg+100<br>mg | Film Coated<br>Tablets | a,<br>Safety and efficacy of Proanthocyanidin in FDC is not established  |
| 391    | Nimesulide+Serration<br>eptidase EC                            | 0 100mg+15m     | n Tablets              | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65 795–796. |
| 390    | 6 Diclofenac<br>Sodium+Paracetamo<br>+Magnesium<br>Trisilicate |                 | m Uncoated table       | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeu use and FDC will lead to misuse and toxicity (hepato and renal)  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment Common Cold and Flu with Multi-Ingredient Combination Products Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseas 4, 73-82.  |

| -   | Chloride+Lidocaine<br>HCl                                    | 1B                   |                     | a, Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse.   |
|-----|--|----------------------|---------------------|--|
| 440 | Diclofenac Sodium IP+Paracetamol IP+Magnesium trisilicate IP | 50mg+325m<br>g+100mg | Uncoated<br>Tablets | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal).  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.   |
| 445 | Paracetamol IP+DL-<br>Methionine BP                          | 650mg+50m            | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.   |
| 451 | Nimesulide<br>BP+Tizanidine HCl<br>IP                        | 100mg+2mg            | Tablets             | a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule.  Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug; 2(4): 452-457   |
| 45  | Paracetamol IP+Domperidone IP+Caffeine(Anhydrus) IP          | g+50mg               | Uncoated<br>Tablets | a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutiuse and FDC will lead to misuse and toxicity.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 795–796 Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
| 4   | 77 Nimesulide+Tazani<br>ne HCl                               | di 100mg+2r          | ng Uncoated tab     | <ul> <li>a,</li> <li>1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children.</li> <li>2. The FDC is pharmacokinetically incompatible as both have different dosing schedule.</li> <li>Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug; 2(4): 452-45</li> </ul>  |
|     | 481 Ofloxacin+Ornida:  | zole 50mg+12         | 5m Oral Liquid      | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |

| 486 N c | limesulide+Diclofena<br>Sodium   | 100mg+50m s<br>g |                 | Nimesulide in combination has potential of misuse and have documanted safety concern.  No additional advantage but hepatotoxic potential of nimesulide and adverse effects add up.  Pharmacodynamically irrationale FDC as both have same mechanism of action (both drugs acting on the same enzyme). Thus, combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations  (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  Kasarla Raju, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2   2013   52-56. |
|---------|--|------------------|-----------------|---|
| 496     | Serratiopeptidase<br>EC+Nimesulide   | 15mg+100m<br>g   | Tablets         | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  |
| 500     | Ammonium Chloride<br>IP+Sodium Citrate<br>IP+Chlorpheniramine<br>Maleate IP+Menthol<br>IP                                | g+4mg+1.25       | Oral Liquid     | a, 1.Potential of misuse in peadiatric population. 2.Pharmaceutical incompatibility and also the dose of each ingredient is subtherapeutic.   |
| 502     | Paracetamol<br>IP+Prochlorperazine<br>Maleate IP   | 325mg+5mg        | Uncoated tablet | a, 1. Pharmacodynamically irrelevant and subtherapeutic dose of Paracetamol. 2. Both ingredients have different indications.  |
| 50      | 4 3 tablets of Serratiopeptidase (enteric coated 2000 units) IP + Diclofent Potassium BP & 2 tablets of Doxycycli HCL IP | ac               | g Kit           | <ul> <li>a,</li> <li>1.It will lead to antibiotic resistance.</li> <li>2. Documented efficacy of Serratiopeptidase not available.</li> <li>3. May lead to misuse</li> <li>4. Do not offer any particular advantage over the individual drugs. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.</li> <li>Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:2795-796</li> </ul>  |
| 50      | 05 Paracetamol IP+Dextromethorph Hydrobromide IP+Phenylephirine HCl IP+Chlorphenirami Maleate IP                         |                  | m Tablets       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. Paracetamol dose is subtherapeutic.  |

| В   |   | 100mg+10m C                  | 'apsules                      | a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  |
|-----|---|------------------------------|-------------------------------|---|
|     |   |                              |                               | Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.   |
|     |   | · ·                          | 8                             |   |
|     | Nimesulide<br>BP+Paracetamol IP                                       | 50mg+125m S                  | Suspension                    | a, 1.Potential misuse in paediatric population 2.Hepatotoxicity   |
| / 1 | Nimesulide<br>BP+Tizanidine HCl<br>IP                                 | 100mg+2mg ]                  | Film Coated<br>Tablets        | a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule.  Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug;2(4): 452-457   |
|     | Nimesulide<br>BP+Dicyclomine<br>Hydrochloride IP                      | 100mg+10m<br>g/20mg/40m<br>g | Tablet                        | a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutiuse and FDC will lead to misuse and toxicity. 2. Combining can result in elevation of the body temperature.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5795–796  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of |
| 568 | Paracetamol IP+DL-<br>Methionine BP                                   | 125mg+12.5<br>mg             | Uncoated dispersible tablet   | Eccles, R., Fielde, I. and Rose, Ostal Flux with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.  |
| 569 | Diclofenac Sodium<br>IP+Paracetamol<br>IP+Magnesium<br>Trisilicate IP | 50mg+250m<br>g+125mg         | Expectorent (uncoated tablet) | a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutiuse and FDC will lead to misuse and toxicity (hepato and renal).  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases 4, 73-82.  |
| 57  | 7 Aceclofenac<br>IP+Paracetamol<br>IP+Famotidine IP                   | 100mg+500<br>mg+20mg         | Uncoated<br>Tablets           | <ul> <li>a,</li> <li>1. Pharmacodynamic irrelevant as each ingredient has different dosing shedule/dosing requirement.</li> <li>2. FDC will lead to misuse and toxicity.</li> </ul>   |
| 57  | 8 Aceclofenac IP+ Zin<br>Carnosine                                    | c 100mg+75m                  | Film Coated<br>Tablets        | a, There is no therapeutic benefit of adding zinc carnosine in FDC.   |
| 58  | 4 Paracetamol IP+DL-<br>Methionine BP                                 | 650mg+50mg                   | n Tablet                      | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.  |

| IP-<br>BP<br>IP-<br>Ho | +Nimesulide I   |                     | m Coated<br>iblets | <ul> <li>a,</li> <li>1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.</li> <li>2. There is pharmacokinetic incompatibility among the drugs.</li> <li>3.Nimesulide has documanted safety concern.</li> <li>4. Hepatotoxic potential of both the drugs</li> </ul> |
|------------------------|---|---------------------|--------------------|--|
|                        |   |                     |                    | Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4 73-82.   |
| d                      | Paracetamol IP+<br>lisodium Hydrogen<br>Citrate IP + Caffeine<br>IP | 130mg+750<br>mg+5mg | Oral               | <ul> <li>a,</li> <li>Pharmacodynamically irrelevant</li> <li>1. Each ingredient has different therapeutic indication.</li> <li>2. As Urine alkalizer, patients will be unnecessarily exposed to paracetamol and caffeine.</li> </ul>   |
| 598                    | Paracetamol + DL<br>Methionine BP                                   | 125mg+12.5<br>mg    | Suspension         | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.   |
| 599                    | Paracetamol IP+ DL<br>Methionine BP                                 | - 125mg+<br>12.5mg  | Oral<br>Suspension | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.   |
| 600                    | Disodium Hydrogen<br>citrate<br>BP+Paracetamol IP                   | 750mg+125<br>mg     | Oral               | <ul> <li>a,</li> <li>1.Pharmacodynamically irrelevant combination-each ingredient has different therapeutic indication.</li> <li>2.As Urine alkalizer, patients will be unnecessarily exposed to paracetamol.</li> </ul>   |
| 603                    | 2 Paracetamol IP+Di-<br>Sodium Hydrogen<br>Citrate BP               | 120mg+500<br>mg     | Syrup              | <ul> <li>a,</li> <li>1.Pharmacodynamically irrelevant combination-each ingredient has different therapeutic indication.</li> <li>2.As Urine alkalizer, patients will be unnecessarily exposed to paracetamol.</li> </ul>   |
| 60                     | 03 Paracetamol<br>IP+Disodium<br>Hydrogen Citrate                   | 125mg+50<br>mg      | 0 Syrup            | a, 1.Pharmacodynamically irrelevant combination-each ingredient has different therapeutic indication. 2.As Urine alkalizer, patients will be unnecessarily exposed to paracetamol.   |

| E   | Vimesulide BP+Diclofenac Sodium IP   | 12.4                             | Jncoated<br>Fablets              | a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. No additional advantage but hepatotoxic potential of nimesulide and adverse effects add up. 3. Pharmacodynamically irrationale FDC as both have same mechanism of action (both drugs acting on the same enzyme). Thus, combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  Kasarla Raju, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2   2013   52-56. |
|-----|--|----------------------------------|----------------------------------|--|
|     | Paracetamol IP +   | I OOIII                          | Film Coated<br>Tablets           | a, 1. There is pharmacokinetics incompatibility among the three drugs, as the dosing intervals are BD for aceclofenac, OD for rabeprazole and TDS/QID for paracetamol. 2. The FDC is not approved anywhere in the world 3. The literature regarding safety and efficacy of this combination is not available in Pubmed & Google scholar  |
| 627 | Nimesulide<br>BP+Paracetamol<br>IP+Phenylephirine<br>HCl IP+Cetirizine<br>HCl IP+Caffeine IP | 100mg+325<br>mg+5mg+5<br>mg+25mg | Uncoated<br>Tablets              | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 634 | Nimesulide<br>BP+Tizanidine HCl<br>IP eq. to Tizanidine                                      | 100mg+2mg                        | Uncoated<br>Bilayered<br>Tablets | <ul> <li>a,</li> <li>1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children.</li> <li>2. The FDC is pharmacokinetically incompatible as both have different dosing schedule.</li> <li>Rayasam SP et al. Int J Basic Clin Pharmacol. 2013 Aug; 2(4): 452-457</li> </ul>  |
| 63  | 5 Nimesulide+Serration eptidase  | 100mg+15m<br>g                   | n Capsules                       | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.   |
| 64  | Hydrochloride IP + Benzyl Alcohol IP   | 150mg+1.0<br>%+1%v/v             | Injection                        | a, 1.Pharmacodynamically irrelevant FDC. 2.Hypersensitivity to lignocaine is also a safety concern.  |

| , | CAE | Paracetamol IP +  | 325mg+15m U   | Jncoated a                              | a,   |
|---|-----|---|---|---|--|
|   |     | Caffeine (Anhydrous) IP + Codeine   | g+5mg   | Tablets   I                             | Pharmacodynamically irrelevant.  1. Close Monitoring is required as codeine increases and caffeine decreases sedation.   |
|   | ×   | Phosphate IP  |   | 9                                       | 2.Effect of interaction is not clear, Potential for drug-drug interaction. 3. An important safety debate concerning multi- ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. |
|   |     |   |   |   | httn://reference.medscape.com/drug-interactionchecker  |
|   | 652 | Aceclofenac IP (SR) +<br>Paracetamol IP   | mg  | bilayered<br>modified<br>release tablet | a, 1.Pharmocokinetic incompatibility-dosing shedule of aceclofenac (SR) and paracetamol are of different duration  |
|   | 658 | Zinc<br>Carnosine+Aceclofen<br>ac IP  | mb  | Tablets                                 | a, There is no therapeutic benefit of adding zinc carnosine in FDC.  |
|   | 683 | Diclofenac Sodium IP+ Paracetamol IP & Inactive Polyethylene Glycol 400 USNF+ Lignocaine HCl IP+ Benzyl Alcohol IP (preservative)+ Sodium Metabisulphate IP | 25mg +<br>75mg &<br>565.53mg<br>10mg 1.0%<br>w/v+ 1mg | Injection                               | a, Hypersensitivity reaction with lignocaine.  |
|   | 690 | Ofloxacin<br>IP+Ornidazole IP   | 500mg+125<br>mg per 5ml                               | Oral suspension                         | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.   |
|   | 69  | 9 Cefixime IP As<br>Trihydrous Eq. to<br>Anhydrous<br>Cefixime+Linezolid  | 200mg+600<br>mg                                       | Tablets                                 | a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.  |
|   | 70  | Ofloxacin+<br>Nitazoxanide  | 50 mg +<br>100mg                                      | oral liquid                             | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ofloxacin for indication of nitazoxanide will lead to emergence of antibiotic resistance and serious health care concern.   |
|   | 7   | 14 Ornidazole<br>IP+Ofloxacin IP  | 125.0mg+50  | ) Suspension                            | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
|   | 7   | 17 Azitromycin dihydra<br>IP Eq. to<br>Azithromycin +<br>Ofloxacin IP   | ate 500mg+400<br>mg                                   | Tablets                                 | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increase risk of emergence of drug resistance due to misuse in FDC .</li></ul>   |

|  | mg   |                          | a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Linezolid is a life saving drug to be used for MRSA infection and inappropriate use of linezolid can lead to drug resistance.   |
|--|--|--------------------------|--|
| floxacin+Ornidazole  | 50mg+125m S  | Suspension               | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
| Azithromycin +<br>Ofloxacin  | 500mg+400<br>mg  | Tablets                  | <ul> <li>a,</li> <li>1Ofloxacin is not safe in children.</li> <li>2. Increased risk of emergence of drug resistance.</li> <li>3. Patient may need only one ingredient and use of FDC may lead to misuse.</li> </ul>  |
| Norfloxacin+<br>metronidazole<br>Benzoate  | 100mg+<br>100mg  | liquid<br>suspension     | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have no been recommended in children. 2. This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poo country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.  |
| Anhydrous<br>azithromycin +-<br>anhydrous<br>levofloxacin  | 250mg/500<br>mg+<br>250mg/500<br>mg  | Tablets                  | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increase risk of emergence of drug resistance due to misuse of FDC.</li></ul>  |
| Cefpodoxime+<br>Levofloxacin   | 200mg+250<br>mg  | Film Coated<br>Tablets   | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increase risk of emergence of drug resistance due to misuse of FDC.</li></ul>  |
|  | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1  |                          |  |
| 4 Azithromycin Dihydrate IP eq. to Azithromycin + Levofloxacin hemi hydrate IP eq. to Levofloxacin | mg   | Tablets                  | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increase risk of emergence of drug resistance due to misuse of FDC.</li></ul>  |
| 5 Cefixime IP (as<br>Trihydrate) Eq. to<br>anhydrous<br>Cefixime+Linezoli<br>IP                    | mg   | 10 Tablets               | <ul> <li>a,</li> <li>1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situatin our resource poor country.</li> <li>2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.</li> </ul>   |
|  | Azithromycin + Ofloxacin  Norfloxacin+ metronidazole Benzoate  Anhydrous azithromycin + anhydrous levofloxacin  Cefpodoxime+ Levofloxacin  Azithromycin to Azithromycin + Levofloxacin hemi hydrate IP eq. to Azithromycin + Levofloxacin bemi hydrate IP eq. to anhydrous Cefixime+Linezoli | Azithromycin + Ofloxacin | Anhydrous azithromycin + anhydrous levofloxacin  Cefpodoxime+ Levofloxacin  Azithromycin + 250mg/500 mg  Cefpodoxime+ 200mg+250 Film Coated Tablets  Aniydrae IP eq. to Azithromycin + Levofloxacin hemi hydrate IP eq. to Levofloxacin  Cefixime IP (as Trihydrous Cefixime) Cefixime P (as Trihydrous Cefixime) Cefixime) Cefixime P (as Trihydrous Cefixime) Cefixime) Cefixime P (as Trihydrous Cefixime) Cefixime P (as Trihydrous Cefixime) Cefixime) Cefixime) Cefixime P (as Trihydrous Cefixime) Cefixime) Cefixime) Cefixime P (as Trihydrous Cefixime) Cefi |

| 746 Offi<br>+O:<br>Aci | oxacın<br>midazole+Lactic<br>d Bacillus                    | 200mg+500<br>mg+2.50<br>Billion<br>Spores |                        | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + netronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended.  2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  3. There is no additional benefit of adding lactic acid bacillus.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56. |
|------------------------|--|---|------------------------|--|
| 747 Ce                 | fíxime<br>+Linezolid IP                                    | 200mg+600<br>mg                           | Film Coated<br>Tablets | a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.   |
| 750 O                  | floxacin<br>P+Nitazoxanide                                 | 50mg+100m<br>g                            | suspension             | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of nitrazoxanide will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 751 C                  | Ofloxacin<br>P+Ornidazole IP                               | 50mg+125m<br>g                            | suspension             | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
|                        | ofloxacin+<br>nitazoxanide                                 | 50 mg+ 125<br>mg                          | suspension             | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ofloxacin for indication of nitazoxanide will lead temergence of antibiotic resistance and serious health care concern.</li> </ul>   |
| 766                    | Ofloxacin<br>IP+Ornidazole IP                              | 50mg+125                                  | m Oral Liquid          | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
| 775                    | azithromycin<br>dihydrate +<br>secnidazole+<br>fluconazole | 1 g+ 1 g+<br>150 mg                       | tablets                | a, 1. Pharmacodynamically irrelevant due to different therapeutic indication of ingredients. FDC may Increase risk of emergence of drug resistance. 2. Patient may require only one ingredient 3. Azithromycin and fluconazole both increase QTc interval, Potential cardiac toxicity.  http://reference.medscape.com/drug-interactionchecker.   |
| 780                    | Offaxacine<br>IP+Ornidazole IP                             |   | 5m Suspension          | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |

| 781 O | Hazaeme  | 50mg/125m Si                      | 2.1  | Both ingredients of the FDC have different therapeutic indcations<br>Inappropriate use of ornidazole will lead to emergence of antibiotic<br>sistance against quinalones.<br>Safety concerns in paediatric patients.   |
|-------|--|-----------------------------------|--|--|
| N     | Norfloxacin+<br>Metronidazole<br>Benzoate  | 100mg+150 S                       | m<br>b<br>2<br>a<br>c                                      | FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + netronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not een recommended in children.  This FDC can rapidly give rise to resistant strains of organisms, which is matter of serious concern to the health care situation in our resource poor ountry.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56. |
| 787   | Ofloxacin<br>IP+Ornidazole IP  | 50mg+125m<br>g                    |  | 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.  3. Safety concerns in paediatric patients.   |
| 790   | Levofloxacin+Azithro<br>mycin  | 0 250mg/500<br>mg+250mg/<br>500mg | Tablets  | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increase risk of emergence of drug resistance due to misuse of FDC.</li></ul>  |
| 793   | Azithromycin Dihydrate IP eq. to Azithromycin + Neomycin Sulphate eq.to Neomycin | 300mg+250<br>mg                   | 5gm Intra<br>Mammary<br>Infusion<br>Disposable<br>Syringes | a,<br>Veterinary FDC - no comments   |
| 79:   | 5 Levofloxacin<br>Hemihydrate<br>IP+Omidazole<br>IP+Alpha Tocopher<br>Acetate IP | 20mg+40mg<br>+5mg                 | Solution   | <ul> <li>a,</li> <li>1. Patient may need only one ingredient and the use of FDC may lead to misuse.</li> <li>2. Increased risk of emergence of drug resistance due to misuse of FDC</li> </ul>   |
| 79    | D6 Levofloxacin Hemihydrate IP+Ornidazole IP+Alpha Tocopher Acetate IP           | +5mg                              | g Clear Solution   | <ul> <li>a,</li> <li>1. Patient may need only one ingredient and the use of FDC may lead to misuse.</li> <li>2. Increased risk of emergence of drug resistance due to misuse of FDC</li> </ul>   |
| 79    | 99 Ofloxacin+Ornidaz   | zole 50mg+125ng                   | m Oral suspensio   | <ol> <li>a,</li> <li>Both ingredients of the FDC have different therapeutic indications</li> <li>Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>Safety concerns in paediatric patients.</li> </ol>   |
| 8     | Nimorazole+Oflox   | xaci 500mg+20<br>mg               | Tablet   | <ul> <li>a,</li> <li>1. Patient may need only one ingredient and the use of FDC may lead to misuse.</li> <li>2. Increased risk of emergence of drug resistance due to misuse of FDC</li> </ul>   |
|       | 812 anhydrous<br>azithromycin +<br>ofloxacin                                     | 500m g+<br>400 mg                 | tablets  | a, 1.Pharmacodynamically irrelevant FDC. 2. Increased risk of emergence of drug resistance due to misuse of FD   |

|  |   |  | http://reference.medscape.com/drug-interactionchecker.   |
|--|---|--|--|
| Ofloxacin<br>IP+Ornidazole IP                    | 50mg+125m   | Suspension   | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.   |
| Azithromycin<br>+ofloxacin                       | 125mg+50m<br>g  | Suspension   | <ul> <li>a,</li> <li>10 floxacin is not safe in children.</li> <li>2. Increased risk of emergence of drug resistance.</li> <li>3. Patient may need only one ingredient and use of FDC may lead to misuse.</li> </ul>   |
| 5 Metronidazole<br>benzoate+Norfloxad            | 100mg+100<br>mg   | Suspension   | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  Kasarla Rajul, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2   2013   52-56   |
| 46 Azithromycin+<br>ofloxacin                    | 250mg+200<br>mg   | Tablet   | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increased risk of emergence of drug resistance due to misuse of FDC.</li></ul>   |
| 48 Ornidazole+Oflox<br>+                         | tacin 125<br>mg+50mg  | Suspension/<br>liquid  | oral a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |
| 352 Cefixime+Levoflon Hemihydrate                | oxaci 400mg+50<br>mg  | 0 Tablet   | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increased risk of emergence of drug resistance due to misuse of FDC.</li></ul>   |
| beclomethasone<br>dipropionate+<br>clotrimazole+ | + 2%  | drops %  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|  | Azithromycin +ofloxacin  Metronidazole benzoate+Norfloxacin  Azithromycin+ ofloxacin  Azithromycin+ ofloxacin  Azithromycin+ ofloxacin  Azithromycin+ ofloxacin  Azithromycin+ ofloxacin  benzoate+Oflox +  Azithromycin+ ofloxacin  ofloxacin  Hemihydrate | P+Ornidazole IP  Azithromycin +ofloxacin  Metronidazole benzoate+Norfloxacin  Metronidazole benzoate+Norfloxacin  Azithromycin+ ofloxacin  Metronidazole benzoate+Norfloxacin  Mag  100mg+100 mg  48 Ornidazole+Ofloxacin + mg  48 Ornidazole+Ofloxacin Hemihydrate  Mag  852 Cefixime+Levofloxaci n Hemihydrate  Mag  853 Ofloxacin + beclomethasone dipropionate+  Mag  0.3% + 0.25% + 1 0.25% + | Azithromycin +ofloxacin   125mg+50m   Suspension   125mg+100   Suspension   100mg+100   Suspensi |

| ]   | Pyrantel Pamoate+   | 50mg<br>+144mg<br>+500mg | 1                  | a,  1. Patient may need only one ingredient and use of FDC may lead to misuse.  2. Dosing shedule mismatch amongst ingredients.   |
|-----|---|--------------------------|--------------------|---|
| 863 | Doxycycline<br>hyclate+Serratiopeptid<br>ase                                    | 100mg+10m<br>g           | Capsule            | a, Pharmacodynamically irrelevant- 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse.  |
| 869 | Ofloxacin+Beclometh<br>asone<br>Dipropionate+Clotrim<br>azole+Lignocaine<br>HCL | 1025% W/V + 1            | Ear Drops          | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 87  | 6 Cefpodoxine+Azithro<br>mycin  | 0 100mg+125<br>mg        | Dispersible tablet | <ul> <li>a,</li> <li>1. Increased risk of emergence of drug resistance.</li> <li>2. Patient may need only one ingredient and use of FDC may lead to misuse.</li> <li>3. Azithromycin decreases effects of cefpodoxime by pharmacodynamic antagonism. Significant interaction possible. Bacteriostatic ingredients may inhibit the effects of bactericidal ingredients.</li> <li>http://reference.medscape.com/drug-interactionchecker.</li> </ul>   |
| 8'  | 79 Cefpodoxime<br>+Azithromycin   | 320mg+50<br>mg           | 0 Tablets          | <ul> <li>a,</li> <li>1. Increased risk of emergence of drug resistance.</li> <li>2. Patient may need only one ingredient and use of FDC may lead to misuse.</li> <li>3. Azithromycin decreases effects of cefpodoxime by pharmacodynamic antagonism. Significant interaction possible. Bacteriostatic ingredients mainhibit the effects of bactericidal ingredients.</li> <li>http://reference.medscape.com/drug-interactionchecker.</li> </ul>   |
|     | 880 Ofloxacin+Ornidaz   | zole 50.0mg+1.0mg        | 25 Liquid oral     | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
|     | 881 Ofloxacin+Ornida  | zole 50.0mg+<br>.0mg     | 125 Liquid oral    | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |

| 882 Of | floxacin+Ornidazole 5  | 0.0mg+125   L1q<br>0mg          |                         | 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |
|--------|--|---------------------------------|-------------------------|--|
| 883 O  | floxacin+Ornidazole  | 50.0mg125. Su                   | spension                | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.   |
| I      | Norfloxacin<br>P+Metronidazole<br>Benzoate IP  | 100mg+100 St                    | uspension               | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56. |
| 886    | Ofloxacin<br>IP+Ornidazole IP  | 50mg+125m S                     | Suspension              | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
| 887    | Cefixime IP eq. to<br>anhydrous<br>Cefixime+levofloxac<br>n Hemihydrate IP eq<br>to Levofloxacin | mg<br>i                         | Tablets                 | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increased risk of emergence of drug resistance due to misuse of FDC.</li></ul>   |
| 890    | 0 Levofloxacin+Azithi<br>mycin   | 250mg/500<br>mg+250mg/<br>500mg | Tablets                 | <ul><li>a,</li><li>1.Pharmacodynamically irrelevant FDC.</li><li>2. Increase risk of emergence of drug resistance due to misuse of FDC .</li></ul>   |
| 89     | Azithromycin<br>IP+Levofloxacin<br>Hemihydrate IP  | 500mg+250<br>mg/500mg           | Film Coated<br>Tablets  | a, 1. Pharmacodynamically irrelevant FDC. Increase risk of emergence of drug resistance as patient may need only one ingredient. 2. Azithromycin and levofloxacin both increase QTc interval.  http://reference.medscape.com/drug-interactionchecker.  |
| 8      | B94 Doxycycline HCL<br>eq. to Doxycycline<br>anhydrous+Tinida<br>IP+Betacyclodextr<br>USP        | zole mg+50mg                    | ) Film Coate<br>Tablets | d a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredients and may lead to misuse 2. There is a risk of antibiotic resistance.  |

| 89 | eq    | to Doxycycline hydrous+Ornidazol P+Betacyclodextrin                                    |                      | Γablets                         | Pharmacodynamically irrelevant-  1. Patient may need only one ingredients and may lead to misuse  2. There is a risk of antibiotic resistance.  |
|----|-------|--|----------------------|---------------------------------|---|
| 90 | T     | efixime (As<br>rihydrate)+Azithrom<br>sin Drihydrate IP                                | 20011-0              | I IIII Comme                    | a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Pharmacokinetic incopmpatibility   |
| 9  | П     | ofloxacin<br>P+Metronidazole<br>P+Zinc Acetate USP                                     | 100mg+200<br>mg+10mg | Oral<br>Suspension              | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of metronidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
| ç  | 906 h | Norfloxacin<br>P+Metronidazole IP  | 200mg+200<br>mg      | Tablets                         | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2. This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56. |
|    |       | Ofloxacin<br>IP+nitazoxanide   | 50mg+100mg           | on Oral<br>Suspension           | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of nitrazoxanide will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
|    | 913   | Norfloxacin IP + Metronidazole Benzoate IP   | 100mg+100<br>mg      | Suspension                      | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have no been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which i a matter of serious concern to the health care situation in our resource poo country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.     |
|    | 910   | Diphenoxylate<br>HCL+Atropine<br>Sulphate+Furazolid                                    | 2.5mg+0.0<br>5mg+50m |                                 | <ul> <li>a, Pharmacodynamically irrelevant-</li> <li>1. Patient may need only one ingredient which may lead to misuse and adverse effect.</li> <li>2. Use of two antispasmodic can develop more risk of adverse effect.</li> <li>3. Use of antibacterial in FDC is irrelevant.</li> </ul>   |
|    | 92    | 2 Fluconazole IP<br>Tablets+One<br>Azithromycin Tabl<br>IP+Two Ornidazol<br>Tablets IP | lets                 | 00 Kit (Film<br>mg Coated Table | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |

|     | Norfloxacin<br>IP+Metronidazole<br>Benzoate IP               | 100mg+120 Sumg      |                                   | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.           |
|-----|--|---------------------|-----------------------------------|---|
| 77  |  |                     |                                   | Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG<br>COMBINATIONS. 2013;3(2):52-56.  |
| 924 | Ofloxacin<br>IP+Ornidazole IP                                | 50mg+125m S         | uspension                         | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
| 926 | Ornidazole<br>IP+Ofloxacin IP                                | 125mg+50m S         | Suspension                        | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 929 | Ofloxacin<br>IP+Ornidazole IP                                | 200mg+500 smg       | Suspension                        | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
| 93  | 0 Ofloxacin<br>IP+Omidazole IP                               | 50mg+125m<br>g      | Oral Liquid                       | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 93  | 33 Ofloxacin<br>IP+Ornidazole IP                             | 50mg+125m<br>g      | Oral<br>Suspension                | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 9   | 39 Ofloxacin+Ornidaz   | 50mg+120m           | Suspension                        | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| ç   | Ofloxacin+Azithro<br>cin Dihydrate                           | omy 100mg+100<br>mg | Uncoated<br>dispersible<br>tablet | <ul> <li>a,</li> <li>1Ofloxacin is not safe in children.</li> <li>2. Increased risk of emergence of drug resistance.</li> <li>3. Patient may need only one ingredient and use of FDC may lead to misuse.</li> </ul>   |
|     | 959 Cefixime Trihydra<br>IP eq. to<br>Cefixime+Linezol<br>IP | mg                  | Film Coated<br>Tablets            | <ul> <li>a,</li> <li>1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situal in our resource poor country.</li> <li>2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.</li> </ul> |

| 960 Off | 10/100  | 50mg+125m Ora<br>g Sus |                        | 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.   |
|---------|---|------------------------|------------------------|---|
| 966 O:  | floxacin<br>P+Ornidazole IP   | 50mg+125m Ora          | al Liquid              | a,  1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.  3. Safety concerns in paediatric patients.  |
| 976 C   | Omidazole<br>P+Ofloxacin IP   | 50mg+125m Or           | al Liquid              | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 979 (   | Ofloxacin<br>IP+Ornidazole IP   | 50mg+125m S            | yrup                   | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 981     | Lignocaine+Clotrim<br>ole+Ofloxacin+Becl<br>methasone<br>Dipropionate | az   270111            | Ear Drops              | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 985     | Cafuroxime Axetil-<br>Linezolid                                       | + 500mg+600<br>mg      | Film Coated<br>Tablets | <ul> <li>a,</li> <li>1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.</li> <li>2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.</li> </ul>  |
| 98      | 7 Cafuroxime<br>Axetil+Linezolid                                      | 500mg+600<br>mg        | Film Coated<br>Tablets | <ul> <li>a,</li> <li>1. Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situatio in our resource poor country.</li> <li>2. Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.</li> </ul>   |
| 98      | 89 Ofloxacin+Ornida   | azole 50mg+125mg       | Suspension             | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 9       | 090 Ofloxacin+Ornid   | Jazole 50mg+125ng      | n Suspension           | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |

| P    | Propionate+Neomycin   | 0.05/011                           | ]                              | Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.    |
|------|---|------------------------------------|--------------------------------|---|
|      | Clobetasol<br>Propionate+Neomycir<br>Sulpahte+Miconazole<br>Nitrate         | 0.05%w/w+<br>10.5%w/w+2.<br>00%w/w | cream                          | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 1010 | Clobetasol Propioina<br>BP+Miconazole<br>Nitrate IP+Neomycii<br>Sulphate IP | 2.070W/W                           | + Cream                        | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 102  | Ofloxacin IP+Ornidazole IP+Zinc bisglycinat                                 | g+50mg                             | m Suspension                   | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 102  | 26 Norfloxacin<br>IP+Metronidazole  | 100mg+10<br>mg                     | 00 Suspension                  | <ul> <li>a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have n been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which a matter of serious concern to the health care situation in our resource po country. Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.</li> </ul>  |
| 10   | 027 Ofloxacin<br>IP+Ornidazole IP   | 50mg+12                            | 25m Oral Liquid                | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| 1    | 1028 Levofloxacin<br>Hemihydrate+Az<br>mycin Dihydrate                      | 250mg/5<br>mg+250<br>IP 500mg      | 500 Film Coated<br>mg/ Tablets | a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC.   |

| 030 N | Norfloxacin<br>P+Metronidazole IP                                      | 400mg+400 Film Coated<br>mg Tablets  | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.  |
|-------|--|--------------------------------------|---|
| 1038  | Metronidazole<br>Benzoate IP eq. to<br>Metronidazole+Norfl<br>xacin IP | 100mg+100 Liquid Oral mg             | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  Kasarla Raju1, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2  2013   52-56   |
| 1043  | 3 Clobetasol+Neomyc<br>+Clotrimazole                                   | in 0.05%w/w + Cream 0.50%w/w + 1%w/w | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 104   | Norfloxacin USP+Metronidazo  | le mg Liquid Oral                    | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have no been recommended in children. 2. This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poc country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.   |
| 10    | Offloxacin<br>IP+Ornidazole IP   | 50mg+125m Suspension                 | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |
| 1     | Ofloxacin<br>USP+Omidazole   | 50mg+125m Suspension                 | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |
|       | 1063 Ofloxacin<br>IP+Ornidazole I                                      | 50mg+125m Suspensi<br>P g            | on  a,  1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.  3. Safety concerns in paediatric patients.  |

| T           | moxicillin<br>rihydrate IP eq. to<br>moxicillin+Bromhex<br>ne Hydrochloride IP                                    | 250mg+8mg I                                      | Capsule F                  | Pharmacodynamically irrelevant- 1. Combining amoxycillin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3   Issue 2   2013   52-56.   |
|-------------|---|--|----------------------------|---|
| I<br>S<br>I | Clobetasole Propionate JSP+Neomycin Sulphate P+Miconazole Nitrate IP+Chlorocresol IP                              | 0.05%w/w +<br>0.5%w/w +<br>2.00%w/w +<br>0.1%w/w |                            | Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
|             | Ciprofloxacin Hydrochloride IP eq. to Cirofloxacin+Fluticas one Acetonide IP+Clotrimazole IP+Neomycin Sulphate IP | 0.5%w/w+<br>0.025%w/w<br>+ 1.0%w/w<br>+ 0.5%w/w  | Cream                      | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 1091        | Metronidazole<br>IP+Furazolidone IP+<br>Loperamide IP   | 1gm+200mg<br>+4mg                                | Uncoated<br>Tablets        | a, 1. antimotility drug will cause toxic megacolon in infective diarrhoea. 2. Loperamide is contra-indicated in infective diarrhea and in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter as it reduces the clearance of pathogens. Hence there is no rationale for combining with antibiotic in an FDC. 3. In bacterial diarrhoea only anti-bacterial drug is effective and antiamoebic drug is useless. Similarly, in intestinal amoebiasis only antiamoebic drug is effective while antibacterial drug is useless. 4. Amoebiasis and bacterial diarrhoea rarely coexist. 5. Only one drug of the combination would be effective and the other one would be useless. |
| 1093        | Doxycycline HCl IP<br>eq. to Doxycycline<br>Base+Lacto Acid<br>Bacillus IH  | 100mg+60<br>Million<br>spores                    | Uncoated<br>Tablets        | a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredients and may lead to misuse 2. There is a risk of antibiotic resistance.   |
| 1095        | Metronidazole IP+Tetracycline HCl   | 300mg+250<br>mg                                  | Film Coated<br>Tablets     | a, Pharmacodynamically irrelevant- May lead to misuse and antibiotic resistance   |
| 1099        | 9 Tetracycline HCl<br>IP+Metronidazole IF   | 333mg+400<br>mg                                  | Oral Film<br>Coated Tablet | a, Pharmacodynamically irrelevant.  Patient may need only one ingredient.  Misuse may lead to development of resistance.  |

| Ofloxacin USP+<br>Ornidazole IP                             | 50mg+125m<br>g   | Oral<br>Suspension  | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |
|---|--|---|---|
| Ofloxacin<br>IP+Ornidazole IP                               | 50mg+125m<br>g   | Suspension  | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| Ofloxacin<br>IP+Ornidazole IP                               | 50mg+125m<br>g   | Suspension  | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| Ofloxacin<br>IP+Ornidazole IP                               | 50mg+125m<br>g   | Oral Liquid   | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| Cephalexin IP+<br>Neomycin Sulphate<br>IP+Prednisolone      | 100mg+100<br>mg+10mg   | Injection   | a, Pharmacodynamically irrelevant- 1. May lead to misuse and neomycin is a potent nephrotoxic. It is no longer indicated by parentral route.  |
| Ofloxacin<br>IP+Omidazole IP                                | 50mg+125m<br>g   | Oral Liquid<br>Syrup  | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |
| Norfloxacin<br>IP+Metronidazole<br>Benzoate IP              | 100mg+120<br>mg  | Oral Liquid<br>Syrup  | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2. This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  |
|   |  |   | Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG<br>COMBINATIONS. 2013;3(2):52-56.  |
| Doxycycline Hydrochloride IP eq. to Doxycycline+Tinidaz ole | 100mg+300<br>mg  | Film coated tablets   | a, Pharmacodynamically irrelevant- 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse.  |
|   | Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Cephalexin IP+ Neomycin Sulphate IP+Prednisolone  Offloxacin IP+Ornidazole IP  Norfloxacin IP+Ornidazole IP | Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Cephalexin IP+ Neomycin Sulphate IP+Prednisolone  Offloxacin IP+Ornidazole IP  Cophalexin IP+ Neomycin Sulphate IP+Prednisolone  Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Norfloxacin IP+Metronidazole Benzoate IP  Doxycycline Hydrochloride IP eq. to Doxycycline+Tinidaz  I00mg+300 mg | Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Offloxacin IP+Ornidazole IP  Cephalexin IP+ Neomycin Sulphate IP+Prednisolone  Offloxacin IP+Ornidazole IP  Oral Liquid Syrup  Norfloxacin IP+Ornidazole IP  Norfloxacin IP+Ornidazole IP  Oral Liquid Syrup  Norfloxacin IP+Metronidazole Benzoate IP  Doxycycline Hydrochloride IP eq. to Doxycycline+Tinidaz  Doxycycline+Tinidaz  Doxycycline+Tinidaz  I00mg+300 mg  Film coated tablets |

| A<br>A<br>A | zithromycin (As<br>ihydrate) IP eq. To<br>nhydrous<br>zithromycin +<br>mbroxol<br>lydrochloride IP                                       | 250mg/500<br>mg+60mg  | Film Coated<br>Tablets      | a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2  2013   52-56.    |
|-------------|--|-----------------------|-----------------------------|---|
| I           | Azithromycin (As<br>Dihydrate) IP eq. To<br>Anhydrous<br>Azithromycin +<br>Ambroxol<br>Hydrochloride IP                                  | 250mg/500<br>mg+60mg  | Film Coated<br>Tablets      | a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3   Issue 2   2013   52-56. |
| 1146        | Azithromycin (As<br>Dihydrate) IP eq. To<br>Anhydrous<br>Azithromycin<br>+Ambroxol<br>Hydrochloride IP (Ir<br>sustained release<br>form) | g                     | m Uncoated bilayered table  | a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.                |
| 114         | 7 Azithromycin (As<br>Dihydrate) IP eq. T<br>Anhydrous<br>Azithromycin<br>+Ambroxol<br>Hydrochloride IP (<br>sustained release<br>form)  | o g                   | Om Uncoated bilayered tab   | a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3 Issue 2 2013   52-56.     |
| 12          | 08 cilnidipine +<br>metroprolol succi<br>+ metroprolol tart  | 10 mg+<br>mate mg+ 50 |                             | a, Pharmacodynamically irrelevant, there is no scientific justification for t derivatives of metoprolol. Same compound in differerent salt form don't make any pharmacodynamic (Synergistic/additive) hence dose of metoprolol sele in the combination is questionable  |
| 12          | 220 Flunarizine+Elen<br>Magnesium  | nental 10mg+          | Uncoated tablets            | a, Pharmacodynamically irrelevant- As there is no published literature supporting use of Elemental Magnesium.   |
| 12          | 229 L-Arginine<br>IP+Sildenafil Cit<br>IP eq. to Sildanif  | 3gm+5                 | Omg Sachet/Fil<br>Coated Ta | m a, Pharmacodynamically irrelevant as there is lack of synergism or additi- effect and also the dose selection is questionable   |

| vitac | tamin D3 + folic  sid + vitamin B12 + II  rridoxine HCL  II | 120,00                          | ñilm coated<br>ablet     | a, Pharmacodynamically irrelevant- 1. Atovastatin has definite indication and combining it with vitamins has no additional benefit. 2. Misuse of FDC as vitamin supplement will cause serious adverse effects of atorvastatin.  |
|-------|---|---------------------------------|--------------------------|---|
|       |   |                                 |                          |   |
|       | Clindamycin+Telmisa<br>tan                                  | 10mg+40mg                       | Tablet                   | a, Pharmacodynamically irrelevant-  1. Use of antibiotic with angiotensin receptor blocker is not rational  |
| lo    | 1 O LLLLOW IN THE   | 20mg/40mg<br>+12.5mg+6.<br>25mg | Hard Geletin<br>Capsules | <ul> <li>a,</li> <li>1. Both diuretics present in the FDC have same mechanism of action.</li> <li>2. Dose trituration will be difficult in FDC.</li> <li>3. Chlorthalidone will increase the level or effect of hydrochlorothiazide by acidic (anionic) drug competition for renal tubular clearance.</li> </ul>  |
| ]     | Prochloperazine<br>Maleate +<br>Paracetamol                 | 5mg+ 650<br>mg                  | tablet                   | a, Pharmacodynamically irrelevant and overdose dose of Paracetamol.   |
|       | Betahistine HCl<br>IP+Ginkgo biloba<br>Extract+Vinpocetin+P | 16mg+60mg<br>+5mg+400m          | Tablets                  | a, Pharmacodynamic irrelevant - each ingredient has different therapeutic u and FDC will lead to misuse.  |
| - 1   | Promethazine HCl<br>IP+Paracetamol IP                       | 5mg+125mg                       | g Oral Syrup             | a, Pharmacodynamically irrelevant  1. Both ingredients have different therapeutic uses.   |
| 1396  | Phenytoin<br>Sodium+Phenobarbite<br>ne                      | 100mg+30r                       | n Tablets                | a, Pharmacodynamically irrelevant.  1. Phenobarbital will decrease the level or effect of phenytoin by affectin hepatic enzyme CYP2C9/10 metabolism. Significant interaction possibl 2. Phenobarbital decreases levels of phenytoin by increasing metabolism 3. Phenobarbital may occasionally not change or even increase (via competitive inhibition) phenytoin levels.  http://reference.medscape.com/drug-interactionchecker. |
| 120   | 7 L-5-  | 7.5mg+10                        | m Tablets                | a,  |
| 139   | Methylterahydrofola   |                                 |                          | Pharmacodynamically irrelevant-  1. No supporting published literature available on the combination.  |

| (    | Flupenthix©l<br>dihydrochloride+Escit<br>alopram Oxalate               | 0.00              | Cablets     | a, Pharmacodynamically irrelevant- 1. No supporting published literature for this FDC. 2. The combination will aggravate the adverse effects.   |
|------|--|-------------------|-------------|---|
| 1408 |  | 1.5mg+1.5m (      | Cough Syrup | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
|      | Promethazine HCl<br>IP+Dextromethorphan<br>Hydrobromide IP             | 5mg+10mg          | Oral Liquid | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 1413 | promethazine HCL+<br>paracetarnol                                      | 5 mg + 125<br>mg  | syrup       | a, Pharmacodynamically irrelevant 1. Both ingredients have different therapeutic uses.  |
| 1414 | pholcodine<br>+Promethazine<br>Hydrochloride                           | 1.5mg+1.5m<br>g   | Oral Syrup  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 1415 | 5 Paracetamol<br>IP+Promethazine<br>HCL IP                             | 125mg+5mg         | Suspension  | <ul><li>a,</li><li>1. Pharmacodynamically irrelevant.</li><li>2. Both ingredients have different indications.</li></ul>   |
| 141  | 7 Flupenathixol<br>dihydrochloride+Esci<br>alopram Oxalate             | 0.5mg+10m<br>t g  | Tablets     | <ul> <li>a,</li> <li>Pharmacodynamically irrelevant-</li> <li>1. No supporting published literature for this FDC.</li> <li>2. The combination will aggravate the adverse effects.</li> </ul>  |
| 143  | 5 Betahistine<br>HCl+Ginkgo Biloba<br>Extract+Vinpocetine<br>Piracetam | +5mg+400n         |             | a, Pharmacodynamic irrelevant - each ingredient has different therapeutic u and FDC will lead to misuse.  |
| 143  | 66 Sodium Fluoride<br>IP+Procaine HCl IP                               | 1%w/v + 2%<br>w/v | 6 injection | a, Pharmacodynamically irrelevant- No published literature in support of this FDC.  |
| 143  | 7 Cetirizine<br>Dihydrochloride<br>IP+D·iethyl<br>Carbamazine Citrate  | 5mg+150m          | Tablets     | a, 1. Patient may need only one ingredient and use of FDC may lead to misuse.   |

|      | Succinate+Pyridoxine  | 10mg+50mg<br>+250mg+32<br>5mg | Tablets                | a, Pharmacodynamically irrelevant- 1. No published literature supporting the FDC. 2. Users who may not be aware of this mefanamic acid content and may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. 3. If misused for morning sickness, it is teratogenic.  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
|------|---|-------------------------------|------------------------|---|
| 1477 | Imipramine HCl IP +<br>Diazepam IP  | 25mg+2mg                      | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction.  http://reference.medscape.com/drug-interactionchecker.   |
| 1482 | Imipramine HCl IP +<br>Diazepam IP  | 25mg+5mg                      | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction.  http://reference.medscape.com/drug-interactionchecker.   |
| 1522 | Flupentixol Di-<br>HCI+Escitalopram<br>oxalate  | 0.5mg+10m<br>g                | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. No supporting published literature for this FDC. 2. The combination will aggravate the adverse effects.   |
| 1530 | Imipramine<br>Hcl+diazepam  | 25mg+2.0m<br>g                | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction.  http://reference.medscape.com/drug-interactionchecker.   |
| 1537 | Pholcodine<br>IP+Promethazine HCl<br>IP   | 1.5mg+1.5m<br>g               | Liquid Oral            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|      | Flupentixol Dihydrochloride BP eq. to Flupentixol+Melitrace n Hydrochloride eq. to Melitracen |                               | Film Coated<br>Tablets | a, Already banned   |
| 1546 | Paracetamol IP +<br>Prochloperazine<br>Maleate IP   | 500mg+5mg                     | Uncoated<br>Tablets    | <ul><li>a,</li><li>1. Pharmacodynamically irrelevant.</li><li>2. Both ingredients have different indications.</li></ul>   |

|      | Chlordiazepoxide,   | mg                                  | Oral Liquid Drop       | a, Pharmacodynamically irrelevant-  1. Trifluoperazine and imipramine both increase QTc interval.  2. High likelihood serious or life-threatening interaction.  3. Trihexyphenidyl and imipramine both decrease cholinergic effects/transmission.  4. chlordiazepoxide and trifluoperazine both increase sedation.  5. Trihexyphenidyl decreases levels of trifluoperazine by pharmacodynamic antagonism.  http://reference.medscape.com/drug-interactionchecker.  a,  1. Pharmacodynamically irrelevant.  2. Both ingredients have different indications. |
|------|---|-------------------------------------|------------------------|--|
| 1571 | Gabapentin<br>USP+Mecobalamin<br>JP+Pyridoxine<br>IP+Thiamine IP  | 37.5<br>mg+500mcg<br>+10mg+25m<br>g | Film Coated tablets    | a, Pharmacodynamically irrelevant- gabapentin decreases levels of cyanocobalamin by inhibition of GI absorption.  http://reference.medscape.com/drug-interactionchecker.   |
| 1579 | Imipramine Hydrochloride +Chlordiazepoxide IP+Trifluoperazine Hydrochloride IP eq. to Trifluoperazine+Trihe xyphenidyl Hydrochloride IP | 25mg+10mg<br>+1.5mg+0.5<br>mg       | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant-  1. Trifluoperazine and imipramine both increase QTc interval.  2. High likelihood serious or life-threatening interaction.  3. Trihexyphenidyl and imipramine both decrease cholinergic effects/transmission.  4. chlordiazepoxide and trifluoperazine both increase sedation.  5. Trihexyphenidyl decreases levels of trifluoperazine by pharmacodynamic antagonism.  http://reference.medscape.com/drug-interactionchecker.  |
| 1590 | ChlorpromazineHCl<br>IP+Trihexyphenidyl<br>HCl IP   | 100mg+2mg                           | Tablets                | a, Pharmacodynamically irrelevant-     1.In current scenerio chlorpromazine is not a drug of choice for the treatment of depression.     2. dose adjustment of Trihexyphenidyl to counteract the adverse effect of chlorpromazine is not possible in FDC formulation     3.There is a risk of potential abuse  |
| 1591 | 1 Chlopromazine<br>USP+Trihexyphenidyl<br>Hcl IP  | 200mg+2mg                           | Tablets                | a, Pharmacodynamically irrelevant- 1. In current scenerio chlorpromazine is not a drug of choice for the treatment of depression. 2. dose adjustment of Trihexyphenidyl to counteract the adverse effect o chlorpromazine is not possible in FDC formulation 3. There is a risk of potential abuse   |
| 160. | 5 Ursodeoxycholic Acid<br>+ Silymarine  | i 300mg<br>+140mg                   | Bilayered<br>Tablets   | a, Pharmacodynamically irrelevant- 1. UDCA is used for PBC and silymarin is a hepatoprotective. 2. Silymarin does not provide any benefit to patients with Primary Biliary Cirrhosis.  |
| 161  | 7 Gliclazide +<br>metformin<br>hydrochloride  | 80 mg + 325<br>mg                   | Tablets                | a,<br>Sub-therapeutic dose of metformin.   |

| 1    |   |  | pilayered tablets           | a, Pharmacodynamically irrelevant- 1.No published literature supporting the superior efficacy of combination of these drugs. 2. Therapeutic use of chromium is doubtfull.                           |
|------|---|--|-----------------------------|---|
|      | pioglitazone HCL+ metformin hydrochloride                                     | 7.5 mg/7.5<br>mg+ 500<br>mg/500 mg           |                             | a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.  |
|      | HCL+Metformin<br>HCL  | 00/1000mg                                    | Bilayed Tablet              | Subtherapeutic dose of Pioglitazone.     Safety issue with Pioglitazone especially as FDC.  |
| 1634 | Glimepiride+Pioglitaz<br>one HCl+Metformin<br>HCl                             | 1mg/2mg/3<br>mg+15mg+1<br>000mg              | Tablets                     | <ul><li>a,</li><li>1. There is no published literature supporting this FDC.</li><li>2. The Pioglitazone has safety concerns.</li></ul>  |
| 1637 | glimepiride+<br>pioglitazone<br>hydrochloride +<br>metformin<br>hydrochloride | 1mg/2mg+<br>15mg/15<br>mg+ 850<br>mg/ 850 mg | tablets                     | <ul><li>a,</li><li>1. There is no published literature supporting this FDC.</li><li>2. The Pioglitazone has safety concerns.</li></ul>  |
| 1645 | Pioglitazone HCL+Metformin HCL  | 7.5mg+500<br>mg                              | Tablet                      | <ul><li>a,</li><li>1. Subtherapeutic dose of Pioglitazone.</li><li>2. Safety issue with Pioglitazone especially as FDC.</li></ul>   |
| 1650 | ) pioglitazone<br>hydrochloride +<br>metformin<br>hydrochloride               | 15 mg+ 850<br>mg                             | film coated<br>tablet       | a, 1. Safety issue with Pioglitazone especially as FDC.   |
| 1659 | Metformin<br>HCl+Gliclazide<br>SR+Pioglitazone                                | 500mg+30m<br>g/60mg+7.5<br>mg                | n<br>n                      | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.   |
| 166  | 2 Voglibose+Pioglitazo<br>ne+Metformin HCl IF                                 | 0.2mg/0.3m<br>g+7.5mg/15<br>mg+500mg         | Tablets                     | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of pioglitazone. 2. Safety concerns of pioglitazone. 3. No published literature supporting this FDC.                                      |
| 166  | Metformin HCl<br>IP+bromocriptine<br>Mesylate IP                              | 500mg+0.8<br>mg                              | Uncoated<br>Tablets         | <ul><li>a,</li><li>Pharmacodynamically irrelevant-</li><li>1. No published literature supporting the use of combination.</li><li>2. Both ingredients have different indication.</li></ul>           |
| 167  | 70 Metformin HCl<br>IP+Glimepiride<br>IP+Methylcobalamin<br>JP                |  | Uncoated<br>bilayered table | a, Pharmacodynamically irrelevant-  1. No published literature supporting the superior efficacy of combination of three drugs.  2. Use of methylcobalamine as prophylaxis in FDC is not documented. |
| 16   | 71 Pioglitazone<br>HCL+Metformin HC   |  | Tablets                     | a,<br>Safety issue with Pioglitazone especially as FDC.   |
| 16   | IP+Pioglitazone HC IP+Metformin HCl   | IP   | Tablets                     | <ul><li>a,</li><li>1. There is no published literature supporting this FDC.</li><li>2. The Pioglitazone has safety concerns.</li></ul>  |
| 16   | Pioglitazone HCL<br>IP+Metformin HCl  |  | ig .                        | Subtherapeutic dose of Ploghtazone.     Safety issue with Pioglitazone especially as FDC.   |
|      | Pioglitazone HCL<br>IP+Metformin HCl  |  | Tablets                     | a,<br>Safety issue with Pioglitazone especially as FDC.   |
|      | 687 Pioglitazone HCL<br>IP+Metformin HCl                                      |  | Tablets                     | a, 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC. a,  |
| 1    | 689 Pioglitazone HCL<br>IP+Metformin HCl                                      | 7.50mg+1<br>0mg                              | bilayered tal               | 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC.  |

|      | Chromium<br>Polynicotinate+Metfor<br>min Hydrochloride IP   |                                | Tablets                          | a, Pharmacodynamically irrelevant- 1. No published literature supporting the superior efficacy of combination of these drugs. 2. There is a controversy regarding the use of chromium.             |
|------|---|--------------------------------|----------------------------------|--|
|      |   | 500mg+80m<br>g+15mg+20<br>0mcg | Tablete                          | a, Pharmacodynamically irrelevant-  1. There is no published literature supporting this FDC.  2. The Pioglitazone has safety concerns.  3. It is at variance from the concept and purpose of FDC.  |
| 1710 | Metformin<br>Hydrochloride<br>IP+Gliclazide<br>IP+Chromium<br>Polynicotinate                                      | 500mg+80m<br>g+200mcg          | Uncoated<br>Tablet               | a, Pharmacodynamically irrelevant- 1. No published literature is available supporting the superior efficacy of combination of three drugs 2. there is a controversy regarding the use of chromium. |
| 1720 | Metformin<br>Hydrochloride IP<br>(SR)+Pioglitazone<br>Hydrochloride+Glimi<br>pride                                | 500mg+7.5<br>mg+1              | Uncoated<br>bilayered tablets    | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.  |
| 1724 | Glibenclamide IP+<br>Metformin<br>Hydrochloride<br>IP(SR)+ Pioglitazone<br>Hydrchloride IP eq. to<br>Pioglitazone | 5mg+500mg<br>+15mg             | Uncoated<br>Bilayered<br>tablets | <ul><li>a,</li><li>1. There is no published literature supporting this FDC.</li><li>2. The Pioglitazone has safety concerns.</li></ul>   |
| 1731 | Metformin Hydrochloride IP (sustainded release)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepri de IP  | 500mg+15m<br>g+3mg             | Uncoated<br>bilayered tablets    | a, Pharmacodynamically irrelevant- 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns. 3. It is at variance from the concept and purpose of FDC.     |
| 1732 | Metformin Hydrochloride IP (sustainded release)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepride IP   | 1000mg+15<br>mg+1mg            | Uncoated<br>bilayered tablets    | a, Pharmacodynamically irrelevant- 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns. 3. It is at variance from the concept and purpose of FDC.     |
| 173: | 5 Metformin<br>Hydrochloride IP<br>(SR)+Pioglitazone<br>Hydrochloride<br>IP+Glimipride IP                         | 500mg+7.5<br>mg+1mg            | Uncoated<br>Bilayered<br>Tablets | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.  |
| 173  | 6 Metformin<br>Hydrochloride IP<br>(SR)+Pioglitazone<br>Hydrochloride IP eq.<br>To Pioglitazone                   | 500mg+7.5<br>mg                | Uncoated<br>Bilayered<br>Tablets | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.  |

| IP<br>D<br>IP | +Beclomethasone  | 5% w/v +   E<br>0.025% w/v<br>+ 1% w/v +<br>2% w/v |                             | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|---------------|--|--|-----------------------------|---|
|               | Ofloxacin<br>P+Beclomethazone<br>Dipropionate<br>P+Clotrimazole<br>P+Lignocaine HCl IP             | 0.025% w/v<br>+ 1% w/v +<br>2% w/v                 | Ear Drops                   | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| -             | Ofloxacin+Beclometh<br>asone Dipropionate +<br>Clotrimazole+<br>Lignocaine HCl                     | 0.3%w/v +<br>0.025% w/v<br>+ 1% w/v +<br>2% w/v    | Ear Drops                   | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 1742          | Clotrimazole + Ofloxaxin + Lignocaine + glycerine and propylene glycol                             | 1%w/v+<br>0.3w/v + 2%<br>w/v + q.s                 | Ear drops                   | <ul> <li>a,</li> <li>Pharmacodynamically irrelevant-</li> <li>1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>2. Combining antibiotic, antifungal, in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>3.NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.</li> </ul>  |
| 1743          | Clotrimazole + Ofloxaxin +Beclomethasone Dipropionate+ Lignocaine + glycerine and propylene glycol | 1% w/v+<br>0.3% w/v+<br>0.025%w/v<br>2%w/v q.s     | otobiotic Plus<br>ear drops | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to the misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 174           | 9 Ofloxacin+Beclomasone Dipropionate+Clotazole+Lignocaine I  | rim 025%w/v+<br>0%w/v+2.                           | 1.                          | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.      |

| a<br>I<br>a<br>I | Dipropionate+Clotrim  | )25%w/v+1  | ar Drops  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------------------|---|--|-----------|---|
|                  | Dipropionate  | 5% w/v + E<br>0.025% w/v<br>+ 1% w/v +<br>2% w/v | ar drops  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|                  | Chloramphenicol+Bec<br>lomethasone<br>Dipropionate<br>IP+Clotrimazole<br>IP+Lignocaine HCl<br>IP+Propylene Glycol<br>IP & Glycerin IP | 5.0%w/v + D.025%w/v + 1.0%w/v + 2.0%w/v          | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 1761             | ofloxacin + beclomethasone+ clotrimazole + lignocaine hydrochloride + glycerine + propylene glycol                                    | .3%w/v +<br>.025% w/v +<br>1% w/v +<br>2% w/v    | ear drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 1762             | 2 ofloxacin+<br>clotrimazole+<br>beclomethasone<br>dipropionate+lignocai<br>ne hydrochloride  | 1.0% w/v+<br>.025%w/v +                          | ear drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 176              | 3 Ofloxacin+beclometh<br>asone<br>dipropropionate+Clot<br>imazole+Lignocaine<br>HCL   | 025%w/v+1  | Ear drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |

|      | IP+Ofloxacin<br>IP+Betamethasone  | 1%w/v +<br>0.3%w/v +<br>0.025%w/v<br>+ 2%        | Ear drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|------|---|--|-----------|---|
| 1780 | Chloramphennicol+Li<br>gnocain+Betamethaso<br>ne+Clotrimazole+Oflo<br>xacin+Antipyrine                  | 2% / 2% /  | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 1783 | Chloramphenicol IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lidocaine BP                          | 5%w/v +<br>0.025%w/v<br>+ 1%w/v +<br>1.73%w/v    | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 1786 | Ofloxacin IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP                           | 0.3%w/v +<br>0.025%w/v<br>+ 1.0%w/v +<br>0.2%w/v | Ear Drops | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.     |
| 1789 | Ofloxacin IP+Clotrimazole IP+Betamethasone Dipropionate USP+Lignocaine HCl                              | 0.3%w/v +<br>1.0%w/v +<br>0.025%w/v<br>+ 2.0%w/v | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 179  | I Gentamicin Sulphate<br>IP+Clotrimazole<br>IP+Betamethasone<br>Dipropionate<br>USP+Lignocaine HC<br>IP | 1.0%w/v +<br>0.025%w/v<br>+ 2.0%w/v              | Ear Drops | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.     |

| ]    | P+Beclomethasone Dipropionate  | 0.3%w/v +<br>0.025%w/v<br>+ 1.0%w/v +<br>2.0%w/v  | Ear Drops    | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|--|---|--------------|---|
| 1798 | Ofloxacin+Beclometh<br>asone<br>Dipropinate+Clotrima<br>zole+Lignocaine HCl                    | 0.3%w/v+0.<br>025%w/v+1.<br>0%w/v+2.0<br>%w/v   | Ear Drops    | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 1806 | Lidocaine<br>BP+Clotrimazole<br>IP+Ofloxacin<br>IP+Beclomethasone<br>Dipropionate IP           | 1.73%w/v +<br>1.00%w/v +<br>0.30%w/v +<br>0.025%w/v   |              | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 180  | 7 Chloramphenicol+Be<br>lomethasone<br>Dipropionate+Clotrii<br>azole+Lidocaine HC              | n = 1.0% w/v + 1.0% w/v | 1            | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 18   | 10 Beclomethasone<br>Dipropionate<br>IP+Chloramphenico<br>IP+Clotrimazole<br>IP+Lignocaine HCl | 5%w/v +<br>1%w/v+<br>2%w/v  | y+ Ear Drops | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to the misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 18   | B11 Clotrimazole IP+Beclomethason Dipropionate IP+Ofloxacin IP+Lignocaine HC                   | + 0.3%w/<br>2%w/v   |              | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.    |

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|      | Dipropionate IP+Clotrimazole  | 0.025%w/v<br>+ 1%w/v +<br>5%w/v +<br>2%w/v        | ar Drops  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|------|---|---|-----------|---|
| 1814 | Chloramphenicol+Bec<br>lomethasone<br>Dipropionate+Clotrim<br>azole+Lignocaine HCl            | 5%w/v+1%<br>w/v+2%w/v                             | ar Drops  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 1816 | Becloemthasone Dipropionate+Clotrim azole+Chloramphenic ol+Gentamycin Sulpahte+Lignocaine Hcl | 0.025%w/v+ I<br>1%w/v+5%<br>w/v+0.3%w/<br>v+2%w/v | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 181  | 7 Clotrimazole+Beclomethasone Dipropionate+Ofloxa in+Lignocaine HCl                           | 5%w/v+0.3   | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 183  | 18 Offoxacin IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl                 | 0.3%w/v +<br>0.025%w/v<br>+ 1.0%w/v +<br>0.2%w/v  | Ear Drops | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 18   | IP+Ofloxacin IP+Beclomethasone Dipropionate IP+Lignocaine HCl                                 |   | Ear drops | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |

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| d<br>P<br>L | ihydrochoride +   | 5mg+<br>500mg+ 10<br>mg        |                           | a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. |
|-------------|---|--------------------------------|---------------------------|---|
|             | Rabeprazole sodium +<br>cinitrapride hydrgen<br>cartrate        | 20 mg+ 3 t                     | ablets                    | <ul><li>a,</li><li>1. Pharmacokinetic incompatibility.</li><li>2. No published literature support this FDC.</li></ul>   |
|             | Flunarizine<br>dihydrochoride +<br>Paracetamole+<br>Domperidone | 5mg+325mg (**)<br>+10mg        | Tablets .                 | a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. |
| 1847        | Zinc<br>Carnosine+Diclofenac<br>Potassium BP                    | 37.31118                       | Tablets                   | a, There is no therapeutic benefit of adding zinc carnosine in FDC.   |
| 1850        | Rabeprazole Sodium IP+Zinc carnosine                            | 20mg+75mg                      | Capsules                  | a, Pharmacodynamically irrelevant- 1. No published literature supporting the FDC. 2. Potential for adverse effects.   |
| 1874        | magaldrate +<br>famotidine +<br>simethicone                     | 400 mg+ 10<br>mg+25 mg         | tablets                   | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Famotidine. 2. No evidence of efficacy exists supporting the use of triple drug combination.   |
| 1876        | 6 cyproheptadine +<br>thiamine citrate                          | 2mg+ 275<br>mg                 | syrup                     | <ul><li>a,</li><li>1. Pharmacodynamically irrelevant.</li><li>2. No publish literature is available to support the FDC.</li></ul>   |
| 187         | 7 Ranitidine HCl IP eq<br>to Ranitidine+<br>Magaldrate IP       | 150mg+200<br>mg                | Fim Coated<br>Tablets     | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.  |
| 187         | 8 Magaldrate IP+Ranitidine +Pancreatin Ip+Domperidone IP        | 400mg+150<br>mg+125mg-<br>10mg | Tablets                   | <ul> <li>a,</li> <li>Pharmacodynamically irrelevant-</li> <li>1. There is no use of combining an antiemetic ingredient (domperidone) with drugs for peptic ulcer as vomiting may not always be associated witt.</li> <li>2. Pharmacokinetic incompatibility.</li> </ul>                 |
| 188         | Rabeprazole Sodiun<br>IP+Zinc Carnosine                         | 20mg+150ng                     | n Hard Gelatin<br>Capsule | No published literature supporting the FDC.     Potential for adverse effects.  |
|             | 12 Ranitidine HCL<br>IP+Magaldrate<br>IP+simethicone IP         | 150mg+20mg<br>mg+20mg          | Tablet                    | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.  |
| 19          | Flunarizine+Dompo<br>done+Paracetamol                           | eri 5mg+10mg<br>325mg          | g+ Tablet                 | a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment. |
| 19          | 929 rabeprazole sodiun<br>zinc carnosine                        | n+ 20 mg+ 75                   | film caoted tablet        | a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.   |

| 1934 | magaldrate + papain+<br>fungul diastase +<br>simethicone                                     | 400 mg+<br>60mg+ 20<br>mg+ 25 mg           | film coated<br>tablet    | a, Pharmacodynamically irrelevant- 1. Papain and fungal diastase are digestive enzymes. Simethicone an anti foaming ingredient is used to reduce bloating sensation due to excessive gas production. 2. No published literature supporting the mechanism of action or efficacy for the combination is available   |
|------|--|--|--------------------------|---|
| 1944 | Rabeprazole sodium+<br>zinc carnosine+<br>domperidone  | 20 mg+ 75<br>mg/37.5<br>mg+ 10<br>mg/20 mg | hard gelatin<br>capsules | a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.   |
| 1945 | Rabeprazole sodium+<br>zinc carnosine  | 20 mg+ 75<br>mg                            | hard gelatin<br>capsules | a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.   |
| 1954 | Famotidine BP+<br>oxytacaine BP+<br>Magaldrate IP  | 20mg+5mg+<br>400mg                         | Uncoated<br>Tablets      | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.  |
| 1964 | Ranitidine+Domperid<br>one+Semithicone   | 150mg+10m<br>g+20mg                        |                          | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.  |
| 1966 | Rabeprazole<br>sodium+domperidone<br>+zinc sulphate  | 20mg+30mg<br>+75mg                         | Capsule                  | a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.   |
| 2013 | Clidinium Bromide<br>USP+Paracetamol<br>IP+Dicyclomine HCl<br>IP+Activated<br>Dimethicone IP | 2.5mg+500<br>mg+10mg+2<br>5mg              | Uncoated<br>Tablets      | a, Pharmacodynamic irrelevant- 1.Each ingredients have different therapeutic use and FDC will lead to misuse. 2.Pain of petic ulcer is not due to spasm and hence there is no rationale for combining with dicyclomine  |
| 2034 | Furazolidone<br>IP+Metronidazole<br>IP+Loperamide HCl<br>IP                                  | 500mg+100<br>0mg+7.5mg                     | Uncoated<br>Tablets      | a, Pharmacodynamically irrelevant- 1.antimotility drug will cause toxic megacolon in infective diarrhoea. 2. Loperamide is contra-indicated in infective diarrhea and in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter as it reduces the clearance of pathogens. Hence there is no rationale for combining with antibiotic in an FDC. 3. In bacterial diarrhoea only anti-bacterial drug is effective and antiamoebic drug is useless. Similarly, in intestinal amoebiasis only antiamoebic drug is effective while antibacterial drug is useless. 4.Amoebiasis and bacterial diarrhoea rarely coexist. 5. Only one drug of the combination would be effective and the other one would be useless. |
| 2075 | Rabeprazole Sodium<br>IP+Diclofenac<br>Potassium<br>BP+Paracetamol IP                        | 10mg+50mg<br>+325mg                        | Hard gelatin capsules    | a, 1.Pharmacokinetic/Pharmacodynamic incompatibility. 2.Subtherapeutic dose of rabeprazole. 3.No published literature support combination of rabeprazole with diclofenac and paracetamol.   |
| 2099 | Ranitidine HCl<br>Ip+Magaldrate IP   | 300mg+200<br>mg                            | Film Coated<br>Tablets   | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.  |
|      | Ranitidine<br>HCl+Magaldrate   | 150mg+200<br>mg                            | Tablets                  | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.  |
| 2120 | Rabeprazole Sodium<br>IP+Domperidone<br>IP+Zinc Carnosine                                    | 20mg+30mg<br>+75mg                         | Hard gelatin capsules    | a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.   |

| 2124 | Paracetamol<br>IP+Domperidone<br>IP+Flunarizine HCl IP                                 | 325mg+10m<br>g+5mg   | Tablets                                | a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment.  |
|------|--|----------------------|--|--|
| 2130 | Norfloxacin+<br>Metronidazole<br>Benzoate + zinc<br>Acetate                            | 100mg+200<br>mg+10mg | oral suspension                        | a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country.  Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56. |
| 2141 | Pancreatin<br>IP+Activated<br>Dimethicone IP   | 170mg+80m<br>g       | Enteric Coated<br>Tablets              | a, 1. Pharmacokinetic incompatibility. 2. Pancreatin is made up of the pancreatic enzymes trypsin, amylase, and lipase. Dimethicone is antiflatulent. No published literature supports the use of combination  |
| 2142 | Zinc<br>Carnosine+Rabeprazo<br>le Sodium<br>IP+Domperidone IP                          | 75mg+20mg<br>+30mg   | Hard Gelatin<br>Capsules               | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC. 2. Fdc will enhance the risk of adverse effects.  |
| 2143 | Zinc<br>Carnosine+Pantoprazo<br>le sodium  | 75mg+40mg            | Hard gelatin capsules                  | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.   |
|      | Zinc<br>Carnosine+Oxetacaine<br>BP   | 50mg+10mg            |  | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.   |
| 2167 | Diethyl Carbamazine<br>Citrate<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaiphenesin IP | 100mg+2mg<br>+60mg   | Film Coated<br>Tablets                 | a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2. Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.   |
|      | Oxetacaine BP+Magaldrate IP+Famotidine IP  | 5mg+400mg<br>+20mg   | Uncoated<br>Tablet                     | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.   |
| 2169 |  | 75mg+500m<br>g       | Uncoated<br>Tablet                     | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.   |
| e: 1 | **************************************   |                      |  |  |
|      | IP+Streptococcus<br>faecalis T-110   |                      | Capsules(Powd<br>er for<br>inhalation) | a, Pharmacodynamically irrelevant-  1. No published literature supporting the use of combination.  2. Mebeverine is used for relieving spasm in treatment of irritable bowel syndrome (IBS) and the associated abdominal cramping.  3. Therapeutic indication of Mebeverine and Probiotic are different.   |

|      | Pantoprazole Sodium<br>sesquihydrate eq. to<br>Pantoprazole (as EC<br>Tablet)+Zinc<br>Carnosine (as FC<br>Tablets)   | 40mg+75mg   | Tablets                     | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.   |
|------|--|---|-----------------------------|--|
| 2240 | Pantoprazole Sodium<br>sesquihydrate eq. to<br>Pantoprazole (as EC<br>Tablet)+Zinc<br>Carnosine (as FC<br>Tablets)   | 40mg+75mg   | Tablets                     | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.   |
| 2241 | Pantoprazole Sodium<br>sesquihydrate eq. to<br>Pantoprazole (as EC<br>Tablet)+Zinc<br>Carnosine (as FC<br>Tablets)   | 40mg+75mg   | Film Coated<br>Tablets      | a, Pharmacodynamically irrelevant- No published literature supporting the FDC.   |
| 2249 | IP+Domperidone<br>IP+Zinc Carnosine  | +37.5mg   | Hard Gelatin<br>Capsules    | a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.  |
| 2251 |  | 0   | Oral Liquid -<br>Suspension | a, Pharmacodynamically irrelevant-  1. No published literature supporting this FDC.  |
| 2252 | Zinc<br>Carnosine+Sucralfate<br>IP   |   | Oral Liquid -<br>Suspension | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.   |
| 2253 | Zinc<br>Carnosine+Oxetacaine<br>BP   |   | Oral Liquid -<br>Suspension | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.   |
| 2255 | Zinc<br>Carnosine+Pantoprazo<br>le Sodium<br>sesquihydrate IP eq. to<br>Pantoprazole(as<br>enteric coated tablets)   |   | Film coated<br>Tablets      | a, Pharmacodynamically irrelevant-  1. No published literature supporting this FDC.  |
| 2256 | Zinc<br>Carnosine+Sucralfate<br>USP  | 75mg+500m<br>g  | Uncoated<br>Tablets         | a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.   |
| 2274 | Mebeverine Hydrochloride IP & Inner HPMC capsule (Streptococcus Faecalis T-110 JPC+Clostridium butyricum TO- A+Bacillus mesentricus TO-A JPC+Lactic Acid Bacillus) | 135mg+60<br>Million+4<br>Million+2<br>Million+ 100<br>Million | capsules                    | a, Pharmacodynamically irrelevant-  1. No published literature supporting the use of combination.  2. Mebeverine is used for relieving spasm in treatment of irritable bowel syndrome (IBS) and the associated abdominal cramping.  3. Therapeutic indication of Mebeverine and Probiotic are different. |
| 231  | 7 Sildenafil Citrate eq.<br>to Sildenafil+Estradiol<br>Valerate  | 25mg+1mg  | Tablets                     | a,     Pharmacodynamically irrelevant-     Both ingredients have different indications.     No clinical studies are found supporting this combination.   |

|      | IP+Ubidecarenone<br>USP+Zinc Sulphate<br>IP+Folic Acid<br>IP+Methylcobalamin   | 25mg+60mg<br>+66mg+5mg<br>+1500mcg+<br>1.5mg+4mg<br>+200mcg+5<br>0mg+20mg | Tablets                | a,  No published literature supporting this combination of a ovulation inducing ingredient( clomiphene) with multivitamins and antioxidants   |
|------|--|---|------------------------|---|
|      | ne (DHEA)<br>(micronized)+Calcium  | B = 0 0 0   | Film Coated<br>Tablets | a, 1. Pharmacodynamically irrelevant. 2. No published literature supporting this combination of DHEA with multivitamins and minerals  |
|      | Thyroxine Sodium IP<br>Eq. to 0.045 mg of<br>anhydrous thyroxine<br>sodium+ Pyridoxine<br>Hydrochloride IP+<br>Folic Acid IP         | 0.05mg+<br>1mg+1.5mg  | Oral Tablet            | a, No clinical studies found supporting the use of this combination   |
|      | Gentamycin+Dexamet<br>hasone+Chlorampheni<br>col+Tobramycin+Oflo<br>xacin  | / 0.1% /  | Eye drops              | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 2493 | Enrofloxacin+Bromhe xine HCl   | 200mg+15m<br>g per ml   | Oral Solution          | a, Pharmacodynamically irrelevant- 1.Enrofloxacin is not approved for human use.  |
| 2497 | Dextromethorphan Hydrobromide IP+Bromhexine HCl+Menthol IP+Ammonium Chloiride IP   | 5mg+4mg+2<br>.5mg+50mg/<br>5ml  | Syrup                  | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  |
| 2503 | Dextromethorphan<br>Hydrobromide+<br>Levocetirizine Hcl<br>IP+Phenylephrine Hcl<br>IP+Zinc Gluconate<br>USP Eq. to Elemental<br>Zinc | g+5mg+7.5<br>mg per 5ml   | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 2504 | Diphenhydramine Hcl<br>IP+Guaiphenesin<br>IP+Bromhexine HCl<br>IP+Ammonium<br>Chloride IPMenthol IF                                  | 100mg+1mg<br>per 5ml  | Syrup                  | a, Pharmacodynamically irrelevant.  • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.   |

| 250  | Nimesulide<br>BP+Loratadine<br>USP+Phenylephrine<br>HCl IP+Ambroxol<br>HCl                                   | 100mg+2.5<br>mg10mg+1<br>mg       |                  | a, Pharmacodynamic irrelevant- 1.Each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Pharmacokinetic mismatch.  |
|------|--|-----------------------------------|------------------|--|
|      |  |                                   |                  | Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br. J Clin Pharmacol / 65:5 / 795–796 Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 250  | 7 Paracetamol<br>IP+Guaiphenesin<br>IP+Ambroxol HCl<br>IP+Phenylephrine HC<br>IP+Chlorpheniramine<br>Maleate | 325mg+100<br>mg+30mg+3<br>0mg+2mg |                  | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 2510 | Ambroxol Hcl IP+Guaiphenesin IP+Chlorpheniramine Maleate IP+Phenylephirine HCl IP+Menthol IP                 | 15mg+50mg<br>+2mg+5mg+<br>1mg     |                  | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule   |
| 2511 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Ambroxol HCl<br>IP+Chlorpheniramine<br>Maleate                     | 125mg+2.5<br>mg+7.5mg+<br>1.0mg   | Oral Drops       | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Potential for drug-drug interaction. 4.Dosing shedule of the ingredients is incompatible. 5.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  |
| 2513 | Paracetamol<br>IP+Ambroxol HCl<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP                  | 125mg+15m<br>g+5mg+2mg            |                  | a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.  |
| 2514 | Bromhexine HCl<br>IP+Phenylephrine HCl<br>IP+Chlorepheniramin<br>e Maleate IP                                | 4mg+5mg+2<br>mg                   | Oral Solution    | a, Pharmacodynamically irrelevant- 1.chlorpheniramine + phenylephrine chlorpheniramine increases and phenylephrine decreases sedation. Effect of interaction is not clear, use caution. 2.Dosing shedule of the ingredients are not compatible   |
|      | Dextromethorphan<br>Hydrobromide+<br>bromhexine<br>hydrochloride+Guaiph<br>enesin                            | 10mg+ 2<br>mg+ 100mg              | Soft gel capsule | a, Pharmacodynamically irrelevant-  1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered  3. Patients may need only one ingredient and use of FDC may lead to misuse.  4. Dosing shedule of the ingredients is incompatible. |
|      | Hydrochloride +  | 2.5mg+<br>500mg+ 15<br>mg+ 10 mg  | tablet           | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule.  |

|     | 2520 Paracetamol + Loratadine + phenylephrine Hydrochloride + Dextromethorpha Hydrochloride + caffeine                                       | 325mg+<br>mg+ 10<br>10 mg+<br>mg     | mg+        | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  |
|-----|--|--------------------------------------|------------|---|
|     | 521 Nimesulide + Phenylephrine hydrochloride + Ceffeine( anhydro + levocetirizine Dihydrous  | 100mg+<br>mg+ 30 r<br>5 mg           |            | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule. 3. Nimesuilide- Safety concern                          |
|     | Azithromycin IP a<br>dihydrate eq to<br>Anhydrous<br>Azithromycin+<br>acebrophyline  | 250 mg /5<br>mg +<br>100mg/<br>100mg | tablet     | a,  1. Pharmacodynamically irrelevant-combining anti-bacterial with bronchodialator is not indicated.  2. Potential misuse as bronchodialator with anti-bacterial will increase the emergence of drug resistance to azithromycin and its adverse effects. |
| 252 | Dextromethorphan Hydrobromide + Paracetamol + clorpheniramine Maleate + phenylephrine hydrochloride  | 5mg+ 125<br>mg+ 1 mg-<br>5 mg        | oral syrup | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.             |
| 253 | l ambroxol<br>hydrochloride +<br>guaiphenesin Ip+<br>phenylepherine<br>Hydrochloride +<br>chlorpheniramine<br>maleate + menthol<br>flavoured | 15 mg+ 50<br>mg + 5 mg+<br>2mg +     | Syrup      | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.   |
|     | Levoctirizine HCL<br>IP+Paracetamol<br>IP+Phenylephrine<br>HCL IP+Caffeine<br>(anhydrous) IP   | 2.5mg+325<br>mg+10mg+1<br>5mg        | Tablets    | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule.  3. Subtherapeutic dose of paracetamol.               |
| 1   | Levocetrizine<br>HCl+Phenylephrine<br>HCl+Paracetamol<br>P+Caffeine  | 2.5mg+10m<br>g+500mg+3<br>0mg        | Tablets    | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule.   |
|     | Paracetamol P+Cetirizine HCL P+Phenylephrine HCl P+Zinc Gluconate ISP Eq. to Elemental inc   | mg+5.0mg+                            | Suspension | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4. Potential for drug-drug interaction.                   |

|  | 2545 Dextrome  | - arothitan   | 10mg+1.25  | Syrup  |  |
|--|--|---|--|--|--|
|  | Hydrobro   | mide<br>idine HCL   | mg+5mg   | Syrup  | a,   |
|  | IP+Pheny   | laine HCL   |  |  | Pharmacodynamically irrelevant-  |
|  | IP I Helly   | lephrine HCI  |  | 1  |  |
|  |  |   |  |  |  |
| - 1  |  |   |  |  | drowsiness and also will interefere with the reflexes.   |
| - 1  | 1  | - 1   |  |  | 3. Centrally acting anti-tussive not to be combined with anti-histam   |
|  | 2547 Devtro  |   |  |  | drug.  |
| - 1  | 2547 Dextrometh<br>Hydrobrom   | norphan   | 10mg+4mg   | Syrup  |  |
|  | IP+Chlorph   | ide   |  | J - P  | a,   |
|  | Maleate IP   | entramine   |  |  | 1 Dosing schedule is incompatible.   |
| - 1  | ·  | - 1   | 1  |  |  |
|  |  |   | - 1  |  | drowsiness and also will interefere with the reflexes.   |
|  |  | 1   | 1  |  | 3. Centrally acting anti-tussive not to be combined with anti-histamin drug.   |
| 2  | 2548 Diphenhydra   | mina  |  |  | o and mistallin  |
| 1  | HCl IP+Terp  |   | 2.5mg+7.5 Or   | ral Liquid   | a  |
|  | Hydrate  |   | g+125mg+1  |  |  |
| 1  | USP+Ammor  | lllim la  | mg+1.5m  |  | Pharmacodynamically irrelevant.  |
|  | Chloride IP+S  | odium   | -  |  | No published literature supporting the combination   |
| 1  | Chloride IP+N  | Aenthol   | - 1  | 1  | ,  |
| 1  | IP   |   |  |  |  |
|  |  | 1   |  |  |  |
| 254  | 49 Paracetamol   |   |  |  |  |
|  | IP+Phenylephri   | ne HOULA  | mg+5mg Tabl  | lets a   |  |
|  | 11+Chlorphenir   | amina   | g+30mg   | 1  | Pharmacodynamicall   |
|  | Maleate IP+Caf   | feine   |  | 2  | Pharmacodynamically and phamacokinetically irrational FDC.  Patients may need only one ingredient and use of FDC may lead to   |
|  | IP   |   |  | [11]   | isuse.   |
|  |  |   |  | 3.   | Dosing shedule of the ingredients is incompatible.   |
| 2550   | 0 Paracetamol  | 5may  | 225  |  | of the higherients is incompatible.  |
|  | IP+Phenylephrin  |   | 325mg Table  |  |  |
|  |  |   | "Sumg  | 1.H  | harmacodynamically and phamacokinetically irrational FDC.  |
|  | Maleate IP+Caffe   | eine  | 1  | 2.F  | atients may need only one ingredient and use of FDC may lead to  |
|  | IP   |   | 1  | Imis   | use. · grant and use of FDC may lead to  |
| 0.7.5  |  |   | 1  | [3.D   | osing shedule of the ingredients is incompatible.  |
| 2553   | Paracetamol  | 500mg   | +10m Uncoat  |  | is incompatible.   |
| - 1  | ID_DL  | Trail   | Uncoat   | ed a,  |  |
| i,   | Thenylephrine  |   | + illm   Tableta   |  |  |
| 1  | IP+Phenylephrine<br>IP+Cetirizine HCl  | ricig+5mg   | +30m Tablets   | 1.Ph   | armacodynamically and phamacolisis is a  |
| 1  | IP+Phenylephrine<br>IP+Cetirizine HCl<br>IP+Caffeine IP  |   | +30m Tablets   | 1.Ph   | armacodynamically and phamacokinetically irrational FDC.   |
| I  | IP+Cetirizine HCI<br>IP+Caffeine IP  | ricig+5mg   | +30m   Tablets   | 1.Ph<br>2.Pa<br>misu   | armacodynamically and phamacokinetically irrational FDC. ients may need only one ingredient and use of FDC may lead to   |
| 2554 N   | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+   | g g   |  | 1.Ph<br>2.Pa<br>misu   | se   |
| 2554 N   | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine  | 100mg+  | 4mg Uncoate  | 1.Ph<br>2.Pa<br>misu<br>3.Do   | sing shedule of the ingredients is incompatible.   |
| 2554 N<br>C<br>M   | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+  | 100mg+<br>+10mg+  |  | 1.Ph<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha  | se. Sing shedule of the ingredients is incompatible.   |
| 2554 N<br>C<br>M   | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCI   | 100mg+<br>+10mg+  | 4mg Uncoate  | 1.Ph<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha  | se. Sing shedule of the ingredients is incompatible.   |
| 2554 N C M PH  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  | 100mg+<br>+10mg+<br>g   | 4mg Uncoate<br>30m Tablets   | 1.Ph<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha  | se   |
| 2554 N<br>C<br>M<br>Pl<br>IP<br>2558 Pa  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ thenylephrine HCL P+ Caffeine IP Iracetamol  | 100mg+<br>+10mg+<br>g   | 4mg Uncoated 30m Tablets   | 1.Pt<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha<br>2.Pati<br>misus   | se. Sing shedule of the ingredients is incompatible.   |
| 2554 N<br>C<br>M<br>PH<br>IP<br>2558 Pa  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ thenylephrine HCL P+ Caffeine IP Tracetamol +Chlorpheniramine  | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/  | 4mg Uncoated 30m Tablets  00 Uncoated 2m Tablets   | 1.Ph<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha<br>2.Pati<br>misus   | rmacodynamically and phamacokinetically irrational FDC. ents may need only one ingredient and use of FDC may lead to   |
| 2554 N<br>C<br>M<br>PH<br>IP<br>IP<br>2558 Pa  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ thenylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine aleate   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/<br>g+10mg/5  | 4mg Uncoated<br>30m Tablets<br>00 Uncoated<br>7ablets  | 1.Ph<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha<br>2.Pati<br>misus   | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  |
| 2554 N<br>C<br>M<br>PH<br>IP-<br>2558 Pa<br>IP-<br>Ma<br>IP-   | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ thenylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine aleate +Phenylephrine HCl  | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/<br>g+10mg/5  | 4mg Uncoated<br>30m Tablets<br>00 Uncoated<br>7ablets  | 1.Ph<br>2.Pa<br>misu<br>3.Do<br>d a,<br>1.Pha<br>2.Pati<br>misus   | rmacodynamically and phamacokinetically irrational FDC. ents may need only one ingredient and use of FDC may lead to   |
| 2554 N C M PH IP- Ma IP-   | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ thenylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP  | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/5<br>g+10mg/5   | 4mg Uncoated<br>30m Tablets<br>00 Uncoated<br>7ablets  | d a, 1.Pha 2.Pati misus  a, 1.Phar 2.Patie misuse  | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  nacodynamically and phamacokinetically irrational FDC.  ts may need only one ingredient and use of FDC may lead to  |
| 2554 N C M Pri IP Ma IP H Ma IP H P H P Ma IP H P H P M P M P M P M P M P M P M P M  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  aracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/<br>g+10mg/5<br>g+30mg/3  | 4mg Uncoated Tablets  Uncoated Tablets  Tablets  | d a, 1.Pha 2.Pati misus  a, 1.Phar 2.Patie misuse  | rmacodynamically and phamacokinetically irrational FDC. ents may need only one ingredient and use of FDC may lead to ents may need only one ingredient and use of FDC may lead to ents may need only one ingredient and use of FDC may lead to   |
| 2554 N C M Pri IP Ma IP H Ma IP H IP H Pri IP H  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP aracetamol +Chlorpheniramine aleate +Phenylephrine HC Caffeine IP acetamol+Phenyle ine   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/s<br>g+10mg/5<br>Ig+30mg/3<br>mg<br>500mg+10  | 4mg Uncoated Tablets  Uncoated Tablets  Tablets  | a, 1.Phar 2.Patie misus  a, 1.Phar 2.Patie misuse 3.Dosir a,   | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  ents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  nts may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  |
| 2554 N C M Pri IP Ma IP + Ma IP + IP + F660 Para phri HCI  | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP aracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramine   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/s<br>g+10mg/5<br>Ig+30mg/3<br>mg<br>500mg+10  | 4mg Uncoated Tablets  Uncoated Tablets  Tablets  | a, 1.Pharmisus  a, 1.Pharmisus  1.Pharmisus  1.Pharmisuse  1.Pharmisuse  1.Pharmisuse  | see. Sing shedule of the ingredients is incompatible.  Imacodynamically and phamacokinetically irrational FDC. ents may need only one ingredient and use of FDC may lead to ents may need only one ingredient and use of FDC may lead to ents may need only one ingredient and use of FDC may lead to g shedule of the ingredients is incompatible.  |
| 2554 N C M Pri IP Ma IP H Ma IP H H C IP H C | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP aracetamol +Chlorpheniramine aleate +Phenylephrine HC Caffeine IP acetamol+Phenyle ine   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/s<br>g+10mg/5<br>Ig+30mg/3<br>mg<br>500mg+10  | 4mg Uncoated Tablets  Uncoated Tablets  Tablets  | a, 1.Pharmisus  a, 1.Pharmisus  1.Pharmisus  1.Pharmisuse  1.Pharmisuse  1.Pharmisuse  | see. Sing shedule of the ingredients is incompatible.  Imacodynamically and phamacokinetically irrational FDC. ents may need only one ingredient and use of FDC may lead to ents may need only one ingredient and use of FDC may lead to ents may need only one ingredient and use of FDC may lead to g shedule of the ingredients is incompatible.  |
| 2554 N C M Pri IP- Ma IP- Ma IP- Ma IP- Ma IP- Mri IP- | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  aracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramine aleate+Caffeine  | 100mg+<br>100mg+<br>100mg+<br>100mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+          | 4mg Uncoated Tablets  00 Uncoated Tablets  m Tablets  m Tablets  | a, 1.Phara 2.Patie misuse 3.Dosir 2.Patie misuse 3.Dosir 2.Patien misuse.  | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  nts may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  s may need only one ingredient and use of FDC may lead to   |
| 2554 N C M Pi IP   | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  Irracetamol +Chlorpheniramine Aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramine aleate+Caffeine   | 100mg+<br>100mg+<br>100mg+<br>100mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+          | 4mg Uncoated Tablets  OO Uncoated Tablets  mm Tablets  mm Tablets  | a, 1.Phara 2.Patie misuse 3.Dosir 2.Patie misuse 3.Dosir 2.Patien misuse.  | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  nts may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  s may need only one ingredient and use of FDC may lead to   |
| 2554 N C M Pi IP   | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  Irracetamol +Chlorpheniramine Aleate IP+henylephrine HCl Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin aleate+Caffeine  Droxol  Levocetrizine Di   | 100mg+<br>100mg+<br>100mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+ | 4mg Uncoated 30m Tablets  Uncoated Tablets  Tablets  Tablets  Tablets  | a, 1. Pharmal a, | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  nacodynamically and phamacokinetically irrational FDC.  nts may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.   |
| 2554 N C M Pi IP IP Ma IP H IP H IP H CI H CI H M I I I I I I I I I I I I I I I I I   | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  Irracetamol +Chlorpheniramine Aleate Phenylephrine HCl Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin Aleate+Caffeine  IP-Coxol IP-Phenylephrine  | 100mg+<br>100mg+<br>100mg+<br>100mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+2mg/5<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+<br>10mg+          | 4mg Uncoated 30m Tablets  Uncoated Tablets  Tablets  Tablets  Tablets  | a, 1. Pharm 2. Patie misus  a, 1. Pharm 2. Patie misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing   | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  nacodynamically and phamacokinetically irrational FDC.  nts may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.   |
| 2554 N C M Pi IP IP Ma IP + IP   | IP+Cetirizine HCI IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP  aracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin aleate+Caffeine   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/s<br>g+10mg/5<br>21 g+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m  | 4mg Uncoated 30m Tablets  Uncoated Tablets  Tablets  Tablets  Tablets  | a, 1. Pharm 2. Patien misus  a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm ingredien   | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  ats may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.   |
| 2554 N C M Pi IP IP Ma IP HCI e ma 633 Amb HCI + | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Irracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin aleate+Caffeine IP-Chlorpheniramin III-Chlorpheniramin III- | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/s<br>g+10mg/5<br>21 g+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m  | 4mg Uncoated 30m Tablets  Uncoated Tablets  Tablets  Tablets  Tablets  | a, 1. Pharm 2. Patien misus  a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm ingredien   | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  ats may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.   |
| 2554 N C M Pri IP Ma IP Ma IP HCI e ma 63 Amb HCI + HC | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Irracetamol +Chlorpheniramine aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine H-Chlorpheniramin aleate+Caffeine Droxol -Phenylephrine Guaiphenesin  | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/3<br>g+10mg/5<br>Ig+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m<br>g   | 4mg Uncoated Tablets  Oo Uncoated Tablets  m Tablets  m Ooral Liquid   | a, 1. Pharm 2. Patien misus  a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 2. Patien misuse. 3. Dosing a, 2. Pharm ingredien 2. Pharma  | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  nacodynamically and phamacokinetically irrational FDC.  nts may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.   |
| 2554 N C M PH IP PH MAIN IP PH | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine Aleate +Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin aleate+Caffeine Droxol -Phenylephrine Guaiphenesin Omethorphan -Bromhexine   | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/3<br>g+10mg/5<br>I g+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m<br>g  | 4mg Uncoated Tablets  Output  Output | a, 1.Pharm 2.Patie misuse. 3.Dosing a, 1.Pharm 2.Patien misuse. 3.Dosing a, 1.Pharm 2.Patrien misuse. 3.Dosing a, 1.Pharm a, 1.Pharm a, 1.Pharm a, 1.Pharm   | see.  sing shedule of the ingredients is incompatible.  rmacodynamically and phamacokinetically irrational FDC.  ents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  ats may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.  acodynamically irrelevant-Patients may not need all the  s and use of FDC may lead to misuse and adverse effects.  cokinetically irrelevant-different dosing shedule   |
| 2554 N C M PH IP PH Ma IP PH I | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine Aleate -Phenylephrine HC -Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin aleate+Caffeine IP-Caffeine IP acetamol+Phenyle ine I+Chlorpheniramin aleate+Caffeine IP-Caffeine IP-Caffeine IP-Caffeine IP-Caffeine IP-Chlorpheniramin Include III-III-III-III-III-III-III-III-III-II  | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/3<br>g+10mg/5<br>Ig+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m<br>g   | 4mg Uncoated Tablets  Oo Uncoated Tablets  m Tablets  m Ooral Liquid   | a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm ingredien 2. Pharma  | see.  Sing shedule of the ingredients is incompatible.  Imacodynamically and phamacokinetically irrational FDC.  Sents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  Into may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  Inacodynamically and phamacokinetically irrational FDC.  In acodynamically irrational FDC may lead to  In |
| 2554 N C M PH IP PH Ma IP PH I | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine Aleate -Chlorpheniramine IP- Iracetamol -Caffeine IP Iracetamol -Caffeine IP Iracetamol -Caffeine IP Iracetamol -Chlorpheniramine Ince IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Iracetamol IP-Iracet | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/3<br>g+10mg/5<br>21 g+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m<br>g   | 4mg Uncoated Tablets  Oo Uncoated Tablets  m Tablets  m Ooral Liquid   | a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm ingredien 2. Pharma a, 1. Dosing s 2. Ingredie   | see. Sing shedule of the ingredients is incompatible.  Imacodynamically and phamacokinetically irrational FDC. ents may need only one ingredient and use of FDC may lead to the ingredient and use of FDC may lead to get shedule of the ingredients is incompatible.  Inacodynamically and phamacokinetically irrational FDC. may lead to get shedule of the ingredients is incompatible.  Inacodynamically and phamacokinetically irrational FDC. may need only one ingredient and use of FDC may lead to shedule of the ingredients is incompatible.  Inacodynamically irrelevant-Patients may not need all the sand use of FDC may lead to misuse and adverse effects. Ecokinetically irrelevant-different dosing shedule chedule is incompatible.   |
| 2554 N C M PH IP PH Ma IP PH I | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine Aleate -Chlorpheniramine IP- Iracetamol -Caffeine IP Iracetamol -Caffeine IP Iracetamol -Caffeine IP Iracetamol -Chlorpheniramine Ince IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Iracetamol IP-Iracet | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/3<br>g+10mg/5<br>21 g+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m<br>g   | 4mg Uncoated Tablets  Output  Output | a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm ingredien 2. Pharma a, 1 Dosing s 2. Ingredie drowsiness   | see.  Sing shedule of the ingredients is incompatible.  Imacodynamically and phamacokinetically irrational FDC.  Sents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  Into may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.  acodynamically irrelevant-Patients may not need all the  s and use of FDC may lead to misuse and adverse effects.  cokinetically irrelevant-different dosing shedule  chedule is incompatible.  and also will aggravate the adverse effects of sedation and and also will aggravate the adverse effects of sedation and and also will in the sand also will aggravate the adverse effects of sedation and and also will in the sand also will aggravate the adverse effects of sedation and and also will in the sand also will be sand also will in the sand also will in the sand also will in the sand also will be sand also will be sand also will be sand also |
| 2554 N C M PH IP PH Ma IP PH I | IP+Cetirizine HCl IP+Caffeine IP  Nimesulide BP+ Chlorpheniramine Maleate IP+ henylephrine HCL P+ Caffeine IP Iracetamol +Chlorpheniramine Aleate -Chlorpheniramine IP- Iracetamol -Caffeine IP Iracetamol -Caffeine IP Iracetamol -Caffeine IP Iracetamol -Chlorpheniramine Ince IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Phenylephrine IP- Iracetamol IP-Iracetamol IP-Iracet | 100mg+<br>+10mg+<br>g<br>500mg/50<br>mg+2mg/3<br>g+10mg/5<br>21 g+30mg/3<br>mg<br>500mg+10<br>g+2mg+30<br>ng<br>15mg+0.8m<br>g+5mg+50m<br>g   | 4mg Uncoated Tablets  Output  Output | a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm 2. Patien misuse. 3. Dosing a, 1. Pharm ingredien 2. Pharma a, 1 Dosing s 2. Ingredie drowsiness   | see.  Sing shedule of the ingredients is incompatible.  Imacodynamically and phamacokinetically irrational FDC.  Sents may need only one ingredient and use of FDC may lead to  macodynamically and phamacokinetically irrational FDC.  Into may need only one ingredient and use of FDC may lead to  g shedule of the ingredients is incompatible.  acodynamically and phamacokinetically irrational FDC.  s may need only one ingredient and use of FDC may lead to  shedule of the ingredients is incompatible.  acodynamically irrelevant-Patients may not need all the  s and use of FDC may lead to misuse and adverse effects.  cokinetically irrelevant-different dosing shedule   |

| 2560   | Nimesulide+Parace<br>mol+Cetrizine<br>HCl+Phenylephrine<br>HCL   | mg+5mg                        |  | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
|--|--|-------------------------------|--|---|
|  | Nimesulide+Phneylej<br>hrine<br>HCl+Chlorphenirami<br>e Maleate+Caffeine   | mg10mg/5                      | m<br>g                                   | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
| ph   | aracetamol+Phenyle<br>nerine+Caffeine+Lev<br>retirizine  | 500mg+10m<br>g+30mg+2.5<br>mg | Tabelts                                  | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| Etc  |  | 1mg+50mg+<br>4mg              | Syrup                                    | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| +gu<br>+ph<br>+chl<br>male<br>IP ar<br>+ ch<br>male<br>HCL | aiphenesin enylephrine HCL lorpheniramine eate +paracetamol IP lorpheniramine eate +bromhexine + guaiphenesin -phenylephrine | ng+100mg/                     | film coated<br>tablet/uncoated<br>tablet | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility  |

| 258  | Paracetamol+Phenylophrine HCL+Cetirizine HCL+Caffeine   | 500mg/500<br>mg/325mg+<br>10mg/10mg<br>10mg+2.5m<br>g/5mg/5mg-<br>30mg/30mg<br>30mg | z/<br>1<br>+ | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|------|---|---|--------------|---|
| 258  | 16 Levocetirizine HCL+<br>Paracetamol+Caffein<br>+ Phenylephrine HCI                                    | e 2.5mg+500   | 5            | a, Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.   |
| 258  | 8 Phenylephrine<br>HCL+Chlorpheniram<br>ne Maleate+Caffeine<br>(Anhydrous)                              | 10mg+2mg+<br>i 30mg   | Tablets      | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 259  | l paracetamol +<br>chlorpheniramine<br>maleate +<br>phenylephrine Hcl +<br>caffiene                     | 650 mg+ 2<br>mg+ 10 mg<br>+ 30 mg   | tablets      | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
| 2592 | paracetamol + cetirizine hydrochloride + dextromethorphan hydrochloride + pseudoephedrine hydrochloride | 250 mg+ 2.5<br>mg+ 5 mg+<br>15 mg   | syrup        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                       |
| 2593 | paracetamol+<br>loratadine +<br>dextromethophan +<br>pseudoepheridine<br>HCL + caffeine                 | 650 mg+<br>3.3. mg+ 10<br>mg+ 60 mg+<br>30 mg                                       | Tablets      | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 2597 | Ambroxol HCL +<br>guaiphenesin+<br>Phenylephrine HCL +<br>chloroheniramine<br>Maleate + menthol         | 15 mg+ 50<br>mg+ 10 mg+<br>2 mg+ 1 mg   | Syrup        | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule  |
| 2598 | paracetamol +<br>levocetrizine Di HC<br>Phenylephrine HCL +<br>Caffeine Anhydrous                       | 325 mg+ 2<br>.5 mg+ 5<br>mg+ 30 mg  | Tablets      | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
| 2599 | chlorpheniramine<br>maleate + ammonium<br>chloride + sodium<br>citarte+                                 | 2.5 mg+ 125<br>mg+ 55 mg  | Syrup        | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract |
|      | maleate +<br>dextromethophan<br>hydrobromide  | mg  | syrup        | a, 1. Potential of misuse in paediatric population 2. Concurrent use of Centrally acting anti-tussive and anti-histaminic is not rational.  |
|      | Ambroxol HCl<br>IP+Levocetirizine HCl<br>IP+Guaiphenesin+Phe<br>nylephrine HCl<br>IP+Menthol IP         | g+50mg+5m   | Syrup        | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule  |

| ne c | 06 Paracetamol+Phenylphrine HCl IP+Chlorpheniramine Maleate IP+Caffeine   | g+4mg+20n<br>g  | n Tablets | <ul> <li>a,</li> <li>1.Pharmacodynamically and phamacokinetically irrational FDC.</li> <li>2.Patients may need only one ingredient and use of FDC may lead to misuse.</li> <li>3.Dosing shedule of the ingredients is incompatible.</li> </ul>   |
|------|---|---|-----------|--|
| 260  | 98 Bromhexine HCl<br>IP+Paracetamol<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaiphenesin IP |   |           | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility 4. Over dose and misuse of paracetamol. |
| 261  | Nimesulide<br>BP+Paracetamol<br>IP+Cetirizine HCl<br>IP+Phenylephrine HC<br>IP+Caffeine IP                          | 100mg/100<br>mg+325mg/<br>325mg+5mg<br>1/5mg+10mg/<br>5mg+25mg/<br>25mg |           | a,  1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  2. There is pharmacokinetic incompatibility among the drugs.  3. Nimesuilide has documanted safety concern.  4. Hepatotoxic potential of both the drugs   |
|      |   |   |           | Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 2612 | Chlorpheniramine<br>Maleate+Ammonium<br>Chloride+Sodium<br>Citrate  | 4mg+125mg<br>+65mg  | Syrup     | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |
| 2616 | Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP+Caffeine IP   | 325mg+10m<br>g+2mg+30m<br>g   |           | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2617 | Cetirizine HCl<br>IP+Phenylephrine HCl<br>IP+Paracetamol<br>IP+Zinc Gluconate                                       | 0 0   | Tablets   | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      | Maleate IP+Codeine  | 4mg/4mg/4<br>mg+10mg/1<br>0mg/10mg                                      | Syrup     | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|      | BP+Chlorpheniramine   | 500mg+2mg<br>+10mg+30m  |           | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.   |

| 2630 | Dextromethorphan<br>Hydrobromide+Cetiri<br>zine<br>HCl+Zinc+Menthol  | 7.5m+2.5mg<br>+7.5mg+1.5<br>mg              | Syrup               | Dosing schedule is incompatible.     Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|------|--|---|---------------------|--|
| 2632 | Ambroxol HCl IP+Guaiphenesin IP+Ammonium Chloride IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Menthol IP | 15mg+50mg<br>+100mg+2.5<br>mg+2mg+0.<br>1mg | Syrup               | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule   |
| 2637 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Cetirizine HCl<br>IP+Caffeine IP                                       | 650mg+10m<br>g+5mg+25m<br>g                 | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2638 | cetirizine<br>hydrochloride+<br>paracetamol +<br>phenylephrine<br>hydrochloride +<br>caffeine ( anhydrous )      | 5 mg+ 650<br>mg+ 10 mg<br>+ 30 mg           | tablets             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2640 | cetirizine<br>hydrochloride+<br>paracetamol+<br>phenylephrine HCl+<br>zinc gluconate                             | 2.5 mg+ 125<br>mg+ 2.5<br>mg+ 3.75<br>mg    | syrup               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2642 | dextromethophen HBr<br>+ bromhexine<br>hydrochloride +<br>chlorpheniramine<br>maleate +<br>guaiphenesin          | 10 mg+ 8<br>mg+ 2 mg +<br>100 mg            | tablets             | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 2644 | Paracetamol+ Phenylephrine hydrochloride + Chlorpheniramine maleate + Caffiene                                   | 325mg + 10<br>mg + 2 mg +<br>30 mg          | uncoated tablet     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2646 | enrofloxacin +<br>bromhexin<br>hydrochloride +<br>glacial acetic acid +<br>polysorbate + 2-<br>pyrrolidinone     | 200mg + 15<br>mg                            | injection           | a, Pharmacodynamically irrelevant- 1.Enrofloxacin is not approved for human use.   |
| 2648 | dextromethophen HBr<br>+ bromhexine<br>hydrochloride +<br>chlorpheniramine<br>maleate +<br>guaiphenesin          | 10mg+ 8<br>mg+ 2 mg+<br>100 mg              | tablets             | <ul> <li>a,</li> <li>1 Dosing schedule is incompatible.</li> <li>2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.</li> <li>3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.</li> </ul> |
| 2650 | levocetirizine dihydrochloride + ambroxol hydrochloride + phenylephrine hydrochloride +guaiphenesin              | 0.8 mg+ 15<br>mg+ 5 mg+<br>50 mg            | syrup               | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule   |

U

| 2654 | dextromethophen HBr<br>+ chlorpheniramine<br>hydrochloride +<br>chlorpheniramine<br>maleate +               | 15 mg+ 5<br>mg+ 2 mg                              | syrup                 | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|------|---|---|-----------------------|---|
| 2655 | cetirizine Di HCL+<br>ambroxol HCL+<br>Guaiphenesin +<br>ammonium chloride+<br>phenylephrineHCL+<br>menthol | 2.5 mg+ 30<br>mg+ 50 mg+<br>100 mg+ 5<br>mg+ 1 mg | syrup                 | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
| 2658 | codiene phasphate+<br>chlorpheniramine<br>maleate   | 10 mg+ 4<br>mg                                    | oral liquid           | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |
| 2659 | chlorpheniramine<br>Maleate +<br>phenylephrine HCL+<br>caffiene   | 500mg+ 2<br>mg+ 10 mg+<br>30 mg                   | uncoated tablet       | a, 1.Pharmacodynamically irrationale FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
| 2660 | dextromethorphan +<br>triprolidine +<br>phenylephrine   | 10 mg+ 1.25<br>mg+ 5 mg                           | oral liquid           | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 2662 | Terpinhydrate+<br>dextromethorphan<br>HBr+ menthol  | 10 mg+ 10<br>mg+ 3.75<br>mg                       | liquid oral<br>dosage | a, Pharmacodynamically irrelevant. No published literature supporting the combination.  |
| 2664 | dextromethorphan<br>HCL+ phenylephrine<br>HCL+ zinc<br>gluconate+ menthol                                   | 2.5 mg+ 5<br>mg+ 2.5<br>mg+ 7.5<br>mg+ 2.5 mg     | syrup                 | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.  |
| 2665 | chlorpheniramine<br>Maleate+ codeine<br>phosphate + sodium<br>citarte + menthol                             | 2 mg+ 10<br>mg+ 1.5<br>mg+ 1.5 mg                 | oral liquid           | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |
| 2666 | paracetamol +<br>phenylephrine HCL+<br>chlorpheniramine<br>Maleate + caffeine                               | 325mg+ 10<br>mg+ 2 mg+<br>30 mg                   | tablets               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
| 2671 | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP  | 10mg+4mg  | Oral Syrup            | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |
| 2672 | Enrofloxacin +<br>bromhexin<br>hydrochloride  | 100mg+7.5<br>mg                                   | Solution              | a, Pharmacodynamically irrelevant- 1. Enrofloxacin is not approved for human use.   |

|      | Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Menthol IP  Levofloxacin Hemihydrate IP+Bromhexine HCl IP |  | Oral Liquid  Solution  | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredient and the use of FDC may lead to misuse. 2. Increased risk of emergence of drug resistance due to misuse of FDC. |
|------|---|--|------------------------|--|
| 2678 | Levocetirizine HCl<br>IP+Ranitidine HCl IP  | 5mg+150mg  | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant as both ingredients are indicated for different indications.   |
| 2682 | Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP+Dextromethorphan Hydrobromide IP+Caffeine IP                                |  | Film Coated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2687 | Bromhexine Hcl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP   | 4mg+5mg+5<br>0mg                                       | Syrup                  | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.   |
| 2688 | Levocetirizine HCl<br>IP+Phenylephrine HCl<br>IP+Ambroxol<br>IP+Guaiphenesin<br>IP+Paracetamol IP                                 | 2.5mg+10m<br>g+60mg+10<br>0mg+325mg                    | Uncoated<br>Tablets    | a, Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3.Potential drug interactions.   |
| 2689 | Dextromethorphan<br>Hydrobromide+Pheny<br>lephrine HCl<br>IP+Chlorpheniranime<br>Maleate IP                                       | 10mg+5mg+<br>2mg                                       | Syrup                  | Dosing schedule is incompatible.     Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|      | Maleate IP+Phenylephrine HCl IP+Caffeine IP   | 500mg+2mg<br>+5mg+16mg                                 | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2695 | hydrochloride+<br>dextromethorphan<br>hydrobromide+   | 2.5 mg+ 7.5<br>mg+<br>5mg+7.5<br>mg+ 125<br>mg+ 2.5 mg | 60 ml syrup            | a,  1.Pharmacodynamically and phamacokinetically irrational FDC.  2.Patients may need only one ingredient and use of FDC may lead to misuse.  3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |

| 2696 | paracetamol+ pseudoephedrine hydrochloride + dextromethorphan hydrobromide+ cetirizine hrdrochloride | 500mg+ 60<br>mg+10 mg+<br>5mg              | tablets                   | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|------|--|--|---------------------------|--|
| 2700 | dextromethorphan+<br>cetirizine HCL+<br>phenylephrine+<br>menthol                                    | 5 mg + 2.5<br>mg+ 5.0<br>mg+ 1 mg          | syrup                     | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2701 | diphenhydamine<br>HCL+ guaiphenesin +<br>ammonium chloride +<br>bromhexine HCL                       | 8 mg+ 50<br>mg+ 100<br>mg+ 4 mg +<br>1 mg  | syrup                     | Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.  |
| 2702 | cetirizine<br>hydrochloride+<br>phenylephrine HCl+<br>paracetamol+<br>Nimusulide+ caffiene           | 5 mg+ 10<br>mg+<br>325mg+ 100<br>mg+ 25 mg | tablets                   | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Nimesulide-safety concern.   |
| 2703 | chlorpheniramine<br>maleate + codiene<br>phosphate   | 4 mg+ 10<br>mg                             | syrup                     | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2708 | Chlorpheniramine Maleate +Dextromethorphan Hydrobromide +Phenylephrine HCL+Paracetamol               | 2mg+10mg+<br>5mg250mg                      | Oral Liquid<br>Suspension | <ul> <li>a,</li> <li>1 Dosing schedule is incompatible.</li> <li>2.Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.</li> <li>3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.</li> </ul>                       |
| 2709 | Dextromethorphen<br>HBr IP+Promethazine<br>HCL IP  | 15mg+5mg                                   | oral liquid<br>(syrup)    | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.   |
| 2710 | Paracetamol+Phenyle<br>phrine<br>HCL+Chlorphenirami<br>ne Maleate + caffeine                         | /325/325/32                                | Tablet                    | <ul> <li>a,</li> <li>1.Pharmacodynamically and phamacokinetically irrational FDC.</li> <li>2.Patients may need only one ingredient and use of FDC may lead to misuse.</li> <li>3.Dosing shedule of the ingredients is incompatible.</li> </ul>   |
| 2711 | Diethylcabamazine<br>citrate IP+Cetrizine<br>HCL IP<br>+Guaiphenesin IP                              | 100mg+3.33<br>mg+50mg                      | Tablet                    | a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2. Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties. |
| 2712 | Pseudoephedrine+Dex<br>tromethorphan<br>HBr+Cetirizine HCL   | 60mg+10mg<br>+5mg                          | Tablet                    | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |

| 2716        | 5 Paracetamol+Chlorph<br>eniramine<br>Maleate+Phenylephrin<br>e HCL+Caffeine   | +5mg+15mg                                   |         | <ul> <li>a,</li> <li>1.Pharmacodynamically and phamacokinetically irrational FDC.</li> <li>2.Patients may need only one ingredient and use of FDC may lead to misuse.</li> <li>3.Dosing shedule of the ingredients is incompatible.</li> </ul>  |
|-------------|--|---|---------|---|
| 2718        | Paracetamol IP+Guaiphenesin IP+Ambroxol HCl IP+Phenylepherine HCl IP+Chlorpheniramin Maleate   | 325mg+100<br>mg+30mg+1<br>0mg+2mg           | Tablets | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 2719        | Ambroxol HCl IP+Guaiphenesin IP+Ammonium Chloride IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Menthol IP  | 15mg+50mg<br>+100mg+2.5<br>mg+2mg+0.<br>1mg |         | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule   |
|             | Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>IP+Paracetamol IP   | 5mg+2mg+2<br>0mg/30mg+<br>325mg             | Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|             | Dextromethorphan<br>Hydrobromide+Guaip<br>henesin<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+100m<br>g+5mg+4mg                      | Syrup   | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|             | Phenylephrine HCl<br>iP+Triprolidine HCl<br>IP   | 5mg+0.625<br>mg                             | Syrup   | a, 1.Pharmacodynamically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse and sedation. 3.Potential for drug-drug interaction.   |
|             | Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide+Amm<br>onium<br>Chloride+Menthol IP  |   | Syrup   | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
| I<br>I<br>I |  | 2mg+5mg+1<br>0mg+0.5mg                      | Syrup   | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|             | No. of the control of | 15mg+1.25<br>mg+7.5mg                       | Syrup   | a,  1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant.  2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drug and their adverse effects.   |

| 2729 | 9 Dextromethorphan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaiphenesin IP | 10mg+4mg+<br>100mg per<br>5ml | Syrup                 | <ul> <li>a,</li> <li>1 Dosing schedule is incompatible.</li> <li>2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.</li> <li>3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.</li> </ul>  |
|------|--|-------------------------------|-----------------------|--|
| 2730 | Terbutaline Sulphate+Bromhexine HCl+Guaiphenesin+D extromethorphan Hydrobromide            |                               |                       | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Patients may need only one ingredient and use of FDC may lead to misuse. 4. Dosing shedule of the ingredients is incompatible. |
| 2733 | Dextromethorphan<br>Hydrobromide<br>IP+Tripolidine HCL<br>IP+Phenylephirine<br>HCl IP      | 10mg+1.25<br>mg+5mg           | Uncoated<br>Tablets   | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2734 | Paracetamol<br>IP+Dextromethorphan<br>Hydrobromide+Chlor<br>pheniramine Maleate<br>IP      | 125mg+5mg<br>+1mg             | Syrup                 | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2735 | Chlorpheniramine<br>Maleate IP+Codeine<br>Phosphate IP                                     | 4mg+10mg                      | Syrup                 | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2738 | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP                                     | 10mg+4mg                      | Oral Liquid           | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.  |
|      |  | 1.5mg+2.5m<br>g+1.5mg         | Oral Syrup            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|      | HCL+Dextromethorp  | 4.0mg+5<br>mg+50mg+2<br>.5mg  | Liquid Dosage<br>Form | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.   |
|      |  | 3                             |                       |  |

| 27:  | 52 Bromhexine<br>hydrochloride +<br>Phenylephrine<br>hydrochloride+<br>Guaiphenesin +<br>Chlorpheniramine<br>maleate+ Paracetamo | 8 mg + 5<br>mg+ 100<br>mg+ 2 mg+<br>325 mg | tablets     | a, Pharmacodynamically irrelevant- 1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic.  |
|------|--|--|-------------|---|
| 275  | 5 dextromethorphan + chlorpheniramine  | 10 mg + 4<br>mg                            | oral liquid | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|      | 7 codeine phosphate+<br>levocetirizine HCL +<br>menthol  | 10 mg+ 1.67<br>mg+ .1 mg                   | syrup       | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  4. There is also a risk of abuse potential.  |
| 2759 | Paracetamol+Phenyle<br>phrine<br>HCL+Dextromethorp<br>han<br>Hydrobromide+Caffei<br>ne+Chloramphenirami<br>ne Maleate            | 500mg+5mg<br>+10mg+25m<br>g+2mg            | Tablet      | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 2760 | mol+cetirizine   | 100mg+325<br>mg+5mg+25<br>mg               | Tablet      | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
| -    |  | +30mg+20m                                  | ablet       | a, Pharmacodynamic irrelevant- 1.Each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Pharmacokinetic mismatch.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |

| 2766 | Nimesulide+paraceta<br>mol+cetirizine<br>HCL+Phenylphrine+c<br>affeine anhydrous             | 100mg+325<br>mg+5mg+10<br>mg+25mg             | Tablet           | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
|------|--|---|------------------|---|
| 2767 | Cetrizine HCL+Dextromethorp han HBr++Acetaminophe n+Phenylephrine HCL+zinc gluconate+Menthol | 2.5mg+7.5m<br>g+125mg+5<br>mg+7.5mg+<br>2.5mg | Syrup            | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|      | paracetamol+<br>phenylephrine<br>hydrochloride+<br>chlorpheniramine<br>maleate + caffeine    | 650 mg+ 10<br>mg+ 4 mg+<br>30 mg              | tablets          | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|      |  |   |                  |   |
|      | chlorpheniramine<br>maleate+ codeine<br>phosphate  | 4 mg+ 10<br>mg                                | liquid oral dose | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.   |
|      | phenylephrine  | 500 mg+ 10<br>mg+ 30 mg+<br>2mg               | uncoated tablet  | a,  1.Pharmacodynamically and phamacokinetically irrational FDC.  2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
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|     |      | dextromethorphan<br>HBR+ ambroxol<br>hydrochloride +<br>guaifenesin +<br>phenylephrine<br>hydrochloride+<br>chlorpheniramine<br>maleate | 10 mg+ 15<br>mg+ 100<br>mg+ 10 mg+<br>2 mg | uncoated tablet        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
|-----|------|---|--|------------------------|---|
|     |      | Cetirizine HCl<br>IP+Phenylephrine<br>HCL IP+<br>Dextromethorphan<br>Hydrobromide IP+<br>Menthol IP                                     | 5mg+ 5mg+<br>10mg+<br>1.5mg                | syrup                  | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.                      |
|     | 2785 | Roxithromycin IP+   | 150mg+10m                                  | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant-  |
|     |      | Serratiopeptidase   | g  | Tablets                | May lead to misuse and drug resistance  |
|     | 2786 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Triprolidine HCl<br>IP  | 325mg+5mg<br>+2.5mg                        | Uncoated<br>Tablets    | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|     |      |   | ji v                                       | ¥.                     |   |
|     | 2789 | Montelukast Sodium<br>IP+Levocetirizine<br>Dihydrochloride<br>IP+Acibrophyllin  | 10mg+5mg+<br>200mg                         | Film coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty.  |
| - 1 |      | Bromohexine   | 4mg+5mg+5                                  | 0                      | a,  |

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|      | Acetaminophen+Loradine+ambroxol HCL+Phenylephrine HCL  Cetirizine HCL+Acetaminopher +Dextromethorphan HBr+Phenyephrine | +30mg+20<br>g                  | m g Tablet            | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.                           |
|------|--|--------------------------------|-----------------------|--|
|      | HCL+Zinc gluconate   |                                |                       | 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 2798 | 8 diethylcarbamazine<br>citrate+ cetirizine<br>hydrochloride +<br>guaifenesin  | 150 mg+ 5<br>mg+ 100 mg        | film coated<br>tablet | a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2. Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties. |
| 2800 | Dextromethophan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaiphenesin<br>IP+Ammonium<br>Chloride IP     | 5mg+2.5mg<br>+50mg+60m<br>g    | Syrup                 | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2802 | Diphenhydramine<br>HCL IP+Guaifenesin<br>IP+Bromhexine HCl<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP                 | 8mg+50mg+<br>4mg+100mg<br>+1mg | Syrup                 | a, Pharmacodynamically irrelevant.     • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.   |
|      | Chlorpheniramine<br>Maleate IP+<br>Ammonium Chloride<br>IP+ Sodium Citrate<br>IP+Menthol IP                            | 4mg+100mg<br>+40mg+1mg         | Cough Syrup           | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |
|      | Chlopheniramine<br>Maleate+Codeine<br>Phosphate  | 4mg+10mg                       | Liquid Syrup          | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.                  |
| I    | P+Dextromethorphan   | 2.5mg+5mg<br>+7.5mg+2.5<br>mg  | Oral Liquid           | a, Pharmacodynamically irrelevant.  1.Patients may need only one ingredient and use of FDC may lead to misuse.  2Pharmacokinetic incompatibility amongst ingredients.  3Use of anti-histamine with centrally acting anti-  |

| 2809 | Paracetamol IP+Phenylephrine HC IP+Desloratadine+Zin c Gluconate USP+Ambroxol HCl IP |  |                                   | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|------|--|--|-----------------------------------|--|
| 2810 | Levocetirizine<br>Dihydrochloride+Para<br>cetamol+Phenylephrin<br>e HCL+Caffeine IP  |  | Film Coated<br>Tablets            | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule.  |
| 2816 | Paracetamol IP+Caffeine IP+Chlorpheniramine Maleate IP+Phenylephrine HCl             | 325mg/325<br>mg+16mg/3<br>0mg+1.5mg/<br>2mg+5mg/1<br>0mg | Uncoated<br>Tablets               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2820 | levocetirizine HCL+<br>montelukast +<br>acebrophylline                               | 5mg + 10<br>mg+ 200 mg                                   | tablets                           | a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty.   |
| 2834 | Dextromethorphan<br>hydrobromide+bromh<br>exine<br>HCL+Guaiphenesin+<br>menthol      | 5mg+4mg+1<br>00mg+2.5m<br>g                              | Syrup                             | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Patients may need only one ingredient and use of FDC may lead to misuse. 4. Dosing shedule of the ingredients is incompatible. |
|      | Dextromethorphan<br>hydrobromide+bromh<br>exine<br>HCL+Phenylephrine<br>HCL+Menthol  | 5mg+4mg+5<br>mg+2.5mg                                    | Syrup                             | a, Pharmacodynamically irrelevant.  • Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  • Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered   |
|      |  | 5mg+5mg+5<br>00mg+30mg                                   | Tablet                            | a,  1.Pharmacodynamically and phamacokinetically irrational FDC.  2.Patients may need only one ingredient and use of FDC may lead to misuse.  3.Dosing shedule of the ingredients is incompatible.   |
|      |  | 8mg+325mg<br>+25mg+5mg                                   |                                   | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.   |
|      | IP+Phenylephrine HCl<br>IP+Caffeine  | 500mg/500<br>mg+10mg/1<br>0mg+32mg+<br>2mg               | Combikit (Film<br>Coated Tablets) | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      | USP+C.M.C.<br>IP+Menthol   | 0.5% +<br>0.005% +<br>0.01% +                            | Drops                             | a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility  |

| 26   | 353 Dextromethorphan  | 110   |         |  |
|------|---|---|---------|--|
|      | Hydrobromide<br>IP+Cetirizine HCl IF  | 10mg+2.5mg                                    | Syrup   | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 28   | 56 nimesulide +<br>paracetamol +<br>levocetirizine HCL+<br>phenylephrine HCL+<br>caffeine | 100 mg+<br>325 mg+ 2.:<br>mg + 5 mg+<br>25 mg |         | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule. 3. Nimesuilide- Safety concern   |
| 28.  | 677 dextromethorphan<br>HBr + phenylephrine<br>HCL+<br>chlorpheniramine                   | 10 mg+ 5<br>mg+ 2 mg                          | syrup   | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 286  | 54 bromhexine HCL+<br>dextromethophan<br>HBr+ ammonium<br>chloride                        | 4 mg+ 5 mg<br>+ 50 mg+<br>2.5 mg              | syrup   | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  |
|      |   | 9   | 14 A    |  |
| 286  | 7 Terbutaline<br>Sulphate+Ambroxol<br>HCl+Guaiphenesin+Z<br>inc+Menthol                   | 1.5mg+15m<br>g+50mg+7.5<br>mg+0.5mg           | Syrup   | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.   |
| 2868 | Paracetamol+Phenyle<br>phrine<br>HCl+Chlorpheniramin<br>e Maleate+Caffeine                | 325mg+5mg<br>+2mg+30mg                        | Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2869 | Codeine<br>Phosphate+Chlorphen<br>iramine<br>Maleate+AlcoholIP+A<br>lcohol                | 10mg+4mg+<br>0.15ml+3%v<br>/v                 | Syrup   | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.  |
| 2878 | Dextromethorphan<br>HCl+Phenylephrine<br>HCl+Guaifenesin+Tri<br>prolidine HCl             | 10mg+5mg+<br>100mg+1.25<br>mg                 | Syrup   | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible. |

|      | Ammomium<br>Chloride+Bromhexine<br>HCI+Dextromethorph<br>an HBR                                | 50.0mg+4.0<br>mg+5.0mg | Dekogest syrup         | a, Pharmacodynamically irrelevant- 1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan decreases the cough impulse so expulsion of                                |
|------|--|------------------------|------------------------|---|
|      |  | - e                    |                        | 2. Dextromethorphan decreases the cough impulse so expulsion of secretion would be hampered   |
|      | Bromhexine<br>HCl+Dextromethorph<br>an<br>Hydrobromide+Amm<br>onium Chloride                   | 4.0mg+5.0m<br>g+50.0mg | Alvex cough<br>syrup   | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
| 2894 | Bromhexine<br>HCl+Ammonium<br>Chloride+Dextrometh<br>orphan Hydrobromide                       | 4.0mg+50.0<br>mg+5.0mg | Syrup                  | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
| 2904 | Paracetamol IP+Dextromethorphan Hydrobromide+Pheny lephrine HCl IP+Chlorpheniramine Maleate IP |                        | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 2907 | Chlorpheniramine<br>Maleate IP+Sodium<br>Citrate<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP   | 4mg+50mg+<br>100mg+1mg | Syrup                  | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract   |
| 2908 | Diethylcarbamazine<br>Citrate IP+Cetirizine<br>HCL IP+Ambroxol<br>HCL IP                       | 150mg+5mg<br>+30mg     | Film Coated<br>Tablets | a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2. Ambroxol is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.  |
| 2909 | Montelukast<br>Sodium+Levocetirizin<br>e HCl<br>IP+Acebrophylline                              |                        | Bilayered<br>Tablets   | a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibility.   |
| 2914 | Ethylmorphine HCl<br>IP+ Noscapine BP+<br>Chlorpheniramine<br>Maleate IP                       | 7.5mg+7.5m<br>g+2.5mg  | Uncoated<br>Tablets    | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |

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| / 1 / 1 | Cetirizine HCl  | 5mg+15mg                                 | Syrup                  | a,   |
|---------|---|--|------------------------|--|
|         | IP+Dextromethorphan   | Jilig+15ilig                             | Syrup                  | 1 Ambroyol: a mucolytic which increases mucus secretion should not   |
|         | Hydrobromide  |  |                        | given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  |
|         | IP+Ambroxol HCl IP  |  |                        | Dextromethorphan decreases the cough impulse so expulsion of   |
|         |   |  |                        | secretion would be hampered  |
|         |   |  |                        | 3.Patients may need only one ingredient and use of FDC may lead to   |
|         | 2   |  |                        | misuse.  |
|         |   |  |                        | 4.Pharmacokinetic incompatibility amongst ingredients.   |
| 6 8     |   |  |                        | 5.Use of anti-histamine with centrally acting anti- tussive ingredient is not  |
|         |   | 9  |                        | rationale  |
| - 1     | 3   |  |                        |  |
|         | Chlorepheniramine   | 4.00mg+10.                               | Syrup                  | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and   |
|         | Maleate IP+Codeine  | 00mg                                     |                        | 2. Both the ingredients will aggravate the adverse cricers of sedation and drowsiness and also will interefere with the reflexes.  |
|         | Phosphate IP  |  |                        | 3. Centrally acting anti-tussive not to be combined with anti-histaminic   |
|         |   |  |                        | drug.  |
|         |   |  |                        | 4. There is also a risk of abuse potential.  |
| 2010    | Bromhexine HCl  | 8mg+5mg+2                                | Lincoated              | a,   |
| 2919    | IP+Phenylephrine HCl  | mg+100mg+                                | Tablets                | Pharmacodynamically irrelevant-  |
| 4       |   | 325mg                                    |                        | 1 Guiaphenesin: a mucolytic which increases mucus secretion should not   |
|         | Maleate   | 520119                                   |                        | given in combination with antihistaminic with anti cholinergic properties,   |
|         | IP+Guaifenesin  |  |                        | because due to anti cholinergic properties mucus secretions is dried up.   |
|         | IP+Paracetamol IP   |  |                        | 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the   |
|         | 240 (4)   |  |                        | drying effect may do more harm because of their tendency to induce   |
|         |   |  |                        | somnolence 3.Multiple ingredients with diverse pharmacological profile susceptible to  |
|         |   |  |                        | pharmaceutically incompatibility   |
| 100     |   |  | -                      | pharmaceatrony meomparess,   |
| 2020    | 0 :0 :  | 100mg+10m                                | Syrun                  | a,   |
| 2920    | Guaifenesin<br>IP+Dextromethorphan  |  | Syrup                  | Pharmacodynamically irrelevant-  |
| 1 1     | Hydrobromide  | g . 51116 . 21116                        |                        | 1 Guainhenesin a mucolytic which increases mucus secretion should not  |
|         | IP+Phenylephrine HCl  |  |                        | given in combination with antihistaminic with anti cholinergic properties,   |
|         | IP+Chlorpheniramine   |  |                        | because due to anti cholinergic properties mucus secretions is dried up.   |
|         | Maleate IP  |  |                        | Dextromethorphan: it decreases the cough impulse so expulsion of   |
|         |   |  |                        | secretion would be hampered 3. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the   |
|         |   |  |                        | 3. Chlorpheniramine :F11 antagonist are said to decrease influence   |
|         |   |  | l .                    | Liming offect may do more harm necalise of their telluction to induce  |
|         |   |  |                        | drying effect may do more harm because of their tendency to induce   |
|         |   |  |                        | somnolence   |
|         |   |  | =                      |  |
| 2021    | Catinizina Hol  | 5mg+10mg+                                | Film Coated            | somnolence 4. All ingredients have different therapeutic indications.  |
| 2921    | Cetirizine Hcl  | 5mg+10mg+<br>20mg+325m                   | Film Coated            | somnolence 4. All ingredients have different therapeutic indications.  a, 1. Pharmacodynamically and phamacokinetically irrational FDC.  |
| 2921    | Cetirizine Hcl<br>IP+Phenylephrine HCl<br>IP+Caffeine   | 5mg+10mg+<br>20mg+325m                   | Film Coated<br>Tablets | somnolence 4. All ingredients have different therapeutic indications.  |
| 2921    | IP+Phenylephrine HCl  | 20mg+325m                                | Film Coated<br>Tablets | somnolence 4. All ingredients have different therapeutic indications.  a, 1. Pharmacodynamically and phamacokinetically irrational FDC.  |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP  | 20mg+325m<br>g                           | Tablets                | somnolence 4. All ingredients have different therapeutic indications.  a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP  | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant-   |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan   | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant-   |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide   | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered   |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium                            | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Brombeving a mucolytic which increases mucus secretion should not  |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol     | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties,  |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium                            | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Brombeving: a mucolytic which increases mucus secretion should not   |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol     | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties,   |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol     | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties,   |
|         | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP<br>Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol     | 20mg+325m<br>g<br>8mg+10mg+              | Tablets                | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties,  |
| 2922    | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP  Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP | 20mg+325m<br>g<br>8mg+10mg+<br>100mg+5mg | Syrup                  | somnolence 4. All ingredients have different therapeutic indications.  a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  |
| 2922    | IP+Phenylephrine HCl IP+Caffeine IP+Paracetamol IP  Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Menthol IP                      | 20mg+325m<br>g<br>8mg+10mg+<br>100mg+5mg | Syrup                  | somnolence 4. All ingredients have different therapeutic indications.  a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  |
| 2922    | IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Paracetamol IP  Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP | 20mg+325m<br>g<br>8mg+10mg+<br>100mg+5mg | Syrup                  | somnolence 4. All ingredients have different therapeutic indications.  a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and   |
| 2922    | IP+Phenylephrine HCl IP+Caffeine IP+Paracetamol IP  Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Menthol IP                      | 20mg+325m<br>g<br>8mg+10mg+<br>100mg+5mg | Syrup                  | somnolence 4. All ingredients have different therapeutic indications.  a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. |
| 2922    | IP+Phenylephrine HCl IP+Caffeine IP+Paracetamol IP  Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Menthol IP                      | 20mg+325m<br>g<br>8mg+10mg+<br>100mg+5mg | Syrup                  | somnolence 4. All ingredients have different therapeutic indications.  a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and   |

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|              | Ambroxol HCl IP+<br>Guaifenesin IP+<br>Phenylephrine HCl<br>IP+ Chlorpheniramine<br>Maleate IP                     | 15mg+50mg<br>+5mg+2mg       | Syrup                  | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule   |
|--------------|--|-----------------------------|------------------------|--|
| 200 00000000 | Cetirizine HCl<br>IP+Paracetamol<br>IP+Phenylephirine<br>HCl IP+Caffeine<br>(anhydrous) IP                         | 5mg+325mg<br>+10mg+30m<br>g |                        | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.   |
| 2928         | Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaiphenesin IP+Ammonium Chloride IP                  | 5mg+2.5mg<br>+50mg+60m<br>g | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2932         | Dextromethorphan<br>Hydrobromide<br>IP+Bromhexine HCl<br>IP+Guaifenesin<br>IP+Chlorpheniramine<br>Maleate IP       | 10mg+4mg+<br>50mg+2.5m<br>g | Syrup                  | <ul> <li>a,</li> <li>1 Dosing schedule is incompatible.</li> <li>2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.</li> <li>3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.</li> </ul>   |
| 2933         | Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Phenylephrine<br>Hydrochloride<br>IP+Menthol IP        | 4mg+5mg+2<br>.5mg+2.5mg     | Syrup                  | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
| 2934         | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP+Zinc<br>Gluconate USP                     | 125mg+2.5<br>mg+1mg+5<br>mg | Suspension             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2937         | Paracetamol<br>IP+Caffeine<br>IP+Phenylephrine HCl<br>IP   | 500mg+25m<br>g+5mg          | Film Coated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2939         | Dextromethorphan<br>Hydrobromide<br>IP+Bromhexine HCL<br>IP+Phenylephrine HCl<br>IP+Menthol IP                     | 5mg+4mg+5<br>mg+2.5mg       | Syrup                  | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  |
| 2940         | Dextromethorphan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaifenesin<br>IP+Ammonium<br>Chloride IP | 5mg+2.5mg<br>+50mg+60m<br>g | Oral Liquid            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |

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| 294  | 3 Dextromethorphan   | 10mg+5mg-                        | + Uncoated  | a,  |
|------|--|----------------------------------|-------------|---|
|      | Hydrobromide IP+Phenylephrine HC IP+Cetirizine HCI IP+Paracetamol IP+Caffeine Anhydrous IP         | 5mg+325mg<br>+30mg               | Tablets     | Dosing schedule is incompatible.     Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.    |
| 294  | 9 Paracetamol<br>IP+Chlorpheniramine<br>Maleate<br>IP+Phenylephrine HC<br>IP+Bromhexine HCl        | 125mg+1.25<br>mg+2.5mg+<br>4.0mg |             | <ul> <li>a, Pharmacodynamically irrelevant. </li> <li>Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.</li> <li>Dosing schedule is incompatible.</li> </ul>                         |
| 295  | 4 Paracetamol<br>IP+Chlorpheniramine<br>Maleate<br>IP+Phenylephrine HCl<br>IP+Bromhexine HCl<br>IP | 125mg+1.25<br>mg+2.5mg+<br>4.0mg | Oral Liquid | a, Pharmacodynamically irrelevant.  • Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  • Dosing schedule is incompatible.  |
| 2958 | Dextromethorphan<br>Hydrobromide<br>IP+Cetirizine HCl IP   | 10mg+2.5m<br>g                   | Syrup       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 2959 | Dextromethophan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP    | 5mg+2.5mg<br>+50mg+60m<br>g      | Syrup       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 2961 |  | 5mg+4mg+5<br>0mg+2.5mg           | Syrup       | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  |
| 2965 | Levocetirizine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Zinc elemental                     |                                  | Syrup       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 2967 | TY 1 1 11  | 10mg+2.5m                        | Syrup       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
|      | IP+Phenylephrine   |                                  |             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |

| Maleate<br>IP+Ammonium<br>Chloride IP+Sodium  | 240mg+240<br>mg+1.25mg  |  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|---|---|--|--|
| Dextromethorphan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaifenesin<br>IP+Ammonium<br>Chloride IP  | 0mg+75mg  | Liquid   | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| Chlorpheniramine<br>Maleate<br>IP+Ammonium<br>Chloride IP+Sodium<br>Chloride IP   | 2.5mg+125<br>mg+55mg  | Syrup  | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |
| Dextromethorphan<br>HBR<br>IP+Guaiphenesin<br>IP+Phenylephrine HCl<br>IP+CPM  | g+5mg+4mg   | Syrup  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| Dextromethorphan<br>Hydrobromide<br>IP+Phenylephrine<br>HCL IP+Paracetamol<br>IP+Chlorpheniramine<br>Maleate IP   | 5mg+5mg+2<br>50mg+2mg   | Syrup  | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| IP+Dextromethorphan   | g+8mg+5mg   |  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. Paracetamol dose is subtherapeutic.   |
| A Commence of the Commence of |   | Syrup  | a,  1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant.  2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.   |
|   | Hydrobromide IP+Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP I Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP Chlorpheniramine Maleate IP+Ammonium Chloride IP Chlorpheniramine Maleate IP+Ammonium Chloride IP Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Chloride IP IP+Chlorpheniramine HCL IP+Penaylephrine HCI IP+Penylephrine HCL IP+Paracetamol IP+Chlorpheniramine Maleate IP  Paracetamol IP+Chlorpheniramine HCL IP+Phenylephrine HCL IP+Phenylephrine HCL IP+Poiphenhydramine HCL IP Salbutamol Sulphate IP eq. to Salbutamol+Bromhexi IP+Guaiphenesin | Hydrobromide IP+Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP  I Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP  Chlorpheniramine Maleate IP+Ammonium Chloride IP  Chlorpheniramine Maleate IP+Guaiphenesin IP+Phenylephrine HCI IP+Phenylephrine HCI IP+Phenylephrine HCI IP+Phenylephrine HCL IP+Paracetamol IP+Chlorpheniramine Maleate IP  Paracetamol IP+Chlorpheniramine Maleate IP  Paracetamol IP+Phenylephrine HCI IP+Phenylephrine HCL IP+Benylephrine HCI IP+Phenylephrine HCI IP+Phenylephrine HCI IP+Phenylephrine HCI IP+Phenylephrine HCI IP+Chlorpheniramine HCI IP+Diphenhydramine HCL IP+Diphenhydramine HCL IP+Diphenhydramine HCI IP+Diphenhydramine HCL IP+Guaiphenesin  Img+2mg+5 Somg+0.5mg  Img+2mg+5 Somg+2 So | Hydrobromide IP+Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP  Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP Chlorpheniramine Maleate IP+Sodium Chloride IP Sodium Chloride IP Sodium Chloride IP Sodium Chloride IP Sodium IP+Phenylephrine HCI IP+CPM  Dextromethorphan HBR IP+Guaiphenesin IP+Phenylephrine HCI IP+Chlorpheniramine Maleate IP  Paracetamol IP+Chlorpheniramine Maleate IP  Paracetamol IP+Dextromethorphan Hydrobromide IP+Dextromethorphan HP-Dextromethorphan HP-Dextrome |

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| 2988 | Nimesulide<br>IP+Paracetamol<br>IP+Cetirizine HCl<br>IP+Phenylephrine HCl<br>IP+Caffeine<br>anhydrous IP     | 100mg+325<br>mg+5mg+5<br>mg+30mg | Enteric Coated<br>Tablets | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs |
|      |  |                                  |                           | Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 2990 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Caffeine<br>IP+Chlorpheniramine<br>Maleate IP                      | 325mg+5mg<br>+16mg+2mg           |                           | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 2997 | Chlorpheniramine<br>Maleate BP+Codeine<br>Phosphate BP   | 4mg+10mg                         | Oral Liquid               | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2998 | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+4mg                         | Syrup                     | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 2999 | Dextromethorphan<br>Hydrobromide<br>IP+Bromhexine HCl<br>IP+Guaifenesin<br>IP+Chlorpheniramine<br>Maleate IP | 10mg+8mg+<br>100mg+2mg           |                           | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3002 | Paracetamol IP+Levocetirizine HCl IP+Phenylephrine HCl IP+Caffeine anhydrous IP                              | 325mg+2.5<br>mg+10mg+1<br>5mg    |                           | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP   |                                  | Syrup                     | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.     There is also a risk of abuse potential.   |
|      | Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP                                | 5mg+125mg<br>+56mg+1mg           | Syrup                     | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |
|      | Chlorpheniramine Maleate IP+Ammonium Chloride IP+Noscapine IP+Sodium Citrate IP                              | 2mg+28mg+<br>7mg+3.25m<br>g      | Syrup                     | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |

| 200  | 6 Chlorpheniramine  | 4mg+10mg                        | Cyrun               | 1 Dosing schedule is incompatible.  |
|------|---|---------------------------------|---------------------|---|
| 3000 | Maleate IP+Codeine<br>Phosphate IP  | 4mg+10mg                        | Syrup               | <ol> <li>Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.</li> <li>Centrally acting anti-tussive not to be combined with anti-histaminic drug.</li> <li>There is also a risk of abuse potential.</li> </ol>   |
| 3009 | O Chlorpheniramine<br>Maleate IP+Codeine<br>Phosphate IP  | 4mg+10mg                        | Syrup               | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.   |
| 3010 | Cetirizine Dihydrochloride IP+Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Guaifenesin IP | 5mg+10mg+<br>8mg+100mg          |                     | a,  1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered  2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  3. Pharmacokinetic incompatibility amongst ingredients.  4. Use of anti-histamine with centrally acting anti- tussive ingredient is not rationale  |
| 3011 | Diethyl Carbamazine<br>Citrate<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaifenesin IP           | 150mg+4mg<br>+100mg             | Uncoated<br>Tablets | a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2. Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.  |
| 3013 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>IP         | 500mg+10m<br>g/5mg+2mg<br>+30mg | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|      |   | 5mg+2.5mg<br>+50mg+60m<br>g     | Syrup               | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|      | Codeine<br>Phosphate+Chlorphen<br>iramine Maleate IP+   | 10mg+4mg                        | Syrup               | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.   |
|      |   | 8mg+100mg<br>+5mg+2mg+<br>325mg |                     | a, Pharmacodynamically irrelevant-  1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence  3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic. |

| 3025 | Ambroxol HCl IP +<br>Guaiphenesin IP+<br>Phenylephrine HCl IP<br>+ Chlorpheniramine<br>Maleate IP + Menthol<br>IP | 15mg+<br>50mg+<br>2.5mg+<br>2mg+1mg | Syrup               | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule   |
|------|---|-------------------------------------|---------------------|--|
| 3026 | Dextromethorphan<br>Hydrobromide<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP                     | 15mg+5mg+<br>2.5mg                  | Syrup               | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3027 | Ketotifen Fumarate<br>IP+Cetirizine<br>Dihydrochloride IP   | 1mg+10mg                            | Uncoated<br>Tablets | a, 1. No supporting published literature available on the combination. 2. Pharmakokinetic incompatibility,   |
| 3033 | Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Dextromethorphan Hydrobromide IP                  | 5mg+2.0mg/<br>1.5mg+50.m            | Suspension          | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3035 | Terbutaline Sulphate<br>IP+Bromhexine HCl<br>IP+Etofylline BP   | 2.5mg+200<br>mg+8mg                 | Uncoated<br>Tablets | <ul> <li>a,</li> <li>1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant.</li> <li>2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.</li> </ul> |
| 3038 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Cetirizine HCl<br>IP+Zinc Gluconate<br>USP                              | 125mg+2.5<br>mg+2.5mg+<br>7.5mg     | Syrup               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3041 | Paracetamol<br>IP+Guaifenesin<br>IP+Bromhexine HCl<br>IP+Chlorpheniramine<br>Maleate IP                           | 200mg+50m<br>g+2mg+2mg              |                     | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 3042 | Paracetamol<br>IP+Cetirizine HCL<br>IP+Phenylephrine HCl<br>IP+Caffeine IP  | 325mg+5mg<br>+5mg+30mg              |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3044 | Ketotifen Fumarate<br>IP+Theophylline<br>(Anhydrous)  | 1mg+200mg                           | Tablets             | a, Pharmacodynamically irrelevant- 1. Theophylline has narrow therapeutic index, and in FDC the toxicity of drug is major concern. 2. Pharmakokinetic incompatibility.   |
| 3045 | Chlorpheniramine<br>Maleate<br>IP+Dextromethorphan<br>Hydrobromide IP   | 4mg+10mg                            | Syrup               | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |

|      | T   | T                                | T                   |   |
|------|---|----------------------------------|---------------------|---|
| 3040 | 6 Ambroxol HCl<br>IP+Salbutamol<br>Sulphate<br>IP+Theophylline IP                       | 30mg+2mg-<br>100mg               | Tablets             | <ul> <li>a,</li> <li>1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant.</li> <li>2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drug and their adverse effects.</li> </ul>   |
|      | 4   |                                  |                     |   |
| 3048 | Bromhexine HCl IP+Dextromethorphan Maleate IP+Ammonium Chloride IP+Menthol IP           | 4mg+5mg+5<br>0mg+2.5mg           | Syrup               | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
|      |   |                                  |                     |   |
| 3053 | Paracetamol<br>IP+Caffeine<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP | 325mg+5mg<br>+5mg+25mg           |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3054 | Paracetamol IP+Caffeine IP+Phenylephrine HCl IP+Cetirizine HCl IP+Nimesulide BP         | 325mg+25m<br>g+5mg+5mg<br>+100mg |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3055 | Cetirizine HCL<br>IP+Nimesulide<br>BP+Phenylephrine<br>HCL IP                           | 5mg+100mg<br>+10mg               | Uncoated<br>Tablets | a, 1.Pharmacodynamically irrelevant as different ingredients have different therapeutic indication 2. Nimesulide: safety concern  |
| 3060 | Montelukast+Levoceti<br>rizine<br>HCI+Acebrophylline<br>SR                              | 10mg+5mg+<br>200mg               | Tablets             | a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty.  |
| 3062 | Paracetamol+Phenyle<br>phrine+Caffeine  | 325mg+10m<br>g+32mg              | Tablets             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| -    | Levocetirizine<br>HCl+Phenylephrine<br>HCl+Ambroxol<br>HCl+Paracetamol                  | 5mg+5mg+3<br>0mg+<br>325mg       | Tablets             | a, Pharmacodynamically irrelevant- 1.Multiple ingredient and diverse pharmacodynamic activity 2.Potential drug interaction. 3. Subtherapeutic dose of paracetamol.  |
| 2.0  |   | g+2mg+30m                        | Uncoated tablet     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|      | HCl+Paracetamol+Ph  | 2.5mg+125<br>mg+5mg+7.<br>5mg    | Syrup               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
|      | phrine+Cetrizine+Zin  | 325mg+5mg<br>+5mg+7.5m<br>g      | Tablets             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |

|      | 68 CPM+Phenylephrine<br>Paracetamol+Zinc<br>Gluconate   | +325mg+7.<br>mg                  |                 | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse. 4. Dosing shedule of the ingredients is incompatible.   |
|------|---|----------------------------------|-----------------|--|
| 307  | 70 Paracetamol+Chloroj<br>heniramine<br>maleate+Phenylephri<br>e+Dextromethorphan<br>Hydrobromide+Caffe<br>ne | +10mg+15mg+30mg                  |                 | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 307  | 2 Chlorpheniramine<br>maleate+Dextromethorphan<br>HBr+Paracetamol+Pl<br>enylephrine HCl                       | 250mg+5mg                        | Suspension      | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                              |
| 307  | Paracetamol+Phenyle<br>phrine<br>HCl+Caffeine+Chlorp<br>heniramine Maleate                                    | g+30mg+2m                        |                 | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3078 | Acetaminophen+Guai<br>fenesin+Dextromethor<br>phan<br>Hydrobromide+Chlor<br>pheniramine Maleate               | 125mg+25m<br>g+7.5mg+5<br>mg+1mg | Syrup           | a, 1. Use of anti-histamine with centrally acting anti- tussive ingredient is not rationale 2. Patients may need only one ingredient and use of FDC may lead to misuse. 3. Different mechanism of action without synergistic action.                                       |
| 3081 | Chlorpheniramine<br>maleate+Dextrometho<br>rphan<br>HBr+Paracetamol+Ph<br>enylephrine HCl                     | 2mg+10mg+<br>250mg+5mg           | Suspension      | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                              |
| 3082 | Paracetamol+Bromhe<br>xine<br>HCl+Guaiphenesin+C<br>hlorpheniramine<br>Maleate+Phenylephrin<br>e HCl          |                                  | Tablets         | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion—and antihistaminic with anti cholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 3086 | Cetirizine Dihydrochloride+Dext romethorphan Hydrobromide+Pheny lephrine HCl+Tulsi                            |                                  | Syrup           | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Use of anti-histamine with centrally acting anti- tussive ingredient is not rationale   |
|      | Cetirizine HCl+Dextromethorph am Hydrobromide+Ambr oxol HCl   | 5mg+10mg+<br>15mg                | Oral Liquid     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|      | Terbutaline<br>Sulphate+Bromhexine<br>HCl+Etofylline  |                                  | Uncoated tablet | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects. |

| 3089 | Dextromethrpahn Hydrobromide+Cetiri zine Dihydrochloride+Phe nylephrine HCl+Menthol                                 | 10mg+5mg+<br>5mg+1.5mg           | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|------|---|----------------------------------|------------------------|--|
| 3092 | 2 Ceterizine<br>HCl+Phenylephrine<br>HCl+Paracetamol+A<br>mbroxol<br>HCl+Caffeine<br>anhydrous                      | 5mg+10mg+<br>325mg+30m<br>g+20mg | Film Coated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.   |
| 3093 | Guaifenesin+Dextrom<br>ethorphan<br>Hydrobromide  | 100mg+10m<br>g                   | 5ml syrup              | a, Pharmacodynamically irrelevant- 1. Guaiphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered |
| 3094 | Paracetamol+Phenyle<br>phrine<br>HCl+Caffeine+Chlorp<br>heniramine Maleate  | g+30mg+2m                        |                        | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3096 | Paracetamol+Bromhe<br>xine<br>HCl+Chlorpheniramin<br>e<br>maleate+Guaiphenesin<br>+Phenylephrine HCl                | +2mg+100m<br>g+5mg               | Tablets                | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 3098 | Levocetirizine Dihydrochloride IP+Paracetamol IP+Phenylephirine HCl IP+Caffeine Anhydrous IP                        | 2.5mg+325<br>mg+10mg+3<br>0mg    | Film Coated<br>Tablets | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule.  |
| 3099 | Dextromethorphan<br>Hydrobromide<br>IP+Paracetamol<br>IP+Phenylephirine<br>HCl<br>IP+Chlorpheniramine<br>Maleate IP | 10mg+250m<br>g+5mg+2mg           | Oral Liquid            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3102 | Paracetamol IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP                    |                                  | Oral Liquid            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3103 | Paracetamol IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP                    | 250mg+10m<br>g+5mg+2mg           | Oral Liquid            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |

| 2105 | Paracetamol  | 325mg+5mg                      | Uncoated tablet        | 9  |
|------|--|--------------------------------|------------------------|--|
| 3103 | IP+Phenylephrine<br>HCl+Chlorpheniramin<br>e Maleate IP+Caffeine<br>(Anhydrous)                                  | +2mg+15mg                      |                        | 1.Pharmacodynamically and phamacokinetically irrational FDC.     2.Patients may need only one ingredient and use of FDC may lead to misuse.     3.Dosing shedule of the ingredients is incompatible.   |
| 3106 | Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Bromhexine HCl IP+Menthol IP                               | 5mg+50mg+<br>2mg+2.5mg         | Syrup                  | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2.Dosing schedule is incompatible.   |
| 3108 | Caffeine (Anhydrous)<br>IP+Paracetamol<br>IP+Phenylephrine HCl<br>IP+ Chlorpheniramine<br>Maleate IP             | 30mg+35mg<br>+2.5mg+2m<br>g    | Uncoated tablet        | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3109 | Paracetamol (Acetaminophen) IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP | 170mg+5mg<br>+2.5mg+1.5<br>mg  | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                                  |
| 3111 | Ketotifen Fumarate<br>IP+Levocetrizine<br>Dihydrochloride IP   | 1mg+5mg                        | Film Coated<br>Tablets | a, 1. No supporting published literature available on the combination. 2. Pharmakokinetic incompatibility  |
| 3112 | Paracetamol IP+Levocetirizine HCl IP+Phenylephirine HCl IP+Zinc Gluconate USP                                    | 325mg+2.5<br>mg+10mg+7<br>.5mg | Film Coated tablets    | a, 1. Paracetamol dose is subtherapeutic. 2. Pharmacokinetic incompatibility. 3. Potential for drug-drug interaction. 4. No published literature supporting addition of Zinc in this FDC.  |
| 3114 | IP+Phenylephrine HCl   | 500mg+5mg<br>+1.25mg+15<br>mg  | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      |  | 5mg+5mg+1<br>25mg+2mg          | Syrup                  | a, Pharmacodynamically irrelevant-1 Dosing schedule is incompatible.  2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.  3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
|      |  | 10mg+100m<br>g+8mg+2mg         | Tablets                | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                                  |
|      |  | 30mg+325m<br>g+10mg+5m<br>g    | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.   |
| I    |  |                                |                        |  |

| 31   | 21 Dextromethorphan<br>Hydrobromide<br>IP+Phenylephirine<br>HCl IP+Guaifenesin<br>IP                               | 10mg+4mg<br>5mg+100m            |                     | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Patients may need only one ingredient and use of FDC may lead to misuse. 4. Dosing shedule of the ingredients is incompatible. |
|------|--|---------------------------------|---------------------|--|
| 312  | 23 Bromhexine HCl<br>IP+Ammonium<br>Chloride<br>IP+Dextromethorphan<br>Hydrobromide IP                             | 4mg+50mg<br>5mg                 | + Syrup             | a,     1.Pharmacologically no synergistic effect     2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility  |
|      | Paracetamol IP+Caffeine IP+Phenylephrine HCl+Chlorpheniramin e Maleate IP  | 500mg+30mg+10mg+4mg             |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 312  | 7 Dextromethorphan<br>Hydrobromide<br>IP+Triprolidine HCl<br>IP+Phenylephrine<br>HCL                               | 10mg+1.25<br>mg+5mg             | Syrup               | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3129 | 9 Guaiphenesin<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Phenylephrine HCI<br>IP+Chlorpheniramine<br>Maleate IP |                                 |                     | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Patients may need only one ingredient and use of FDC may lead to misuse. 4. Dosing shedule of the ingredients is incompatible. |
| 3133 | Ambroxol HCl IP+<br>Levocetirizine HCl<br>IP+ Phenylephrine<br>HCl IP+ Guaiphenesin<br>IP+ Menthol IP              | 15mg+0.8m<br>g+5mg+50m<br>g     | Syrup               | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule   |
| 3135 |  | 5mg+325mg<br>+5mg+30mg          |                     | a, Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule.   |
| 3138 | Maleate  | 2.5mg+125<br>mg+55mg<br>per 5ml | Syrup               | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |
|      | Pseudoephedrine HCl<br>IP+Cetirizine HCl IP  |                                 | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant.  1.Both increase the sedation as adverse effect.  2.Dosing schedule is incompatible.  |

| 3140 | Dextromethorphan<br>Hydrobromide<br>IP+Guaifenesin<br>IP+Bromhexine HCl<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+100m<br>g+8mg+2mg                     |                     | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|------|--|--|---------------------|--|
| 3147 | Dextromethorphan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP | 5mg+2mg+5<br>0mg+2.5mg                     | Syrup               | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3151 | Cetirizine HCl<br>IP+Paracetamol<br>IP+Caffeine<br>IP+Phenylephirine<br>HCl IP                                 | 5mg+325mg<br>+30mg+5mg                     |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.   |
|      | Ambroxol HCl<br>IP+Guaiphenesin<br>IP+Chlorpheniramine<br>Maleate<br>IP+Phenylephirine<br>HCl IP+Menthol IP    | 15mg+50mg<br>+2mg+2.5m<br>g+1mg            | Liquids             | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule   |
| 3155 | Nimesulide<br>BP+Paracetamol<br>IP+Cetirizine HCl<br>IP+Phenylephrine HCl<br>IP+Caffeine IP                    | 100mg+325<br>mg/500mg+<br>5mg+5mg+3<br>0mg | Tablets             | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol.  2. There is pharmacokinetic incompatibility among the drugs.  3.Nimesuilide has documanted safety concern.  4. Hepatotoxic potential of both the drugs |
|      |  |  |                     | Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
|      | Levocetirizine Dihydrochloride IP+Paracetamol IP+Phenylephrine HCI IP+Caffeine Anhydrous IP                    |  | Uncoated<br>Tablets | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule.  |
|      | Paracetamol IP+Caffeine Anhydrous IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP                          | 325mg+25m<br>g+5mg+2mg                     |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      |  | 2mg+105mg<br>+100mg                        | Oral Liquid         | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.   |

| 316  | Salbutamol Sulphate IP eq. to Salbutamol +Thoephylline IP+Bromhexine HCI IP  | +8mg                              | g Uncoated<br>Tablets  | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.   |
|------|--|-----------------------------------|------------------------|--|
| 316  | 5 Dextromethorphan<br>Hydrobromide<br>IP+Guaiphenesin<br>IP+Bromhexine HCl<br>IP+Chlorpheniramine<br>Maleate IP    | 10mg+100m<br>g+8mg+2mg            |                        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 316  | 6 Paracetamol IP+Guaiphenesin IP+Ambroxol HCl IP+Phenylephrine HC IP+Chlorpheniramine Maleate IP                   |                                   | Film Coated tablets    | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 3167 | 7 Codeine<br>Phosphate+Chlorphen<br>iramine Maleate IP   | 10mg+4mg                          | Oral Liquid            | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.     There is also a risk of abuse potential.   |
| 3169 | Nimesulide<br>BP+Paracetamol<br>IP+Cetirizine HCl<br>IP+Phenylephirine<br>HCl IP+Caffeine IP                       | 100mg+325<br>mg+5mg+10<br>mg+25mg | Film Coated<br>Tablets | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs |
|      |  | *                                 | ,                      | Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
|      | Ambroxol HCl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaiphenesin<br>IP+Phenylephrine HCl<br>IP+Menthol IP         | 15mg+2mg+<br>50mg+5mg+<br>1mg     | Oral Liquid            | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule  |
|      | Chlorpheniramine<br>maleate<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Guaifenesin<br>IP+Phenylephrine HCl<br>IP | 4mg+5mg+1<br>00mg+5mg             | Oral Liquid            | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|      |  | 325mg+5mg 1<br>+2mg+30mg          | Film Coated<br>Fablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |

| 3178 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>anhydrous IP                  |                        | Film Coated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|------|--|------------------------|------------------------|--|
| 3179 | Dextromethorphan<br>Hydrobromide<br>IP+Cetirizine HCl<br>IP+Ambroxol HCl   | 10mg+5mg+<br>15mg      | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.          |
| 3181 | Paracetamol IP+Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP                   | per 5ml                | Oral<br>Suspension     | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.          |
| 3186 | Chlorpheniramine<br>Maleate<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Paracetamol<br>IP+Phenylephrine HCl<br>IP | 2mg+15mg+<br>325mg+5mg | Film Coated<br>Tablets | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 3193 | Paracetamol+Phenyle<br>pherine<br>HCl+Chlorpheniramin<br>e Maleate+Caffeine  | 500mg+5mg<br>+2mg+30mg | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3194 | Dextromethorphan<br>HBr+BromohexineHC<br>I+Chlorpheniramine<br>maleate+Guaiphensin                                 |                        | Uncoated tablet        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.          |
| 3195 | Codeine<br>Phosphate+Chlorphen<br>iramine maleate  | 10mg+4mg               | Oral Liquid            | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.    |
| 3196 | Caffeine anhydrous+<br>Paracetamol+<br>Chlorpheniramine<br>maleate   | 25mg+325m<br>g+2mg     | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      | Dextromethorphan<br>Hydrobromide+<br>Sodium Citrate+<br>Chlorpheniramine<br>maleate                                | 7.5mg+130<br>mg+2.5mg  | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.          |
|      | Paracetamol+Phenyle<br>phrine<br>HCl+Dextromethorph<br>an<br>Hydrobromide+chlorp<br>heniramine maleate             | g+15mg2.0              | Uncoated tablet        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.           |

|      | Destromethorphan<br>Hydrobromide+<br>Guaiphenesin+<br>Phenylephrine HCl+<br>Chlorpheniramine<br>maleate                        | 10mg+100m<br>g+5.0mg+4.<br>0mg            |                 | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|------|--|---|-----------------|--|
| 320  | 3 Ammonium<br>Chloride+Dextrometh<br>ophan+Cetirizine<br>HCl+Menthol   | 50mg+5mg+<br>2.5mg+2.5mg                  |                 | <ul><li>a,</li><li>1. Pharmacodynamically irrelevant.</li><li>2. Pharmacokinetic incompatibility amongst the ingredients</li><li>3.Use of anti-histamine with centrally acting anti- tussive ingredient is not rationale</li></ul>   |
| 320  | 4 Paracetamol+Phenyle<br>phrine<br>HCl+Levocetirizine<br>HCl+Caffeine<br>anhydrous   | 500mg+10m<br>g+2.5mg+30<br>mg             |                 | t a,  1.Pharmacodynamically and phamacokinetically irrational FDC.  2.Patients may need only one ingredient and use of FDC may lead to misuse.  3.Dosing shedule of the ingredients is incompatible.   |
| 320: | Nimesulide+Chlorphe<br>niramine<br>maleate+Phenylephrin<br>e HCl+Caffeine<br>anhydrous   | +10mg+30m                                 |                 |  |
|      |  |   |                 | Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.  |
| 3207 | Dextromethorphan<br>HBr+Paracetamol+Ce<br>tirizine<br>HCl+Phenylephrine<br>HCl   | 10mg+325m<br>g/500mg+5<br>mg+5mg          | Uncoated tablet | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3210 | Chlorpheniramine<br>maleate+Terpin<br>Hydrate+Antimony<br>Potassium<br>Tartrate+Ammonium<br>chloride+Sodium<br>Citrate+Menthol | 4mg+8mg+0<br>.6mg+100m<br>g+100mg+1<br>mg | Syrup           | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract  |
| 3221 | Bromhexine<br>HCl+Dextromethorph<br>an<br>Hydrobromide+Amm<br>onium<br>Choride+Menthol   | 8mg+10mg+<br>100mg                        | Oral liquid     | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
| 3222 | Codeine<br>Phosphate+Chlorphen<br>iramine maleate  | 10mg+4mg                                  |                 | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.  |

| 3224 | Paracetamol+Bromhe xine HCl+Chlorpheniramin e maleate+Phenylephrin e HCl+Guaiphenesin  | +2mg+5mg+                       | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
|------|--|---------------------------------|------------------------|---|
| 3225 | Promethazine<br>HCl+Pholcodine   | 1.5mg+1.5m<br>g                 | Oral liquid            | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 3226 | Terbutaline<br>Sulphate+Etofylline+<br>Ambroxol HCl  | 2.50mg+100<br>mg+30mg           | Uncoated tablet        | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| 3227 | Dextromethorphan<br>Hydrobromide+Brom<br>hexine<br>HCl+Ammonium<br>Chloride+Menthol  | 5.0mg+4.0m<br>g+50mg+2.5<br>mg  | Syrup                  | a, Pharmacodynamically irrelevant.  Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered  Ammonium Chloride: increase the mucus secretion in respiratory tract |
| 3232 | Phenylephrine HCl<br>IP+Bromhexine<br>Hydrobromide<br>IP+Guaiphenesin<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol IP   | 5mg+8mg+1<br>00mg+2mg+<br>325mg | Tablets                | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2.Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.  |
| 3233 | Paracetamol IP+Phenylephrine HCl IP+Cetirizine Dihydrochloride IP+Caffeine anhydrous IP  | 325mg+10m<br>g+5mg+30m<br>g     |                        | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|      | IP+Phenylephrine HCl   |                                 |                        | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|      | Section of the sectio | 10mg+5mg+<br>5mg+1.5mg          |                        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |

| 323  | 8 Nimesulide<br>BP+Paracetamol<br>IP+Phenylephrine HC<br>IP+Cetirizine HCl<br>IP+Caffeine IP     | 100mg+325<br>mg+5mg+5<br>1 mg+30mg                | Tablets         | a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3. Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs  Eccles, R., Fietze, I. and Rose, UB. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82. |
|------|--|---|-----------------|---|
| 3244 | Dextromethophan<br>Hydrobromide<br>IP+Bromhexine HCl<br>IP+Ammonium<br>Chloride IP               | 5mg+4mg+5<br>0mg                                  | Liquids         | a, Pharmacodynamically irrelevant  • Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered  • Ammonium Chloride: increase the mucus secretion in respiratory tract  • Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.   |
| 3247 | Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Dextromethorphan Hydrobromide IP | 250mg/250<br>mg+2mg/2m<br>g+2.5mg/5m<br>g+5mg/5mg |                 | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 3248 | Paracetamol<br>IP+Chlorpheniramine<br>Maleate<br>IP+Phenylephrine HCl<br>IP+Caffeine IP          | 325mg/500<br>mg+2mg+5<br>mg+30mg                  | Uncoated tablet | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3251 | Phenylephrine HCI<br>IP+Paracetamol<br>IP+Bromhexine HCI<br>IP+Chlorpheniramine<br>Maleate IP    | 2.5mg+125<br>mg+2.0mg+<br>1mg                     | Liquids         | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  |
| 3252 |  | 5mg+5mg+3<br>25mg+30mg                            | Tablets         | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
|      |  | 1.5mg+1.5m<br>g+2.5mg                             | w .             | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|      |  | 5mg+325mg<br>+15mg+2mg                            | Tablets         | a,  1.Pharmacodynamically and phamacokinetically irrational FDC.  2.Patients may need only one ingredient and use of FDC may lead to misuse.  3.Dosing shedule of the ingredients is incompatible.  |

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| 3268 | Dextromethorphan<br>Hydrobromide<br>IP+Tripolidine HCl<br>IP+Phenylephirine<br>HCl IP                | 10mg+1.25<br>mg+5mg          | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|------|--|------------------------------|---------------------|---|
| 3273 | Triprolidine HCl<br>IP+Phenylephrine<br>IP+Paracetamol IP  | 0.625mg+5<br>mg+125mg        | Syrup               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3277 | Bromhexine HCl<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP    | 8mg+10mg+<br>100mg+5mg       | Syrup               | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.   |
| 3278 | Paracetamol<br>IP+Caffeine<br>Anhydrous<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP | 325mg+30m<br>g+10mg+2m<br>g  |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3279 | Chlorpheniramine<br>Maleate<br>IP+Ammonium<br>Chloride IP+Sodium<br>Citrate IP+Menthol IP            | 2.5mg+125<br>mg+55mg+1<br>mg | Syrup               | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract   |
| 3282 | Paracetamol<br>IP+Caffeine<br>Anhydrous<br>IP+Chlorpheniramine<br>Maleate IP                         | 320mg+20m<br>g+4mg           | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Paracetamol dose is subtherapeutic. 2. Potential for drug-drug interaction.   |
| 3283 | Guaifenesin IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Chlorpheniramine Maleate IP     | 50mg+5mg+<br>60mg+2.5m<br>g  | Syrup               | a, Pharmacodynamically irrelevant- 1. Guaiphenesin:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Ammonium Chloride: increase the mucus secretion in respiratory tract 4. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 5. All ingredients have different therapeutic indications. |
| 3288 | Phenylephrine HCl<br>IP+Paracetamol<br>IP+Caffeine<br>IP+Chlorpheniramine<br>Maleate IP              | 5mg+325mg<br>+15mg+2mg       |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |

|      | Paracetamol IP+Caffeine (Anhydrous) IP+Phenylephrine HCl IP+CetirizineDihydro chloride IP         | 325mg+30m<br>g+10mg+5m<br>g | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.  |
|------|---|-----------------------------|---------------------|---|
|      | Paracetamol IP+Codeine Phosphate IP+Chlorpheniramine Maleate IP                                   | 325mg+10m<br>g+2mg          | Uncoated<br>Tablets | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Paracetamol dose is subtherapeutic. 4.There is also a risk of abuse potential.  |
|      | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP  | 10mg+4mg                    | Liquid Oral         | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |
|      | Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaiphenesin IP+Ammonium Chloride IP | 5mg+2.5mg<br>+50mg+60m<br>g | Oral Liquid         | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 17   | Paracetamol İP+Pseudoephedrine HCI IP+Cetirizine HCI IP+Caffeine (Anhydrous) IP                   | 500mg+60m<br>g+5mg+30m<br>g |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Caffeine is CNS stimulant where as Pseudoephedrine leads to sedation. 4.Dosing shedule of the ingredients is incompatible.                         |
| 3302 | Ambroxol HCl<br>IP+Guaiphenesin<br>IP+Phenylephrine<br>HCL<br>IP+Chlorpheniramine<br>Maleate IP   | 15mg+50mg<br>+5mg+2mg       | Syrup               | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule   |
| 3304 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>IP           | 500mg+5mg<br>+2mg+30mg      | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3305 | Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Chlorpheniramine Maleate IP+Guaifenesin IP  | 5mg+60mg+<br>2.5mg+50m<br>g |                     | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 3307 | Ambroxol Hcl IP+<br>Guaifenesin IP+<br>Chlorpheniramine<br>Maleate IP+<br>Phenylephrine HCl IP    | 15mg+50mg<br>+2mg+5mg       | Liquid Oral         | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule  |
| 3309 | Paracetamol<br>IP+Ambroxol HCl<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP       | 125mg+15m<br>g+5mg+2mg      | Syrup               | a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.   |

|      | 10 Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP   |                                | Syrup                 | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.     There is also a risk of abuse potential.   |
|------|---|--------------------------------|-----------------------|--|
| 331  | Paracetamol IP+Phenylephrine HC IP+Desloratadine+Zir c Gluconate USP+Ambroxol HCL IP                  | mg+15mg                        |                       | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 331  | 3 Paracetamol<br>IP+Phenylephrine HC<br>IP+Desloratadine+Zin<br>c Gluconate<br>USP+Ambroxol HCl<br>IP |                                | Oral Liquid           | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 332  | 3 Dextromethorphan<br>Hydrobromide<br>IP+Bromhexine HCl<br>IP+Ammonium<br>Chloride IP                 | 5mg+4mg+5<br>0mg               | Liquid Oral           | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.   |
| 332  | 7 Phenylephrine<br>HCl+Paracetamol<br>IP+Caffeine<br>Anhydrous+Chlorphe<br>niramine Maleate           | 5mg+500mg<br>+30mg+2.0<br>mg   | Uncoated<br>Tablets   | a, 1. Pharmacodynamically and phamacokinetically irrational FDC. 2. Patients may need only one ingredient and use of FDC may lead to misuse. 3. Dosing shedule of the ingredients is incompatible.   |
| 3329 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Caffeine<br>(anhydrous) IP                                  | 500 mg + 10<br>mg + 32 mg      | Tablets               | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3330 | Chlorpheniramine<br>Maleate<br>IP+Ammonium<br>Chloride IP+Sodium<br>Citrate IP+Menthol IP             | 2.5mg+125<br>mg+55mg+0<br>.5mg | Syrup                 | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine:H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract                                 |
| 3333 |   | 2.5mg+125<br>mg+1.25mg         | Oral Liquid           | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract                                |
| 3334 | USP+ Ambroxol<br>Hydrochloride IP+  | -                              | Film Coated<br>Fablet | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Potential for Drug-Drug interaction. 4. Indication of N-acetyl cystine in the FDC is irrelevant. |
|      |   | ng+1.25mg                      | Syrup                 | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                      |

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|     | 3345 Dextrome<br>Hydrobro<br>IP+Amm<br>de IP+Bro<br>Hydrochlo<br>IP+Menth                     | mide<br>oniumChlo<br>omhexine<br>oride    | 2mg+2.51                          | ng+ Syrup                           | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  |
|-----|---|---|-----------------------------------|-------------------------------------|--|
|     | Chlorphen<br>maleate Ip<br>Phosphate  | +Codeine<br>Ip                            | 4mg+10m                           |                                     | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.     There is also a risk of abuse potential.   |
| 3   | 351 Paracetamo<br>IP+Phenylo<br>Hydrochlor<br>rizine Hydr<br>IP+Caffein<br>Anhydrous          | ephrine<br>rideIP+Ceti<br>rochloride<br>e | g+5mg+30                          | un Uncoated<br>Tablets              | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 33  | Bromhexine<br>Hydrochlor<br>IP+Dextrom<br>Hydrobrom<br>IP+Ammon<br>Chloride IP-<br>IP         | ide<br>nethorphan<br>ide<br>ium           | 0mg+2.5mg                         | 5 Liquid Orals                      | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. |
| 335 | Paracetamol<br>IP+Chlorphe<br>Maleate<br>IP+Caffeine(<br>us) IP                               | niramine                                  | 300mg+4mg<br>+15mg                | Expectorent<br>(uncoated<br>tablet) | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Paracetamol dose is subtherapeutic. 4.Dosing shedule of the ingredients is incompatible. 5. Potential for drug-drug interaction.  |
| -   | 5 Chlorphenira<br>Maleate IP+C<br>Phosphate IP  | Codeine                                   | 4mg+10mg                          | Oral Liquid                         | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.  |
| 8   | Paracetamol IP+Phenyleph Hydrochloride IP+Cetirizine Hydrochloride IP+Caffeine (anhydrous) IP | rine m<br>g<br>+,<br>g                    | ng+5mg/5m<br>+5mg/5mg<br>30mg/30m | Film Coated<br>Tablets              | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|     | Salbutamol Su<br>IP eq. to<br>Salbutamol+Co<br>Hydrochloride<br>IP+Ambroxol<br>Hydrochloride  | etirizine 0n                              | ng+5mg+3 I                        | Γablets                             | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.   |

| 336  | Paracetamol IP+Phenylephrine Hydrochloride IP+Levocetirizine Hydrochloride IP+Caffeine (anhydrous) IP                                     | 500mg+5mg<br>+5mg+30mg        | Film Coated Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|------|---|-------------------------------|---------------------|---|
| 336. | B Dextromethorphan Hydrobromide IP+Phenylephrine Hydrochloride IP+Bromhexine Hydrochloride IP+Guaifenesin IP9 Chlorpheniramine Maleate IP | 10mg+5mg+<br>8mg+50mg+<br>2mg |                     | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 3364 | Paracetamol IP+Phenylephirine Hydrochloride IP+Chlorpheniramine Maleate IP+Caffeine (anhydrous) IP  | 500mg+10m<br>g+2mg+30m<br>g   |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3367 | Dextromethorphan<br>Hydrobromide<br>IP+Triprolidine<br>Hydrochloride<br>IP+Phenylephrine<br>Hydrochloride IP                              | 10mg+1.25<br>mg+5mg           | Oral Liquid         | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. |
| 3368 | Dextromethorphan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+4mg                      | Syrup               | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                                 |
| 3369 | Dextromethorphan<br>Hydrobromide+Chlor<br>pheniramine<br>Maleate+Phenylephrin<br>e Hydrochloride  | -                             | Oral Liquid         | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                                 |
| 3379 | Paracetamol IP+Bromhexine HCl IP+Chlorpheniramine maleate ip+Guaiphenesin IP  | 300mg+8mg<br>+2mng+50m<br>g   |                     | a, Pharmacodynamically irrelevant.  • Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  • Dosing schedule is incompatible.   |
|      | Salbutamol Sulphate<br>IP eq. to<br>Salbutamol+Theophyl<br>line Anhydrous<br>IP+Bromhexine HCl<br>IP                                      |                               | Uncoated<br>Tablets | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.    |
|      | Nimesulide<br>BP+Cetirizine Hcl<br>IP+Phenylephrine Hcl<br>IP   | 0 0                           | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Potential for nimesulide toxicity and misuse in FDC. 4.Potential for drug-drug interaction.                                      |

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| 338  | 4 Dextromethorphan<br>Hydrobromide   | 10mg+8mg+<br>2mg+100mg                                | Uncoated<br>Tablets | a, 1 Dosing schedule is incompatible.  |
|------|--|---|---------------------|--|
|      | IP+bromhexine Hcl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaiphenesin IP  |   |                     | Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 338: | Naphazoline Hcl<br>USP+Chlorphenirami<br>ne Maleate IP+Zinc<br>Sulphate IP+Boric<br>Acid Ip+Sodium<br>chloride<br>IP+chlorobutol IP (As<br>Preservative) | + 0.12% w/v<br>+ 1.25% w/v<br>+ 0.05% w/v<br>+ 0.035% |                     | a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility  |
| 3386 | Paracetamol IP+Phenylephrine Hcl IP+Chlorpheniramine Maleate IP+Caffeine (anhydrous ) IP   | 325mg+10m<br>g+2mg+30m<br>g                           |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3387 | ParacetamolIP+Brom<br>hexine<br>HcIIP+Phenylephrine<br>HcI<br>IP+Chlorpheniramine<br>Maleate<br>IP+Guaifenesin IP  | 325mg+4mg<br>+5mg+4mg+<br>50mg                        |                     | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  3. Paracetamol dose is subtherapeutic.   |
| 3388 | ParacetamolIP+Levoc<br>etirizine Hcl<br>IP+Caffeine<br>(anhydrous)<br>IP+Phenylephrine Hcl<br>IP   | 500mg+2.5<br>mg+30mg+1<br>0mg                         | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3389 | Salbutamol Sulphate<br>IP eq. to<br>Salbutamol+Bromhexi<br>ne HydrochlorideIP  | 2mg+8mg   | Uncoated<br>Tablets | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects. |
| 3390 | ParacetamolIP+Phenyl<br>ephrine Hcl<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>(anhydrous) IP  | 325mg+5mg<br>+2mg+15mg                                | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|      | Hydrobromide   | 0 0   | Uncoated<br>Tablets | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.                               |

| 330  | 2 Guaifenesin+   | 100 mg+ 8                      | tablet      | a,  |
|------|--|--------------------------------|-------------|---|
|      | Bromhexine HCL+<br>Chlorpheniramine<br>HCL+ Paracetamol  | mg+ 5 mg+<br>2 mg              |             | Pharmacodynamically irrelevant- 1. Guaiphenesin:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. paracetamol: addition of paracetamol express the consumers to the hepatotoxic effect of antipyretic unnecessarily. 3. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence |
| 9    |  |                                |             | 4.All ingredients present in the FDC have different indications.  |
| 339: | 5 Paracetamol<br>IP+Phenylephrine HC<br>Chlorpheniramine<br>Maleate IP+Caffeine<br>IP(Anhydrous)               | 500mg+10m<br>g+2mg+30m<br>g    |             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3399 | Phenylephrine<br>HCl+Chlorpheniramin<br>e<br>Maleate+Caffiene+Par<br>acetamol                                  |                                |             | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3403 | Chlorpheniramine Maleate IP+Ammonium Chloride IP+Chloroform IP+Menthol IP                                      | 3mg+110mg<br>+18.5mg+0.<br>9mg | Solution    | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract   |
| 3404 | Betholite-PD<br>(Salbutamol Sulphate<br>IP+Choline<br>Theophylinate<br>BP+Ambroxol HCl IP                      | 1mg+50mg+<br>15mg              | Oral Liquid | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| 3405 | Guaiphenesin<br>IP+Dextromethophan<br>Hydrobromide+Chlor<br>pheniramine Maleate<br>IP+Phenylephirine<br>HCl IP | 10mg+10mg<br>+4mg+5mg          | Oral Liquid | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Patients may need only one ingredient and use of FDC may lead to misuse. 4. Dosing shedule of the ingredients is incompatible.  |
| 3406 |  | 1mg+50mg+<br>15mg              | Oral Liquid | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| 3409 | Chlorpheniramine<br>Maleate + Codeine<br>Phosphate IP  | 4mg+10mg                       | Oral Liquid | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.  |

| 341  | 0 Dextromethorphan<br>Hydrobromide+Guaife<br>nesin+Chlorphenirami<br>ne<br>Maleate+Phenylephrin<br>e Hcl | 100mg+5mg                    | Oral Liquid | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
|------|--|------------------------------|-------------|---|
| 341  | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+4mg                     | Syrup       | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |
| 3415 | Codeine Phosphate<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+4mg                     | Syrup       | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4.There is also a risk of abuse potential.   |
| 3420 | Chlorpheniramine<br>Maleate IP+Codeine<br>Phosphate<br>IP+Menthol IP                                     | 4mg+10mg+<br>0.1mg           | Nil         | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |
| 3424 | Dextromethorphan<br>Hydrobromide+Guaife<br>nesin+Chlorphenirami<br>ne<br>Maleate+Ammonium<br>Chloride IP |                              | Syrup       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 3432 | Dextromethorphan<br>Hydrobromide+Cetiri<br>zine HCl<br>IP+Phenylephirine<br>Hcl IP+Menthol IP            | 10mg+5mg+<br>5mg+1.5mg       | Syrup       | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 3433 |  | 5mg+100mg<br>+40mg+1mg       | Syrup       | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract                             |
| 3439 |  | 2mg+5mg+1<br>0mg             | Syrup       | a, 1 Dosing schedule is incompatible. 2.Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 3443 | Maleate  | 3mg+130mg<br>+65mg+0.5<br>mg | Oral Liquid | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract                             |
|      | Chlorpheniramine<br>Maleate IP+Codeine<br>Phosphate IP   | 4mg+10mg                     | Oral Liquid | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential. |

| 344  | 48 Chlorpheniramine<br>Maleate<br>IP+Ammonium<br>Chloride IP+Sodium<br>Citrate IP+Menthol II                    | +65mg+0.5<br>mg                  | g Oral Liquid       | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract   |
|------|---|----------------------------------|---------------------|---|
| 344  | P Diphenyhydramine<br>HCl IP+Terpine<br>Hydrate<br>USP+Ammonium<br>Chloride IP+Sodium<br>Citrate IP             | 12.5mg+7.5mg+125mg<br>55mg+1.5ng | +                   | a, Pharmacodynamically irrelevant. No published literature supporting the combination   |
| 345  | 1 Chlorpheniramine<br>Maleate IP+Codeine<br>Phosphate IP  | 4mg+10mg                         | Oral Liquid         | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.     There is also a risk of abuse potential.  |
| 345  | 2 Pseudoephedrine HCl<br>IP+Bromhexine HCl<br>IP  | 60mg+8mg                         | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant.  1.Mucokinetic increases mucus secretion and decongestant will dry up secretions.  2.Dosing schedule is incompatible.  |
| 3450 | 3 Cetirizine HCl<br>IP+Phenylephrine HCl<br>IP+Paracetamol<br>IP+Caffeine<br>(Anhydrous)<br>IP+Nimesulide BP    | 5mg+10mg+<br>325mg+25mg+100mg    |                     | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 3455 | Dextromethorphan<br>Hydrobromide<br>IP+Bromhexine HCl<br>IP+Ammonium<br>Chloride IP+Menthol<br>IP               | 5mg+4mg+5<br>0mg+50mg            | Syrup               | a, Pharmacodynamically irrelevant.  1. Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  2. Dosing schedule is incompatible.  |
| 3456 | Guaifenesin<br>IP+Dextromethorphan<br>Hydrobromide<br>IP+Phenylephrine HCl<br>IP+Chlorpheniramine<br>Maleate IP | 100mg+10m<br>g+5mg+4mg           | Syrup               | a, Pharmacodynamically irrelevant- 1. Guaiphenesin:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 4. All ingredients have different therapeutic indications. |
|      | Hydrobromide+Levoc  | 10mg+2.5m<br>g+5mg+7.5<br>mg     | Expectorent         | Dosing schedule is incompatible.     Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
|      |   | 0ml+5mg+<br>50mg+60mg            | Syrup               | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |

| 3468 | Levocetirizine+Parace<br>tamol+Phenylephrine+<br>Caffeine   | 5mg+325mg<br>+5mg+25mg              | Uncoated<br>Tablets    | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule. 3. Subtherapeutic dose of paracetamol.  |
|------|---|-------------------------------------|------------------------|---|
| 3472 | Levocetirizine Hcl<br>IP+Ambroxol HCl<br>IP+Guaifenesin<br>IP+Phenylephirine<br>HCl IP+Menthol IP                       | 0.8mg+15m<br>g+50mg+5m<br>g         | Oral<br>Suspension     | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule  |
| 3473 | Paracetamol IP+Phenylephrine HCl IP+Levocetirizine HCl IP+Sodium Citrate IP   |                                     |                        | <ul> <li>a,</li> <li>1.Pharmacodynamically and phamacokinetically irrational FDC.</li> <li>2.Patients may need only one ingredient and use of FDC may lead to misuse.</li> <li>3.Dosing shedule of the ingredients is incompatible.</li> <li>4. Potential for drug-drug interaction.</li> </ul>                                     |
| 3476 | Ambroxol HCl IP+<br>Salbutamol Sulphate<br>IP eq. to Salbutamol+<br>Choline<br>Theophyllinate BP+<br>Menthol IP         | 15mg+lmg+<br>55mg+lmg               | Oral Liquid<br>Syrup   | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drug and their adverse effects.   |
| 3489 | Paracetamol IP+Chlorpheniramine maleate IP+Caffeine Anhydrous IP  | 325mg+2mg<br>+25mg                  | Uncoated tables        | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Paracetamol dose is subtherapeutic. 4.Dosing shedule of the ingredients is incompatible. 5. Potential for drug-drug interaction.   |
| 3504 | Paracetamol IP+Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate IP+Caffeine IP                                   | 500mg+10m<br>g+2mg+25m<br>g         | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
|      | Paracetamol IP+Chlorpheniramine Maleate IP+Ambroxol Hydrochloride IP+Guaifenesin IP+Phenylephrine Hydrochloride IP      | 0                                   | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant.  • Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  • Dosing schedule is incompatible.   |
|      | Levocetirizine Hydrochloride IP+Phenylephrine Hydrochloride IP+Ambroxol Hydrochloride IP+Guaiphenesin IP+Paracetamol IP | 2.5mg+10m<br>g+60mg+10<br>0mg+325mg | Uncoated tablets       | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule. 3. Potential drug interation. 4. Subtherapeutic dose of paracetamol.  |
|      | Levocetirizine Hydrochloride IP+Paracetamol IP+Phenylephrine Hydrochloride IP+Caffeine anhydrous eq. to caffeine        | 2.5mg+500<br>mg+10mg+3<br>0mg       | Uncoated<br>tablets    | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule.   |
| 3511 | ChlorpheniramineMal<br>eate IP+Codeine<br>Phosphate<br>IP+Menthol IP  | 4mg+10mg+<br>0.1mg                  | Oral Liquid            | <ol> <li>Dosing schedule is incompatible.</li> <li>Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.</li> <li>Centrally acting anti-tussive not to be combined with anti-histaminic drug.</li> <li>There is also a risk of abuse potential.</li> </ol> |

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| 351  | 2 Chlorpheniramine<br>Maleate IP+Vasaka<br>Extract eq. to Vasaka<br>IP '66+Tolubalsm<br>IP+Ammonium<br>Chloride IP+Sodium<br>Citrate IP+Menthol IF | +6.25mg+10<br>0mg+60mg+<br>1mg   |                        | a, Pharmacodynamically irrelevant- 1. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract.   |
|------|--|----------------------------------|------------------------|--|
| 351  | 3 Bromhexine Hcl<br>IP+Cetrizine Hcl<br>IP+Phenylephrine HC<br>IP+Guaifenesin<br>IP+Menthol IP   | 4mg+2.5mg<br>+5mg+50mg<br>l +1mg | Oral Liquid            | a, 1.Pharmacologically no synergistic effect 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility. 3. Pharmacokinetically incompatibility.   |
| 3514 | 4 DextromethorphanHy<br>drobromide<br>IP+Ambroxol Hcl<br>IP+Ammonium<br>Chloride<br>IP+Chlorpheniramine<br>Maleate IP+Menthol<br>IP                | 5mg+15mg+<br>50mg+2mg+<br>2.5mg  |                        | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 3515 | Ambroxol Hcl IP+Chlorpheniramine Maleate IP+Phenylephrine Hcl IP+Guaifenesin IP+Menthol IP   | 15mg+2mg+<br>5mg+50mg+<br>1mg    |                        | a,  1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.  2. Pharmacokinetically irrelevant-different dosing shedule   |
| 3518 | Dextromethorphan Hydrobromide IP+PhenylephrineHCl IP+Cetirizine HCl IP+Zinc Gluconate USP as elemental Zinc+Menthol IP                             | 10mg+5mg+<br>5mg+7.5mg<br>+1.5mg | Oral Liquid-<br>Syrup  | a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                                      |
| 3520 | Diethylcarbamazine<br>Citrate<br>IP+Guaiphenesin<br>IP+Chlorpheniramine<br>Maleate   | 100mg+60m<br>g+2mg               | Film Coated<br>Tablets | a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.    |
| 3521 | Diethylcarbamazine<br>Citrate<br>IP+Guaiphenesin<br>IP+Chlorpheniramine<br>Maleate   |                                  | Film Coated<br>Tablets | a, Pharmacodynamic irrelevant -  1. Patient may need only one ingredient and use of FDC may lead to misuse.  2. Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties. |
| 3522 |  | _                                | Film Coated<br>Tablets | a, Pharmacodynamic irrelevant -  1. Patient may need only one ingredient and use of FDC may lead to misuse.  2. Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties. |

|      | Terbutaline Sulphate<br>IP+ N-Acetyl L-<br>Cysteine USP+<br>Guaifenesin IP                           | 2.5mg+200<br>mg+100mg       | Sachets                | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects. |
|------|--|-----------------------------|------------------------|--|
|      | Calcium Gluconate<br>IP+Levocetirizine<br>Dihydrochloride IP   | 500mg+5mg                   | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1.Each ingredients have different indication. 2.This combination does not follow the concept and purpose of FDC   |
|      | Paracetamol<br>IP+Levocetirizine Di<br>hydrochloride<br>IP+Pseudoephedrine<br>Hcl IP                 | 650mg+2.5<br>mg+60mg        | Film Coated<br>Tablets | a, 1. Paracetamol dose high 2. Pharmacokinetic incompatibility. 3. Potential for drug-drug interaction.  |
| d    | Dextromethorphan Hydrobromide IP+Chlorpheeniramin e Maleate IP+Guaifenesin IP+Ammonium Chloride IP   | 5mg+2.5mg<br>+50mg+60m<br>g | Liquid Orals           | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                              |
| 3548 | Chloropheniramine<br>maleate IP+Codeine<br>Phosphate IP  | 4mg+10mg                    | Syrup                  | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.                        |
| 3550 | Dextromethorphan<br>Hydrobromide<br>IP+Cetirizine Hcl<br>IP+Phenylephrine HCl<br>IP+Menthol IP       | 10mg+5mg+<br>5mg+1.5mg      | Syrup                  | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.                              |
| 3553 | Salbutamol Sulphate<br>eq. to Salbutamol<br>IP+Choline<br>Theophylinate<br>BP+Carbocisteine BP       | 1mg+50mg+<br>50mg           | Liquids Oral           | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects. |
| 3560 | Paracetamol<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>Anhydrous<br>IP+Phenylephrine HCl<br>IP | 500mg+2mg<br>+30mg+10m<br>g | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3561 | Chlorpheniramine<br>maleate IP+Vitamin C<br>IP   | 2mg+30mg                    | Syrup                  | a,<br>Pharmacodynamically irrelevant FDC   |
| 3562 | Calcium Gluconate<br>IP+Chlorpheniramine<br>Maleate IP+Vitamin C<br>IP                               | 500mg+4mg<br>+50mg          | Solid Oral             | a, Pharmacodynamically irrelevant- 1.Each ingredients have different indication. 2.This combination does not follow the concept and purpose of FDC   |

| 3566 | Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine IP  | 500mg+5mg<br>+2mg+30mg               | Uncoated<br>Tablets    | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
|------|--|--------------------------------------|------------------------|--|
| 3568 | ChlorpheniramineMal<br>eate IP+Paracetamol<br>IP+Pseudoephedrine<br>HCl IP+Caffeine<br>(anhydrous) IP  | 2mg+500mg<br>+60mg+30m<br>g          | Film Coated<br>Tablets | a, 1.Pharmacodynamically irrationale FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Caffeine is CNS stimulant where as Pseudoephedrine leads to sedation.   |
| 3569 | Guaifenesin IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP+Serratiopeptidase IP(as enteric coated granules)10000 SP Unts | 2mg+5mg+3<br>25mg+5mg                | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Guaiphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. paracetamol: as cough and cold not allows accompanied by fever, addition of paracetamol express the consumers to the hepatotoxic effect of antipyretic unnecessarily 4. All ingredients have different therapeutic indications. |
| 3570 | Paracetamol<br>IP+Pheniramine<br>Maleate IP  | 500mg+12.5<br>mg                     | Uncoated<br>Tablets    | a, Pharmacodynamically irrelevant- 1. Both ingredients have different indications. 2. Misuse and toxicity of paracetamol.  |
| 3571 | Paracetamol<br>IP+Phenylephrine HCl<br>IP+Caffeine<br>anhydrous<br>IP+Chlorpheniramine<br>Maleate IP   | 500mg+5mg<br>+15mg+2mg               | Uncoated<br>Tablets    | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 3575 | Clobetasol<br>Propionate+Ofloxacin<br>+Ornidazole+Terbinaf<br>ine HCl  |                                      | Cream base             | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 3579 | Dipropionate+Clotrim   | 0.025% w/w<br>++1% w/w<br>+ 0.5% w/w | Cream                  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |

| 3593  | Betamethasone Dipropionate Ip Eq. to Betamethasone+Genta micin Sulphate IP Eq. to Gentamicin+Miconaz ole Nitrate IP  |   | Cream      | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|-------|--|---|------------|---|
| 3600  | Betamethasone<br>Valerate +Fusidic<br>Acid+Gentamycin<br>Sulphate+Tolnaftate+I<br>odochlorhydroxyquino<br>line(ICHQ) |   |            | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3603  | Miconazole Nitrate +<br>clorocresol +<br>neomycin Sulphate   | 2.00%w/w +<br>0.10%w/w<br>+0.50%w/w                           | cream      | a, Pharmacodynamically irrelevant- Patient may need only one ingredient Drug may be misused as it has both antifungal and antibacterial ingredients. In advertent use of antimicrobials may lead to emergence of resistence.  |
| 3606  | Beclomethasone Dipropionate IP+Clotrimazole IP+Neomycin Sulphate IP Eq. to Neomycin+Chlorocres ol IP                 | 0.025% w/w<br>+ 1.00%<br>w/w +<br>0.50% w/w<br>+ 0.10%<br>w/w | Cream base | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3615  | Dipropionate   | 1.00% w/w<br>+ 0.025%<br>w/w + 0.5%<br>w/w                    | Cream      | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| v - 1 | Dipropionate<br>IP+Clotrimazole  | 0.025% w/w<br>+ 1% w/w +<br>0.5% w/w<br>+0.1% w/w             | Cream      | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |

| 3632 | Clobetasol<br>Proionate+Ofloxacin+<br>Miconazole<br>Nitrate+Zinc Sulphate                             | 0%w/v+3.0   | Lotion | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|------|---|---|--------|---|
| 3635 | Betamethasone+Genta<br>mycin<br>Sulphate+Miconazole   | 0.10%w/w+   | Cream  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  |
|      |   | »<br>«  |        | 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3638 | Ofloxacin+ Ornidazole + Terbutaline HCl + Clobetasol Propionate + Methyl Paraben + Propyl Paraben     | 0.75%w/w+<br>2.0%w/w+1.<br>0%w/w+0.0<br>5%w/w+0.2<br>0%w/w+0.0<br>2%w/w | Cream  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3641 | beclomethasone Dipropionate + clotrimazole + neomycin sulphate + chlrocresol                          | 0.025 %<br>w/w + 1%<br>w/w + 0.5 %<br>w/w + 0.1 %<br>w/w                | 1      | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3642 | clobetasol propionate+<br>neomycin sulphate +<br>clotrimazole   | 0.05%w/w +<br>0.5 % w/w +<br>1.0%w/w                                    | cream  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3649 | Clotrimazole IP+beclomethasone Dipropionate IP+Neomycin Sulphate IP+Methylparaben IP+Propylparaben IP | 1% w/w +<br>0.025% w/w<br>+ 0.5% w/w<br>+ 0.15%<br>w/w +<br>0.08% w/w   | Cream  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |

| 3653 | Ofloxacin IP +Ornidazole IP+Terbinafine HCl BP+Clobetasol Propionate BP+Methyl Paraben IP+Propyl Paraben IP  | 0.75% w/w<br>+ 2.0% w/w<br>+ 1.0% w/w<br>+0.05% w/w<br>+ 0.20%<br>w/w +<br>0.02% w/w | Topical Cream | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                             |
|------|--|--|---------------|---|
| 3654 | Clobetasole Propionate USP+Gentamicin IP+Miconazole Nitrate IP+Zinc Sulphate IP  | 0.05% w/w<br>+ 0.1% w/w<br>+ 2.0% w/w<br>+ 2.5%w/w                                   | Topical Cream | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                             |
| 3659 | Clobetasol Propionate<br>USP+Miconazole<br>Nitrate IP+Neomycin<br>Sulphate<br>IP+Chlorocresol IP   | 0.05% w/w<br>+ 2% w/w +<br>0.5% w/w +<br>0.1% w/w                                    | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                             |
| 3660 | Bethamethasone<br>Valerate<br>IP+Gentamicin<br>Sulphate IP eq. to<br>Gentamicin+Tolnaftat<br>e+Idochlorhydroxyqui<br>noline IP+Borax<br>BP+Chlorocresol IP | + 0.1% w/w<br>+ 1.5% w/w<br>+ 1.5% w/w<br>+ 0.05%                                    | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid, iodochlorohydroxyquinone in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|      | terbinafine+ ofloxacin+ orniazole + clobetasole propioanate + methylparaben + propylparaben  | 1% w/w +<br>0.75% w/w+<br>2% w/w+<br>0.05% w/w+<br>0.20% w/w<br>+ 0.02%<br>w/w       | cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
|      | terbinafine HCL+<br>clobetasole propionate<br>+ methylparaben+<br>propylparaben  | 0.75%w/w+<br>2.0% w/w +<br>1.0%w/w+<br>.05% w/w+<br>.20%<br>w/w+.02%w<br>/w          |               | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |

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| 3670 | ambroxol HCL+  | 2.5 mg+ 60<br>mg+ 5 mg+<br>325 mg  | tablets        | <ul><li>a,</li><li>1 Dosing schedule is incompatible.</li><li>2. Patients may need only one or two ingredients and use of FDC may lead to misuse.</li></ul>   |
|------|--|--|----------------|---|
| 3673 | clobetasol propionate<br>+ gentamycin sulphate<br>+ miconazole nitarte+<br>borax+ chlorocresol     | .05% w/w+<br>.1% w/w+<br>2,0 % w/w+<br>2.5 % w/w+<br>.05 % w/w+<br>.1% w/w | cream          | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3678 | Permethrin + Cetrimide IP + Menthol IP   | 1.0%w/w +<br>0.5%w/w +<br>1.0%w/w  | Soap           | a, 1. This FDC has no therapeutic value.  |
| 3679 | Clobetasol Propionate<br>BP+Neomycin<br>Sulphate<br>IP+Miconazole<br>Nitrate<br>IP+Chlorocresol IP | 0.05%w/w +<br>0.5% w/w +<br>2.0% w/w +<br>0.1%w/w                          | Cream          | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3680 | Clobetasol Propionate<br>BP + Ofloxacin<br>IP+Miconazole<br>Nitrate IP+Zinc<br>Sulphate BP         | 0.025%w/v<br>+ 0.1%w/v +<br>2.0%w/v<br>+3.0%w/v                            | Topical Lotion | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3686 | beclomethasone<br>dippropionate+<br>clotrimazole +<br>neomycin sulphate                            | 0.025%w/w<br>+ 1% w/w +<br>.5% w/w   | cream          | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3687 | Clotrimazole +<br>beclomethasone<br>dipropionate +<br>neomycin sulphate                            | 1% w/w.+<br>.025% w/w<br>+ .5% w/w   | cream          | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |

| 3691 | Clobetasol Propionate<br>+ Clotrimazole +<br>Neomycin Sulphate +<br>Chlorocresol                      | 0.05%w/w+<br>1.00%w/w+<br>0.5%w/w+0.<br>10%w/w  | Topical Cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|---|---|---------------|---|
| 3695 | Clindamycin +<br>Nicotinamide +<br>Allantoin  | 1.0%w/w+4.<br>0%w/w+0.5<br>0%w/w                | Gel           | a, Pharmacodynamically irrelevant- 1. Study did not show any added advantage of clindamycin phosphate 1% in combination with nicotinamide gel 4% over clindamycin phosphate 1% alone.  Dos SK, Barbhuiya JN, Jana S, Dey SK Comparative evaluation of clindamycin phosphate 1% and clindamycin phosphate 1% with nicotinamide gel 4% in the treatment of acne vulgaris. Year: 2003   Volume: 69   Issue: 1   Page: 8-9  |
| 3701 | Clotrimazole IP+Beclomethasone Dipropionate IP+Neomycin eq. to Neomycin                               | 1.0% w/w +<br>0.025%w/w<br>+0.5%w/w             | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3707 | Offoxacin + Ornidazole + Terbutaline HCl+Clobetasol Propionate  | 0.75%w/w +<br>2%w/w +<br>1%w/w +<br>0.05%w/w    | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3723 | Clobetasole<br>Propionate BP +<br>Neomycin Sulphate IP<br>+ Miconazole Nitrate<br>IP + Imidurea USPNF | 0.05%w/w +<br>0.5%w/w +<br>2.0%w/w +<br>0.3%w/w | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3727 | Clobetasol Propionate<br>BP+Gentamicin+Mico<br>nazole Nitrate<br>IP+Chlorocresol IP                   |   | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |

| 3734 | beclomethasone<br>dipropionate +<br>clotimazole +<br>neomycin sulphate +<br>iodochlorohydroxyqui<br>none | .025% w/w<br>+ 10 % w/w<br>+ 5 % w/w +<br>1% w/w         | cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid, iodochlorohydroxyquinone in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|--|--|---------------|---|
| 3736 | clobetasol propionate<br>+ miconazole nitrate +<br>neomycin sulphate +<br>chlorocresol                   | .05% w/w +<br>2% w/w + .5<br>% w/w + .10<br>% w/w        | topical cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                         |
| 3744 | Clobetasol Propiionate<br>BP+Ofloxacin<br>IP+Miconazole<br>Nitrate IP                                    | 0.025%w/w<br>+ 0.1%w/w<br>+ 2.0%w/w                      | Lotion        | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3746 | Neomycin Sulphate +<br>Doxycycline HCl   | 100mg+100<br>mg  | Powder        | a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredient 2. Drug misuse should not be there for diagnostic uncertainty 3. Inadvertent use of antimicrobials may lead to emergence of resistence 4. No published literature supporting this combination of products found  |
| 3748 | Ciprofloxacin Cl + Fluocinolone Acetonide + Clotrimazole + Neomycin Sulphate + Chlorocresol              | 0.5%w/w+0.<br>25%w/w+1.<br>0%w/w+0.5<br>%w/w+0.1%<br>w/w | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3749 | + Ofloxacin +<br>Ketoconazole + Zinc   | 0.025%w/v+<br>0.1%w/v+2.<br>0%w/v+3.0<br>%w/v            | Lotion        | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
|      |  |  |               |   |

| 3752 | Clobetasol Propionate  | 0.05%w/w+  | Cream    | a,  |
|------|--|--|----------|---|
|      | + Neomycin Sulphate  | 0.5%w/w+2  |          | Pharmacodynamically irrelevant-   |
|      | + Miconazole Nitrate   | %w/w+0.1%  |          | 1. Each ingredients of FDC has different therapeutic indication and is at   |
|      | + Chlorocresol   | w/w  |          | variance from the concept and purpose of FDC.   |
|      |  | -  |          | 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to  |
|      | 122  |  | 51       | be misuse and emergence of resistance and adverse effects.  |
|      |  |  |          | 3. Use of steroid in case of fungal infection might actually worsen the   |
|      |  |  |          | 3. Use of stelloid in case of fungal infection inight actually worsen the   |
|      | 2  |  | <u> </u> | treatment as it encourages fungal growth. NO study is found supporting  |
|      |  |  |          | the combined use of an antibacterial with an antifungal ingredient.   |
|      |  |  |          |   |
|      | 27 7. 130  |  |          |   |
|      |  |  |          |   |
| 3757 | Clotrimazole+Beclom  | 1%w/w+0.0  | Cream    | a,  |
|      | ethasone   | 25%w/w+0.  |          | Pharmacodynamically irrelevant-   |
|      | Dipropionate+Neomy   | 5%w/w+0.1  |          | 1. Each ingredients of FDC has different therapeutic indication and is at   |
|      | cin Sulphate+Methyl  | 5%w/w+0.0  |          | variance from the concept and purpose of FDC.   |
|      | Paraben+Propyl   | 8%w/w  | 11       | 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to  |
|      | The state of the s | 07000700   |          | be misuse and emergence of resistance and adverse effects.  |
|      | Paraben  |  |          | 2 III Committee and emergence of resistance and adverse effects.  |
|      |  |  |          | 3. Use of steroid in case of fungal infection might actually worsen the   |
|      | 20 80  |  |          | treatment as it encourages fungal growth. NO study is found supporting  |
|      |  |  |          | the combined use of an antibacterial with an antifungal ingredient.   |
|      |  |  |          |   |
|      |  |  | 100      |   |
|      |  |  |          |   |
| 3762 | Fluocinolone   | 0.025%w/w  | Cream    | a,  |
|      | Acetonide+Miconazol  | +2.0%w/w+  |          | Pharmacodynamically irrelevant-   |
|      | e Nitrate+Neomycin   | 0.5%w/w  |          | 1. Each ingredients of FDC has different therapeutic indication and is at   |
|      | Sulphate   | 0.07011711   |          | variance from the concept and purpose of FDC.   |
|      | Suipilate  |  | × "      | 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to  |
|      |  |  |          | 2. Combining antibiotic, antifuligal, steroid in the present PDC is habit to  |
|      |  |  | 32.1 &   | be misuse and emergence of resistance and adverse effects.  |
| 200  |  |  |          | 3. Use of steroid in case of fungal infection might actually worsen the   |
|      |  |  |          | treatment as it encourages fungal growth. NO study is found supporting  |
|      |  |  |          | the combined use of an antibacterial with an antifungal ingredient.   |
|      | -  |  |          | and comonica and or an annual and an an annual and an   |
|      |  |  | 14       |   |
|      |  |  |          |   |
| 3768 | Clobetasol   | 0.05%w/w+  | Cream    | a,  |
| 5700 |  |  | 0.000    |   |
|      | Propionate+Neomycin  | 0.5%w/w+2  |          | Pharmacodynamically irrelevant-   |
|      | Propionate+Neomycin  |  | _        | Pharmacodynamically irrelevant-   |
|      | Sulphate+Miconazole  | 0.5%w/w+2<br>%w/w  | -        | 1.Each ingredients of FDC has different therapeutic indication and is at  |
|      |  |  |          | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.   |
|      | Sulphate+Miconazole  |  |          | <ol> <li>Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to</li> </ol>   |
|      | Sulphate+Miconazole  |  |          | <ol> <li>1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> </ol>   |
|      | Sulphate+Miconazole  |  |          | <ol> <li>1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> </ol>   |
|      | Sulphate+Miconazole  |  |          | <ol> <li>Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>Use of steroid in case of fungal infection might actually worsen the</li> </ol>  |
|      | Sulphate+Miconazole  |  |          | <ol> <li>Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting</li> </ol>   |
|      | Sulphate+Miconazole  |  |          | <ol> <li>Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>Use of steroid in case of fungal infection might actually worsen the</li> </ol>  |
|      | Sulphate+Miconazole  |  |          | <ol> <li>Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting</li> </ol>   |
|      | Sulphate+Miconazole  |  |          | <ol> <li>Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.</li> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting</li> </ol>   |
|      | Sulphate+Miconazole<br>Nitrate   | %w/w   | C        | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom   | %w/w 1.00%w/w+   | Cream    | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.     2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.     3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone  | %w/w 1.00%w/w+ 0.025%w/w   | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-   |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone  | %w/w 1.00%w/w+   | Cream    | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.     2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.     3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy   | %w/w<br>1.00%w/w+<br>0.025%w/w<br>+0.500%w/                                  | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl   | %w/w<br>1.00%w/w+<br>0.025%w/w<br>+0.500%w/<br>w+0.150%w                     | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl  | 1.00%w/w+<br>0.025%w/w+<br>0.500%w/<br>w+0.150%w/<br>w+0.080%                | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl   | %w/w<br>1.00%w/w+<br>0.025%w/w<br>+0.500%w/<br>w+0.150%w                     | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.   |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl  | 1.00%w/w+<br>0.025%w/w+<br>0.500%w/<br>w+0.150%w/<br>w+0.080%                | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl  | 1.00%w/w+<br>0.025%w/w+<br>0.500%w/<br>w+0.150%w/<br>w+0.080%                | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting   |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl  | 1.00%w/w+<br>0.025%w/w+<br>0.500%w/<br>w+0.150%w/<br>w+0.080%                | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the  |
| 3772 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl  | 1.00%w/w+<br>0.025%w/w+<br>0.500%w/<br>w+0.150%w/<br>w+0.080%                | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting   |
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|      | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl  | 1.00%w/w+<br>0.025%w/w+<br>0.500%w/<br>w+0.150%w/<br>w+0.080%                | Cream    | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting   |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol  | %w/w<br>1.00%w/w+<br>0.025%w/w<br>+0.500%w/<br>w+0.150%w<br>/w+0.080%<br>w/w |          | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+  | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at   |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+  | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.   |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a, Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a, Pharmacodynamically irrelevant-  1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to   |
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| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the   |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the   |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting  |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the   |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the treatment as it encourages fungal growth. NO study is found supporting |
| 3777 | Sulphate+Miconazole Nitrate  Clotrimazole+Beclom ethasone Dipropionate+Neomy cin Sulphate+Methyl Paraben+Propyl Paraben  Clobetasol Propionate+ Neomycin Sulphate+   | %w/w  1.00%w/w+ 0.025%w/w +0.500%w/ w+0.150%w /w+0.080% w/w  0.5%+0.5%       |          | 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  a,  Pharmacodynamically irrelevant-  1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the treatment as it encourages fungal growth. NO study is found supporting |

| 3782 | Clobetasol<br>Propionate+<br>Ofloxacin+<br>Miconazole Nitrate+<br>Zinc Sulphate+ P-<br>Chlorocresol | 0.025%w/w<br>+0.1%w/w+<br>2.0%w/w+3.<br>0%w/w+0.1<br>%w/w | Cream                  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|------|---|---|------------------------|---|
| 3795 | Miconazole Nitrate<br>IP+Gentamicin<br>Sulphate<br>IP+Clobetasone<br>Butyrate BP                    | 2.0%w/w +<br>0.1%w/w +<br>0.05%w/w                        | Cream                  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3802 | Clotrimazole IP+Beclomethasone Dipropionate IP+Gentamicin Sulphate IP                               | 1.00%w/w +<br>0.025%w/w<br>+ 0.10%w/w                     | Cream                  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3807 | Clotrimazole IP+Beclomethasone Dipropionate IP+Clindamycin Phosphate BP                             | 1%w/w +<br>0.025%w/w<br>+ 1%w/w                           | Cream for external use | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3810 | Beclomethasone Dipropionate IP+Clotrimazole IP+Neomycin Sulphate IP Eq. to Neomycin                 | 0.025%w/v<br>+ 1.0%w/v +<br>0.5%w/v                       | Lotion                 | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 3814 | Clotrimazole IP+Beclomethasone Dipropionate IP+Neomycin Sulphate IP                                 | 1.00%w/w +<br>0.025%w/w<br>+ 0.50%w/w                     | Cream                  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |

|      | Betamethasone Valerate IP+Gentamicin Sulphate IP+Tolnaftate IP+Iodochlorhydroxyq uinoline IP                                | 0.50mg+1.0<br>0mg+15.00<br>mg+15.00m<br>g                        | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid, iodochlorohydroxyquinone in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|---|--|---------------|---|
| 3822 | IP+Dexamethasone Acetate USP+Fradiomycin Sulphate JP (Neomycin Sulphate IP)+Methyl Paraben IP+Propyl Paraben IP             | 0.10%w/w +<br>0.10%w/w +<br>0.50%w/w +<br>0.08%w/w +<br>0.04%w/w |               | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3839 | Clobetasol Propioinate<br>BP+Miconazole<br>Nitrate IP+Neomycin<br>Sulphate IP   | 0.05%w/w +<br>2.0%w/w +<br>0.5%w/w                               | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3843 | Clobetasol Propionate<br>USP+Gentamicin<br>Sulphate<br>IP+Tolnaftate<br>IP+Idochlorhydroxyqu<br>inone<br>IP+Ketoconazole IP | 0.05%w/w +<br>0.10%w/w +<br>1.00%w/w +<br>1.00%w/w +<br>2.00%w/w | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3847 | IP+Neomycin   | 2%w/w +<br>0.5%w/w +<br>0.1%w/w                                  | Topical Cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3851 | Dipropionate<br>IP+Neomycin   | 0.025%w/w<br>+ 0.5%w/w<br>+ 1%w/w +<br>0.1%w/w                   | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |

|   |   |  | *  |
|---|---|--|--|
| Propionate BP+Neomycin Sulphate IP+Miconazole Nitrate IP+Zinc Sulphate IP                             | 0.5%w/w   | +  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 3 Flucinolone Acetonid<br>IP+Gentamicin<br>Sulphate<br>IP+Clotrimazole IP                             |   | +  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 5 Clobetasol Propionate<br>USP+Neomycin<br>Sulphate<br>IP+Miconazole<br>Nitrate<br>IP+Chlorocresol IP | 0.05%w/w +<br>0.5%w/w +<br>2.0%w/w +<br>0.1%w/w   |  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| Clobetasol Propionate<br>IP+Neomycin<br>Sulphate<br>IP+Miconazole<br>Nitrate IP                       |   |  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| +Terbinafine<br>HCl+Clobetasol  | 2.0%w/w+1.<br>0%w/w+0.0   | Cream  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
|   |   | Cream  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
|   | BP+Neomycin Sulphate IP+Miconazole Nitrate IP+Zinc Sulphate IP  3 Flucinolone Acetonid IP+Gentamicin Sulphate IP+Clotrimazole IP  5 Clobetasol Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP  Clobetasol Propionate IP+Neomycin Sulphate IP+Neomycin Sulphate IP+Neomycin Sulphate IP+Neomycin Sulphate IP+Neomycin Sulphate IP-Neomycin Sulphate IP-Niconazole Nitrate IP  Ofloxacin+Ornidazole +Terbinafine HCl+Clobetasol Propionate | Propionate BP+Neomycin Sulphate IP+Miconazole Nitrate IP+Zinc Sulphate IP  3 Flucinolone Acetonide IP+Gentamicin Sulphate IP+Clotrimazole IP  5 Clobetasol Propionate USP+Neomycin Sulphate IP+Hiconazole Nitrate IP+Chlorocresol IP  Clobetasol Propionate IP+Neomycin Sulphate IP+Chlorocresol IP  Clobetasol Propionate IP+Neomycin Sulphate IP+Neomycin Sulphate IP+Neomycin Sulphate IP+Chlorocresol IP  Clobetasol Propionate IP+Neomycin Sulphate IP-Neomycin Sulphate IP-Neomyc | Propionate BP+Neomycin Sulphate IP+Miconazole Nitrate IP+Zinc Sulphate IP  SIlphate IP+Clotrimazole IP  SIlphate IP+Clotrimazole IP  SIlphate IP+Chlorocresol |

| 390  | R Fluocinolone Acetonide+Miconazo e Nitrate+Neomycin Sulphate  | 0.025%w/w<br>+2.0%w/w+<br>0.5%w/w   |               | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to  |
|------|--|---|---------------|---|
|      |  |   |               | be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|      |  |   |               | * -   |
| 393  | 7 Betamethasone<br>Dipropionate<br>IP+Neomycin<br>Sulphate<br>IP+Tolnaftate<br>USP+Iodo Chloro<br>Hydroxy Quinoline<br>IP+Cholorocresol IP | 0.61mg+0.5<br>mg+5mg+15<br>mg+1.0mg   |               | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid, iodochlorohydroxyquinone in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3938 | Clobetasole Propionate Usp+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP  | 0.05%w/w +<br>0.5%w/w +<br>2.0%w/w +<br>0.1%w/w                             | Topical Cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
| 3971 | Ofloxacin<br>IP+Ornidazole<br>IP+Terbinafine HCL<br>BP+Clobetasol<br>Propionate<br>BP+Methyl Paraben<br>IP+Propyl Paraben IP               | 0.75%w/w +<br>2.0%w/w +<br>1.0%w/w +<br>0.05%w/w<br>+0.20%w/w<br>+ 0.02%w/w | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                             |
|      | ,  | 0.05%w/w +<br>0.5%w/w<br>2.0%w/w +<br>0.1%w/w                               | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
|      | IP+Clindamycin   | 2%w/w +<br>2%w/w +<br>2%w/w   |               | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                             |
|      |  |   |               |   |

| 399: | Clotrimazole IP+beclomethasone Dipropionate IP+Neomycin  | 1%w/w + 0.025%w/w + 0.5%w/w + 0.15%w/w         | 1             | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  |
|------|--|--|---------------|---|
|      | Sulphate<br>IP+Methylparaben<br>IP+Propylparaben IP  | + 0.08%w/w                                     |               | <ol> <li>Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.</li> <li>Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.</li> </ol>   |
|      | -  |  |               |   |
| 3996 | Clobetasol Propionate<br>BP+Miconazole<br>Nitrate IP+Neomycin<br>Sulphate IP+Glycerin<br>IP+Cetrimide IP | 2%w/w +<br>0.5%w/w +                           | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 3998 | Beclomethasone Dipropionate USP+Clotrimazole IP+Neomycin Sulphate IP+Chlorocresol IP                     | 0.025%w/w<br>+ 1%w/w +<br>0.5%w/w +<br>1.0%w/w | Topical cream | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting   |
| 2    | (2) (2) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4   |  |               | the combined use of an antibacterial with an antifungal ingredient.   |
| 4002 | Clahataaal Duanianata  | 0.05%w/w +                                     | Cucam         |   |
| 4002 | Clobetasol Propionate<br>USP+Neomycin<br>Sulphate<br>IP+Miconazole<br>Nitrate IP                         | 0.05%W/W +<br>0.1%W/W +<br>2.0%W/W             | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|      |  |  |               |   |
| 4004 | Beclomethasone Dipropionate +Gentamicin Sulphate IP+Miconazole Nitrate IP                                | 0.10%w/w+                                      | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|      |  |  |               |   |
|      | Clotrimazole+Beclom<br>ethasone<br>Dipropionate+Neomy<br>cine sulpahte                                   | 1.0%w/w+0.<br>025%w/w+0<br>.5%w/w              | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|      |  |  |               |   |

| . 4006 | clobetasol<br>Propionate+Neomycin<br>Sulpahte+Miconazole<br>Nitrate+Clotrimazole              | 0.05%w/w+<br>0.1%w/w+2.<br>0%w/w+1.0<br>%w/w   | topical cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|--------|---|--|---------------|---|
| 4007   | Fluocinolone<br>Acetonide+Neomycin<br>sulpahte+Clotimazole                                    | 0.01%+0.5%+1.0%  | topical cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 4010   | Ketoconazole+Tea Tree oil+Allantion+zinc Oxide+Aloe Vera+Jojoba oil+Lavander oil+Soap noodles | 2.0%w/w+1.<br>5%w/w+0.2<br>%w/w+0.5%<br>w/w+0.5%w<br>/w+1.0%w/<br>w+1.0%w/w<br>+0.25%w+1<br>00%w/w | 2             | a, Pharmacodynamically irrelevant as the combination does not give any therapeutic benefit.   |
| 4018   | Clobetasol Propionate<br>IP+Ofloxacin<br>IP+Ornidazole<br>IP+Terbutaline HCl IP               | 0.75%w/w +<br>2.00%w/w +   | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| 4025   | IP+Terbinafine HCL<br>BP+Clobetasol<br>Propionate   | 0.75%w/w +<br>2.00%w/w +<br>1.00%w/w +<br>0.05%w/w +<br>0.20%w/w +<br>0.02%w/w                     | Cream         | n, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 4027   | Sulphate  | 0.05%w/w +<br>0.5%w/w +<br>2.00%w/w +<br>2.00%w/w  | Cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |

| 4036             | Clobetasol<br>propionate+Miconazol<br>e nitrate+Neomycin<br>sulpahte+chlorocresol             | 0.05%w/w+<br>2.0%w/w+0<br>5%w/w+0.1<br>%w/w                                   |               | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to the misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
|------------------|---|---|---------------|---|
| -                | Miconazole<br>nitrate+Neomycin<br>Sulpahte+clobetasol<br>propionate+chlorocres<br>ol          | 2%w/w+0.5<br>%w/w+0.05<br>%w/w+0.1%<br>w/w                                    | Topical cream | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|                  | Beclomthasone Dipropionate+ Clotrimazole+Chlora mphenicol+Gentamyci n Sulpahte+Lignociane Hcl | 0.025%w/v+<br>1%w/v+5%<br>w/v+0.3%w/<br>v+2%w/v                               | cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
|                  | zole+Neomycin   | 0.025%w/w<br>+1.0%w/w+<br>0.25%w/w+<br>0.025%w/w                              | cream         | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| ]<br>]<br>[3     | IP+Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Methyl Paraben IP+Propyl               | 1.0%w/w +<br>0.025%w/w<br>+ 3500 units<br>per<br>g+0.15%w/<br>w +<br>0.08%w/w | Cream         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |
| I<br>S<br>I<br>1 | Propionate<br>USP+Neomycin  | 0.05% w/w<br>+ 0.5%w/w<br>+ 2.0%w/w<br>+ 0.10%w/w                             | Ointment      | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.   |

| 410  | l Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Tolnaftate USP+Iodochlorhydrox yquinoline IP+Chlorocresol IP  | 0.25mg+0.5<br>mg+15mg+1<br>5mg+1mg                               | Ointment       | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid, iodochlorohydroxyquinone in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|---|--|----------------|---|
| 4104 | Betamethasone Di-   | 0.05% w/w  | Topical Cream  | a,  |
| 4100 | Propionate eq. to Betamethasone BP+Gentamycin Sulphate eq. to Gentamycin BP+Miconazole Nitrate eq. to Miconazole BP   | 0.03% w/w<br>+ 0.1% w/w<br>+ 2% w/w                              | Topical Clean  | Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                              |
| 7.   | L   |  | m 1 12         |   |
| 4107 | Betamethasone Di-<br>Propionate eq. to<br>Betamethasone<br>BP+Gentamycin<br>Sulphate eq. to<br>Gentamycin BP+Zinc<br>Sulphate<br>IP+Clotrimazole<br>IP+Chlorocresol<br>IP(As preservative)  | 0.05% w/w<br>+ 0.1%w/w<br>+ 2.5% w/w<br>+ 1.0% w/w<br>+ 0.1% w/w | Topical Lotion | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                           |
|      |   |  |                |   |
|      |   |  |                |   |
| 4121 | Clobetasole<br>Propionate<br>USP+Clotrimazole<br>IP+Neomycin<br>Sulphate IP   | 0.005% w/v<br>+ 2.0% w/v<br>+ 3500<br>units/ml                   | Suspension     | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                             |
|      | Propionate<br>USP+Clotrimazole<br>IP+Neomycin<br>Sulphate IP  | + 2.0% w/v<br>+ 3500<br>units/ml                                 |                | Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                              |
|      | Propionate USP+Clotrimazole IP+Neomycin Sulphate IP  Benfotiamine+Vitami n A Acetate IP+Riboflavin IP+Pyridoxine Hcl IP+Cyanocobalamin IP+Ascorbic Acid IP+Vitamin D3 IP+Vitamin E Acetate IP+Folic acid IP+Nicotinamide IP+Calcium Pantotenate IP+Biotin | + 2.0% w/v<br>+ 3500   | Tablets        | Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting  |

| 41   | 43 Clobetasol Propionat<br>BP+Neomycin<br>Sulphate<br>IP+Clotrimazole IP          | 0.05%w/w+<br>0.50%w/w+<br>1%w/w   |                     | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|---|---|---------------------|---|
| 415  | Paracetamol IP+Phenyephrine Hydrochloride IP+Caffeine (anhydrous) IP              | 500mg+2.5<br>mg+30mg  | Uncoated<br>Tablets | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 416  | Paracetamol<br>IP+Caffeine<br>IP+Chlorpheniramine<br>Maleate IP                   | g+2mg   | Uncoated tablets    | a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of paracetamol. 2. Caffeine causes stimulation whereas, Chlorpheniramine causes sedation.   |
| 416  | 2 Paracetamol<br>IP+Promethazine<br>Hydrochloride IP                              | 250mg+2.5<br>mg   | Suspension          | <ul><li>a,</li><li>1. Pharmacodynamically irrelevant.</li><li>2. Both ingredients have different indications.</li></ul>   |
| 4169 | IP+Naphazoline<br>Hydrochloride<br>BP+Menthol<br>IP+Camphor<br>IP66+Sodium methyl | 0.050%w/v<br>+3% w/v +<br>3% w/v +<br>0.0025%w/v<br>+ 0.0025w/v<br>+<br>0.023%w/v | Eye Drops           | a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility   |
|      | dipropionate IP+Clotrimazole  | 0.025%w/v   F<br>+ 1%w/v +<br>2%w/v +<br>5%w/v                                    | Ear Drops           | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|      | acetate IP+Atropine 1   | ).5%w/v + E<br>%w/v +<br>).5%w/v  | ye Drops            | a, Pharmacodynamically irrelevant- Indication of both ingredients are different.  |

| 4177           | Codeine phosphate<br>IP+Chlorpheniramine<br>Maleate IP   | 10mg+4mg                                   | Syrup               | 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4. There is also a risk of abuse potential.   |
|----------------|--|--|---------------------|---|
| 4179           | Bromhexine<br>Hydrochloride<br>IP+Dextromethorphan<br>Hydrobromide IP  | 4mg+5mg                                    | Syrup               | a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.  |
|                | e  | + 2  |                     |   |
| 4182           | Paracetamol IP+DL-<br>Methionine BP  | 325mg+50m<br>g                             | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.  |
| 4204           | Salbutamol(as<br>Salbutamol Sulphate<br>IP)+Hydroxyethyltheo<br>phylline IP<br>85(Etofylline)+Bromh<br>exine Hydrochloride<br>IP | 2mg+200mg<br>+8mg                          | Uncoated<br>Tablets | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| 4207           | Paracetamol IP+DL-<br>Methionine BP  | 125mg+12.5<br>mg                           | Suspension          | a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated.  |
| 4213           | Chloramphenicol IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine Hydrochloride IP                                    | 5%w/v +<br>0.025%w/v<br>+ 1%w/w +<br>2%w/v | Ear Drops           | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 1554VILOS. 104 | Salbutamol<br>IP+Etofyline+<br>Bromhexine HCI IP   | 2mg+200mg<br>+8mg                          | Uncoated<br>Tablets | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| 2.2            | 25.50  | 10mg+2mg+<br>4mg                           | Uncoated<br>Tablets | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |

| 422  | 8 Guaifenesin<br>IP+Bromhexine<br>Hydrochloride<br>IP+Phenylephrine<br>Hydrochloride<br>IP+Chlopheniramine<br>Maleate<br>IP+Paracetamol IP   | 100mg+8mg<br>+5mg+2mg+<br>325mg                          |          | a, Pharmacodynamically irrelevant- 1. Guaiphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. paracetamol: as cough and cold not allows accompanied by fever, addition of paracetamol express the consumers to the hepatotoxic effect of antipyretic unnecessarily 4. All ingredients have different therapeutic indications. |
|------|--|--|----------|--|
| 423  | Menthol<br>IP+Anesthetic Ether<br>IP   | 0.1% w/v +<br>1% v/v                                     | Spirit   | a, Pharmacodynamically irrelevant-  1. No published literature supporting the use of combination.  |
| 424  | 2 Ferric ammonium<br>Citrate IP+L-Lysine<br>Hydrochloride<br>USP+Niacinamide<br>IP+D-Panthenol<br>IP+Pyridoxine<br>Hydrochloride<br>IP+Folic Acid<br>IP+Cyanocobalamine<br>IP+Elemental Zinc | 150mg+50m<br>g+45mg+5m<br>g+1.5mg+1<br>mg+7.5mg+<br>10mg |          | a, • Overdose of vitamin B12   |
| 4244 | Dextrometharphan<br>Hydrobromide<br>IP+Chlopheniramine<br>Maleate<br>IP+Ammonium<br>Chloride IP+Sodium<br>Citrate IP+Menthol IP  | 10mg+4mg+<br>240mg+240<br>mg+1.25mg                      | Syrup    | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| 4256 | Clobetasol+Neomycin<br>+Clotrimazole   | 0.05%w/w +<br>0.50%w/w +<br>1%w/w                        | Cream    | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |
| 4262 | dipropionate<br>IP+Miconazole  | 0.025%w/w<br>+ 2%w/w +<br>0.5%w/w +<br>0.250%w/w         | Ointment | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.  |

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| 42   | 64 Clobetasole Propionate BP+Neomycin sulphate IP+Miconazole Nitrate IP+Chlorocresol (As Preservatives) IP Chlorocresol (as preservative) IP | 0.05%w/w<br>0.5%w/w +<br>2%w/w +<br>0.1%w/w |                     | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.              |
|------|--|---|---------------------|--|
| 426  | Bromhexine<br>hydrochloride<br>IP+Guaifenesin<br>IP+Phenylephrine<br>hydrochloride<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol IP    | 8mg+100mg<br>+5mg+2mg-<br>325mg             |                     | a, Pharmacodynamically irrelevant- 1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic. |
| 427  | Ergotamine Tartrate<br>IP+Belladona dry<br>extract IP+Caffeine<br>(anhydrous)<br>IP+Paracetamol IP   | 1mg+10mg+<br>100mg+250<br>mg                | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Belladona dry extract not indicated for migraine. 2. Dose of paracetamol is subtherapeutic.  |
| 4275 | Dextromethorphan<br>hydrobromide<br>IP+Chlorpheniramine<br>Maleate IP  | 10mg+4mg                                    | Syrup               | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 4277 | Phenytoin<br>IP+Phenobarbitone<br>sodium IP  | 100mg+50m<br>g                              | Uncoated<br>Tablets | a, Pharmacodynamically irrelevant.  1. Phenobarbital will decrease the level or effect of phenytoin by affecting hepatic enzyme CYP2C9/10 metabolism. Significant interaction possible.  2. Phenobarbital decreases levels of phenytoin by increasing metabolism.  3. Phenobarbital may occasionally not change or even increase (via competitive inhibition) phenytoin levels.  http://reference.medscape.com/drug-interactionchecker.  |
|      |  |   | · ,×                |  |
|      | Imipramine<br>hydrochloride<br>IP+Diazepam IP  |   | Film Coated Fablets | a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction.  |

| 4296 | Nimesulide<br>BP+Serratiopeptidase<br>(enteric<br>coated)(30,000<br>serratiopeptidase<br>units)<br>(30,000<br>serratiopeptidase<br>units) | 100mg+15m<br>g                     | Film Coated<br>Tablets | a, 1. Safety concern with nimesulide 2. No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration.  Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795–796.  |
|------|---|------------------------------------|------------------------|---|
| 4299 | Gliclazide<br>IP+Metformin HCL<br>IP  | 40mg+400m<br>g                     | Uncoated<br>Tablets    | a,<br>Sub-therapeutic dose of metformin.  |
| 4307 | Clotrimazole<br>IP+Neomycin<br>Sulphate IP eqvt. To<br>Neomycin+Beclometh<br>asone dipropionate IP  | 1%w/w +<br>0.5% w/w +<br>0.025%w/w | Cream                  | a, Pharmacodynamically irrelevant- 1. Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 4317 | Paracetamol<br>IP+Ambroxol HCL<br>IP+Phenylephrine<br>HCL<br>IP+Chlorpheniramine<br>Maleate IP  | 250mg+15m<br>g+5mg+2mg             | Syrup                  | a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Potential for drug-drug interaction.  |
| 4320 | Paracetamol IP+ Ambroxol Hydrochloride IP+ Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate  | 125mg+7.5<br>mg+2.5mg+<br>lmg      | Drops                  | a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.   |
| 4322 | Paracetamol IP+Ambroxol Hydrochloride IP+ Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate   | 500mg+30m<br>g+10mg+2m<br>g        |                        | a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.   |
| 4344 | Dextromethorphan<br>Hydrobromide<br>IP+Chlorpheniramine<br>Maleate<br>IP+Pheylephrine<br>Hydrochloride<br>IP+Paracetamol IP               | 5mg+1.5mg<br>+2.5mg170<br>mg       | Oral                   | a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.   |
| 4345 | Oflaxacin IP+<br>Ornidazole IP  | 50mg+125m<br>g                     | Suspension             | a, 1. Both ingredients of the FDC have different therapeutic indications 2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.  |
|      | Albuterol Sulphate IP<br>eq. to Albuterol+<br>Etofylline IP+<br>Bromhexine HCl IP+<br>Menthol IP  | 1mg+<br>50mg+<br>4mg+1mg           | Liquid                 | <ul><li>a,</li><li>1. Etofylline is a narrow therapeutic indexed drug and requires close monitoring.</li><li>2. Patients may need only one ingredient and use of FDC may lead to misuse.</li></ul>  |

| 435 | B<br>T                          |   | 2mg+8mg+1   00mg  | Hard Gelatin<br>Capsules | a, 1. Theophylline is a narrow therapeutic indexed drug and requires close monitoring. 2. Patients may need only one ingredient and use of FDC may lead to misuse.  |
|-----|---------------------------------|---|---|--------------------------|---|
| 435 | 59 C<br>Pr<br>U<br>S<br>G<br>ol | lobetasole<br>ropionate<br>ISP+Gentamycin<br>ulphate IP eq. to  | 0.05% w/vw<br>+ 0.10%<br>w/w +<br>2.00% w/w<br>+ 0.10%<br>w/w | Cream                    | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 433 | S<br>II<br>Ii<br>(              | salbutamol (As<br>salbutamol Sulphate<br>P)+<br>Hydroxyethyltheophyl<br>ine IP 85'<br>Etofylline)+<br>Bromhexine HCl IP | 1mg+50mg+<br>4mg  | Syrup                    | a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.  |
| 44  | I<br>I<br>N                     | Phenylephrine HCl<br>P+Paracetamol<br>P+Chlorpheniramine<br>Maleate IP+Caffeine<br>Anhydrous IP                         | 5mg+325mg<br>+2mg+30mg  | Uncoated<br>Tablets      | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 44  | 1                               | Paracetamol<br>Ip+Ambroxol Hcl<br>IP+Phenylephrine Hcl<br>IP+Chlorpheniramine<br>Maleate IP                             | 125mg+15m<br>g+5mg+2mg  |                          | a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.   |
| 44  |                                 | Phenylephrine HCl<br>IP+Paracetamol<br>IP+Chlorpheniramine<br>Maleate IP+Caffeine<br>Anhydrous IP                       | 5mg+325mg<br>+2mg+15mg  |                          | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.   |
| 44  |                                 | Codeine Phosphate<br>IP+Chlorpheniramine<br>MaleateIP   | 10mg+4mg  | Oral Liquid              | Dosing schedule is incompatible.     Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.     Centrally acting anti-tussive not to be combined with anti-histaminic drug.     There is also a risk of abuse potential.  |
| 4   | 443                             | Levocetirizine HcIIP+Phenylephrine HcI IP+Paracetamol IP+Caffeine (Anhydrous)   | 2.5mg+10m<br>g+325mg+3<br>0mg                                 |                          | a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule.   |
| 4   | 448                             | Ofloxacin<br>IP+Ornidazole IP   | 50mg+125n<br>g  | n Syrup                  | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2. Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>   |

| Lavocatirizina UCI   | 0.8mg+15m  | Oral  | a,  |
|--|--|---|---|
| IP+Ambroxol Hcl<br>IP+Guaifenesin  | g+50mg+5m<br>g   |   | Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2. Pharmacokinetically irrelevant-different dosing shedule.   |
|  | +1.25mg+60   |   | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4. Potential for drug-drug interaction.   |
| Paracetamol<br>IP+Propyphenazone<br>IP+Caffeine<br>(Anhydrous) IP                                      | 300mg+150<br>mg+50mg   | Uncoated<br>Tablets   | a, Pharmacodynamically irrelevant- 1. Paracetamol dose is subtherapeutic. 2. Suceptibility of adverse drug reaction is very high. 3. Misuse potential.  |
| Chlorpheniramine<br>Maleate<br>IP+Phenylephrine Hcl<br>IP+Guaifenesin<br>IP+Dextromethorphan<br>Hcl IP | 4mg+5mg+1<br>00mg+10mg   | Liquid Orals  | a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Centrally acting anti-tussive not to be combined with anti-histaminic drug.  |
| Phenytoin Sodium<br>IP+Phenobarbitone IP   | 100mg+30m<br>g   | Uncoated<br>tablets   | a, Pharmacodynamically irrelevant.  1. Phenobarbital will decrease the level or effect of phenytoin by affecting hepatic enzyme CYP2C9/10 metabolism. Significant interaction possible.  2. Phenobarbital decreases levels of phenytoin by increasing metabolism.  3. Phenobarbital may occasionally not change or even increase (via competitive inhibition) phenytoin levels. |
| , s  |  |   | http://reference.medscape.com/drug-interactionchecker.  |
| 4<br>9   |  |   |   |
|  |  | Syrup   | a, Pharmacodynamically irrelevant- • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.  |
| Paracetamol IP+Caffeine (Anhydrous) IP+Chlorpheniramine Maleate IP                                     | 325mg+20m<br>g+2mg   | Uncoated tablets  | a, Pharmacodynamically irrelevant- 1. Paracetamol dose is subtherapeutic. 2. Potential for drug-drug interaction.   |
| Dried Alumnium<br>Hydroxide Gel<br>IP+Propantheline<br>Bromide<br>IP+Diazepam IP                       | 100mg+15m<br>g+2mg   | Capsules  | a, Pharmacodynamically irrelevant- 1. No published literature supporting the FDC. 2. In present scenario Propanthaline has safety concerns. 3. Use of diazepam is irrational.   |
|  | IP+Guaifenesin IP+Phenylephrine Hcl IP  Paracetamol IP+Phenylephrine Hcl IP+Levocetirizine HCl IP+Sodium Citrate IP  Paracetamol IP+Propyphenazone IP+Caffeine (Anhydrous) IP  Chlorpheniramine Maleate IP+Phenylephrine Hcl IP+Guaifenesin IP+Dextromethorphan Hcl IP  Phenytoin Sodium IP+Phenobarbitone IP  Propacetamol IP-Caffeine (Anhydrous) IP+Chlorpheniramine Maleate IP  Dried Alumnium Hydroxide Gel IP+Propantheline Bromide | IP+Ambroxol Hcl IP+Guaifenesin IP+Phenylephrine Hcl IP  Paracetamol IP+Phenylephrine Hcl IP+Sodium Citrate IP  Paracetamol IP+Sodium Citrate IP  Paracetamol IP+Propyphenazone IP+Caffeine (Anhydrous) IP  Chlorpheniramine Maleate IP+Dextromethorphan Hcl IP  Phenytoin Sodium IP+Phenobarbitone IP  Indicate | IP+Ambroxol Hcl   IP+Guaifenesin   IP+Phenylephrine Hcl   IP  |

|      | Bromhexine Hcl<br>IP+PhenylephrineHcl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol IP                    | 8mg+5mg+2<br>mg+ 325mg                           | Tablets                | a, Pharmacodynamically irrelevant- 1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic.                               |
|------|---|--|------------------------|--|
| 4571 | Bromhexine Hcl<br>IP+PhenylephrineHcl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol IP                    | 4mg+2.5mg<br>+2mg+125m<br>g                      | Suyrup                 | a, Pharmacodynamically irrelevant- 1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Potential misuse in FDC formulation is likely to be hepatotoxic.  |
| 4573 | Beclomethasone<br>Dipropionate+Clotrim<br>azole+Gentamicin<br>Sulphate+Iodo-<br>Chlorhydroxyquinolin<br>e       | 0.025% w/w<br>+ 1% w/w +<br>0.1% w/w +<br>1% w/w | Cream                  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.  2. Combining antibiotic, antifungal, steroid, iodochlorohydroxyquinone in the present FDC is liable to be misuse and emergence of resistance and adverse effects.  3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.                |
| 4590 | Paracetamol<br>IP+Phenylephrine Hcl<br>IP+Chlorpheniramine<br>maleate IP+Caffeine<br>(anhydrous ) IP            | 325mg+10m<br>g+2mg+30m<br>g                      | Uncoated<br>Tablets    | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 4591 | Paracetamol<br>IP+PhenylephrineHcl<br>IP+Caffeine<br>(anhydrous ) IP  | 325mg+10m<br>g+32mg                              | Tablets                | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.  |
| 4592 | Bromhexine Hcl<br>IP+Phenylephrine Hcl<br>IP+Guaifenesin<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol IP | 8mg+5mg+1<br>00mg+2mg+<br>325mg                  | Film Coated<br>Tablets | a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine: H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility 4. Misuse of paracetamol. |

|      | Propionate IP eq. to<br>Betamethasone+Genta<br>mycin Sulphate IP eq.<br>to<br>Gentamycin+Miconaz<br>ole Nitrate IP                   |                                    | External<br>Preparation  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
|------|--|------------------------------------|--------------------------|---|
| 4643 | Ofloxacin<br>IP+Ornidazole IP  | 50mg+125m<br>g                     | Oral suspension          | <ul> <li>a,</li> <li>1. Both ingredients of the FDC have different therapeutic indications</li> <li>2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones.</li> <li>3. Safety concerns in paediatric patients.</li> </ul>  |
|      | Glibenclamide<br>IP+Metformin Hcl IP<br>(In sustained release<br>form)+ Pioglitazone<br>Hcl IP eq. to<br>Pioglitazone                | 5mg+500mg<br>+15mg                 |                          | <ul><li>a,</li><li>1. There is no published literature supporting this FDC.</li><li>2. The Pioglitazone has safety concerns.</li></ul>  |
| 4651 | Telmisartan +<br>Metformin   | 40 mg +<br>1000 mg                 | Tablet                   | a, Pharmacodynamically irrelevant as no study supports this combination.  |
| 4873 | Allantoin BP+<br>Vitamin-E Acetate+<br>Tea tree oil  | 0.25%/w/w+<br>0.25w/w+0.<br>50%w/w | Medicated Soap           | a, 1. This FDC has no therapeutic value.  |
|      |  | *                                  |                          |   |
| 4874 | Allantoin BP+Vitamin-<br>E Acetate+Tea tree<br>oil+Titanium Dioxide<br>IP  | 0.25%w/w+                          | Medicated Soap           | a, 1. This FDC has no therapeutic value.  |
| 4906 | Ammonium<br>Citrate+Vitamin B<br>12+Folic Acid+Zinc<br>Sulphate Monohydrate  | 160mg+7.5<br>mg+0.5mg+<br>20.61mg  | Soft Gelatin<br>Capsules | a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. ingredients susceptible to pharmaceutically incompatibility   |
| 4981 | methylcobalamin+ folic acid+ pyridoxine HCL+ inositol + alpha lipoic acid+ chromium+ vanadyl sulphate+ seleniuos acid+ zinc sulphate |                                    | hard gelatin<br>capsule  | a, 1. Over dose of metylcobalamin 2. Multiple ingredient susceptible to pharmaceutically incompatibility and susceptible dose   |
| 4988 | levothyroxine<br>Sodium+<br>pyridoxineHCL+<br>nicotinamide   | 25 mg+ 1<br>mg+ 25 mg              | tablets                  | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.   |

| 513:    | beta carotene + nicotinamide + pyridoxine hydrochloride+ cholecalciferol + folic acid+ cyanocobalamin +light magnesium oxide+ zinc sulphate+ manganese sulphate+ copper sulphate+ chromium picolinate+ selenious acid + sodium molybdenum+ alpha lipoic acid | 30 mg+ 1.5<br>mg+ 1000<br>IU+ 1000<br>mcg+ 5 mcg<br>+ 100 mg+<br>22.5 mg +<br>22.5 mg+ 2<br>mg + .2 mg_<br>.055 mg+<br>.05 mg + .01<br>mg + 100<br>mg |         | a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility 3.Dose of Folic acid & nicotinamide sub-therapeutic. |
|---------|--|---|---------|--|
| 5158    | pyridoxine HCL+ niacinamide + thiamine HCL+ calcium pantothenate+ ascorbic acid+ methionine+   | 9mg+ 22.5<br>mg+ 2.75<br>mg+ 2.5<br>mg+ 37.5<br>mg+ 2 mg  | syrup   | a, 1. exceeds therapeutic dose of pyridoxine. 2. ingredients susceptible to pharmaceutically incompatibility 3. dose selection is not accurate   |
| 5275    | Biotin USP+Vitamin<br>B6 IP+Niacinamide<br>IP+Folic Acid<br>IP+Cyanocobalamin<br>IP+Calcium<br>Pantothenate IP+Zinc<br>Sulphate IP+Lactic<br>Acid Bacilli  | 100mcg+1.5<br>mg+45mg+5<br>mcg+20mcg<br>+50mg+100<br>Lacs spores  |         | a, Pharmacodynamically irrelevant-  1. Therapeutic area not clear  2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility  |
| 5617    | Calcium Orotate+Zinc<br>Sulfate+Folic<br>Acid+Cyanocobalami<br>n   | mg+50mcg+   | Tablets | a, Pharmacodynamically irrelevant- 1.Each ingredients have different indication. 2.This combination does not follow the concept and purpose of FDC 3. Sub-therapeutic dose of Vit-B12  |
| 1000000 | Hydrolysate+Iron<br>Choline<br>Citrate+Thiamine  | 500mg+150<br>mg+0.5mg+<br>0.5mg+0.25<br>mg+25mcg+<br>0.5mcg   | Syrup   | a, sub-therapeutic dose of vitamin B12   |
|         | eq. to Nitrogen+Iron<br>Choline Citrate eq. to<br>elemental Iron+Zinc<br>Sulphate  | 10mg+20.0<br>mg+15mg+7<br>.5mg+0.5mg<br>+0.5mg+0.2<br>5mg+0.25m<br>cg   | Syrup   | a, sub-therapeutic dose of vitamin B12   |

| 5837 | Thyroid IP'85<br>+Thiamine<br>Mononitrate IP+<br>Riboflavin IP+<br>Pyridoxine HCl IP+<br>Calcium Pantothenate<br>IP+ Tocopheryl<br>Acetate  | 15mg+<br>2.5mg+<br>2.5mg 1mg+<br>5mg+<br>10mg+25mg  | Film Coated<br>Tablets            | a, No clinical studies found supporting the use of this combination   |
|------|---|---|-----------------------------------|---|
| 5958 | IP+Nicotinamide IP Ascorbic Acid IP+ Manadione Sodium Bisulphate+ Rutin NF, XI + Dibasic Calcium Phosphate IP + Adrenochrome Mono Semicarbazone   | g+ 50mg+<br>132mg+0.5   | Uncoated<br>Tablets               | a, Pharmacodynamically irrelevant-     1. Therapeutic area not clear     2. Multiple ingredients with diverse pharmacological profile.  |
| 5973 | Lactic Acid Bacillus<br>+ Folic Acid IP+<br>Cyanocobalamin IP   | 180 Million<br>+1500 mcg<br>+15mcg  | Uncoated<br>Dispersible<br>tablet | a, 1. Pharmacodynamically irrelevant. 2. Role of lactic acid in this combination is not clear   |
| 6189 | Phenylephrine Hcl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol<br>IP+Bromhexine Hcl<br>IP  | 2.5mg+1.0m<br>g+125mg+4<br>mg   | Syrup                             | a, Pharmacodynamically irrelevant.  1.Mucolytic increases mucus secretion and antihistaminic with anticholinergic properties dry up secretions.  2.Dosing schedule is incompatible.   |
| 6191 | Phenylephrine Hcl<br>IP+Chlorpheniramine<br>Maleate<br>IP+Paracetamol<br>IP+Bromhexine Hcl<br>IP+Caffeine<br>(anhydrous) IP   | 5mg+2mg+5<br>00mg+8mg+<br>15mg  |                                   | a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.  |
| 6198 | Clotrimazole IP+Beclomethasone Dipropionate IP+Lignocaine HCl IP+Ofloxacin IP+Acitic Acid IP+(Preservatives) Sodium Methyl Paraben IP+Propyl Paraben IP   | 1% w/v +<br>0.025% w/v<br>+ 2% w/v +<br>0.3% w/v +<br>2.0% w/v +<br>0.1% w/v +<br>0.02% w/v | Ear Drops                         | a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic, antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. |
| 6211 | Thiamine Mononitrate IP+Riboflavin Sodium Phosphate eq. to Riboflavin (Vitamin B2)+ Nacinamide IP+ Pyridoxine Hcl IP+ Vitamin A concentrate (Oily form) (As Palmitate)+ Cholecalciferol + Ascorbic Acid IP + D- Panthenol IP +Tocopheryl Acetate IP | +10mg<br>+1.0mg<br>+3000 IU+<br>400 IU+<br>40mg<br>+3.0mg +5.0<br>IU                        | Oral                              | a, Pharmacodynamically irrelevant- 1 Multiple ingredient of diverse group 2 Sub therapeutic combinations 3 Pharmacodynamic role is not clear  |

| 5214 Zinc Sulphate IP eq. | 25mg+5.7m  | Oral | a,  |
|---------------------------|------------|------|---|
| to elemental              | g+1600     |      | Pharmacodynamically irrelevant-                               |
| Zinc+Vitamin A            | IU+200     |      | 1. Therapeutic area not clear                                 |
| Palimate IP+Vitamin       | IU+1.5mg+1 |      | 2. Combination irrational.                                    |
| D3 IP+Vitamin B1          | .5mg+1.0mg |      | 3. Element are of different class hence have diverse activity |
| IP+Vitamin B2             | +15mg      |      |   |
| IP+Vitamin B6             |            | 8 4  |   |
| IP+Niacinamide IP         |            |      |   |
|                           |            |      |   |

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## **BRIEF DETAILS ABOUT THE EXPERT COMMITTEE**

**Prof.** (Dr.) Chandrakant Kokate is a Vice-Chancellor, KLE UNIVERSITY, BELGAUM. Karnataka. He is also serving in Chairman-Expert Panel Committee for approval of Fixed Dose Combinations, (FDC's) Ministry of Health and also a Chairman/ Member of UGC Committees for Universities. He is also a scientific coordinator in EDUCON, SAKAAL Group, Pune and National Adviser in Society of Pharmacognosy. Dr Kokate has completed his Ph.D degree in 1972 followed by Post Doctoral Research at Bundesanstalt Fuer Fett Forschung, Germany. He was also a Visiting Scientist in Germany (1986) on invitation by DAAD.



Prof. C. K. Kokate (Chairman)

He held numerous of prestigious and influential positions, notably President of Pharmacy Council of India, Indian Pharmaceutical Association, and Indian Society of Pharmacognosy. He also served as executive Committee Member of All India Council for Technical Education (AICTE) and Chairman of All Indian Board of Pharmacy, AICTE. He was also a member of UGC Standing Committee for Projection of Indian Higher Education Abroad (PIHEAD), Review and Plan Grant Committees and National Board of Accreditation of AICTE and Task Force of Department of Biotechnology, Government of India. He has 31 national and international awards and fellowships. He has guided 17 students for Ph.D programme and 40 students for PG in Pharmacy. He is also credited to authored Seven Books in Pharmacognosy / Pharmacy and published about 115 research papers in National and International Journals.

Dr. C. L. Kaul retired as a founder Director of National Institute of Pharmaceutical Education and Research (NIPER). He had his earlier education in Punjab and graduated in pharmacy from the university of Gujarat. He proceeded to U.K. for his post Graduate studies in Pharmacology at the Chelsea College of Science and Technology, University of London and then moved to University of Glasgow from where he was awarded the Doctorate degree in Pharmacology in1964. Apart from carrying out research at Ciba and Boots in India, he has worked at several research centers abroad in U, K. and Switzerland.



Prof. C.L. Kaul (Member)

His work spanning over a period of more than 4 decades has centered around development and pre-clinical studies of new drugs, stability studies, bioavailability, pharmaceutical formulations, quality control and chemical development. Dr. kaul is associated with many universities and pharmacy institutions and is on the governing body of many institutes. Dr. kaul was the President of Indian Pharmaceutical Association, Editor Indian Journal of Pharmaceutical sciences. The Indian Pharmaceutical association conferred on him the Eminent Pharmacist Award 2003. Dr. Kaul has travelled extensively, has published 150 papers in peered review journals, 20 patents and 4 book chapters.

Dr. C. D. Tripathi is a Director-Professor and Head Department of Pharmacology and also Academic Registrar at Vardhman Mahavir Medical College and Safdarjung Hospital New Delhi. He has completed his MBBS degree and M.D. in Pharmacology from B.R.D. Medical College, Gorakhpur. He is the member of Sub-committee for preparing "Guidelines for Clinical Evaluation Of Drugs, Devices, Diagnostics and Vaccines and also held the post of Co-investigator for ICMR project on Monitoring of Adverse Effects of Drugs Editor, DSPRUD Medical Newsletter. He is also the Chairman of Ethical Committee of Central Insecticides Laboratory, Ministry of Agriculture, Govt. of India and Therapeutic Use Exemption Committee, NADA.



Dr. C. D. Tripathi (Member)

He is a life member of Indian Pharmacological Society Member Institutional Ethical committee of VMMC and SJ Hospital Associate Editor of Indian Journal of Pharmacology. Dr Tripathi is an awardee of Palepu Perindevi Surya kumar award and O.D. Gulati awards. Around nine projects are undergoing in his supervision. He is credited for 35 publications and 3 books.

**Dr. Bikash Medhi** is Additional Professor& Joint Medical Superintendent in PGIMER, Chandigarh. He is also Coordinate the Pharmacovigilance Centre and Regional Resource Centre for Northern Region for Training and Technical Support at PGIMER, Chandigarh. He completed his MBBS degree from Assam Medical College (AMC) and M.D in Pharmacology from A.I.I.M.S, New Delhi. Dr. Medhi has garnered with numerous of prestigious awards, few of them are Dr. D N Prasad memorial award, Bharat Joti Award, Dr V K Bhargava Award etc. He was elected as Fellow of International Medical Sciences Academy (FIMSA) and also a Member of National Medical Academy (MAMS).



Dr. Bikash Medhi (Member)

He is a member of Investigational New Drug committee in Ministry of Health. He is a secretary of Clinical Pharmacology of Indian Pharmacology Society. Selected as Core panel of expert for Task Force to frame guidelines for submission of dossiers or proposals for regulation of biotech products (R& D product), Govt of India. Dr Medhi elected for National advisory board member in JK science, Journal of Medical Education and research and for editorial Board member of World Journal of Gastroenterology, Journal of Neuroscience and Behavioral Health. He is also a trained GLP as well as GCP inspector. Dr Medhi contributed a lot in research also. He has more than 200 national and international publications and author of two books. He headed more than 15 extramural projects and guided about 75 students including DM/MCh/PhD/MD/MS/M,Sc.

Prof. Sanjay Singh did his graduation, post-graduation and doctoral degree in Pharmacy from Dept. of Pharmaceutics, Institute of Technology, Banaras Hindu University in the year 1985, 1987 and 1992, respectively. He has been awarded Best Research Paper by Indian Drug Manufacturer Association in 50<sup>th</sup> annual meeting, Mumbai. He has authored/co-authored for 102 research and review papers in peer-reviewed international and national journals, presented 83 papers in various national and international conferences and has also published three chapters in book. He is also the deputy coordinator of the Special Assistance Program, University Grants Commission, New Delhi awarded to Dept. of Pharmaceutics, IIT, BHU.



Prof. Sanjay Singh (Member)

Prof. Singh is also a member of various bodies like AICTE, PCI and UPTU which grant approval for running of pharmacy courses in different colleges in India. He is a member of the Publication and Information Technology Committee of Indian Pharmacopoeial Commission and also the working group member of the PvPI, Ministry of Health and Family Welfare, Govt. of India. Recently, he has also honored with membership of NASI, India. He has supervised 7 Ph.D. and 30 M. Pharm. students of Pharmaceutics and Pharmacology specialization and 1 M.D. and presently 1 P.D.F, 7 Ph. D. and 10 M. Pharm. students are registered under his guidance. His current area of research focused on design and conducts pharmacological and toxicological evaluation of nanoparticulate formulations of various drugs with an objective to reduce their dose and cost of therapy, improve patient compliance and enhances their therapeutic efficacy

**Dr. Sanjeev Sinha,** Professor, Department of Medicine, All India Institute of Medical Sciences, New Delhi is an expert physician. He has contributed a lot in research. He has more than 50 national and international research articles in peer reviewed journals. Currently he has involved in more than 10 clinical studies. He is member of Editorial board of "Cases Journal" and Association of Physician of India, Member of Indiaclen, Member of Medical Board Antarctica Expedition, Govt. of India, Goa and Member of National Academy of Medical Sciences (MNAMS).



Dr. Sanjeev Sinha (Member)

Prof. R. K. Khar is the Principal of B. S. Anangpuria Inst. of Pharmacy, (Pt BD Sharma University of Health Sciences) Alampur, Faridabad. Prof. Roop Krishen Khar is a renowned academician and a research scientist. Dr. Khar has served in various Administrative and Academic positions for more than 35 years at Jamia Hamdard (Hamdard University) in the capacities of DEAN and HOD of Faculty of Pharmacy, Dean Students Welfare, Placement officer and Proctor of Jamia Hamdard. He was selected by Ministry of H.R.D. Govt. of India for a Ph.D. fellowship under Indo-Bulgaria cultural exchange programme during 1982-86.



Prof. Roop Krishen Khar (Co-opted Member)

Dr. Khar has received several prestigious award, few of them are University Gold Medal for standing first at B. Pharm., Awarded Motan Devi Dandiya Prize for the year 2002-2003 best paper, First prize for best poster in poster session at the 5th International Symposium of Controlled Release Society Indian Chapter on Advances in Technology and Business Potential of New Drug Delivery Systems, Awarded "Best Pharmacy Teacher of the Year 2002 by Association of Pharmacy Teachers of India, Fellow Indian Pharmaceutical Association etc. He is the Chairman of various National & International Conferences. He is the member of Fixed Dose Combination by Ministry of Health, DCGI, and Govt. of India 2015. He also sits in the recruitment Board Member Selection Committees of Universities, Regional Research Laboratories, UPSC & other Institutions. He is also examiner of pharmacy courses. Dr. Khar was elected for Research Board of Advisors of the American Biographical Institute. He has supervised 55 PhD, 85 M.Pharm. theses and published more than 255 research papers in International & National journals with cumulative impact factor of more than 378; H index of 43 and citation of 7394. He is the life member of different professional and academic bodies.

Minutes of the Meeting of Expert Committee held on 17.08.2015 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

## Members present:

- 1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India Chairman
- 2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard Member
- 3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi Member
- 4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi Member
- 5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh-Member
- 6. Dr. Sanjeev Sinha, Addl. Prof. (Medicine), AIIMS, New Delhi Member
- 7. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi Member

Dr. G. N. Singh, Drugs Controller General (India) welcomed the members of Expert Committee. He thanked all the members of the Committee for their remarkable efforts in categorization of various FDCs, applications of which were received by CDSCO for proving safety and efficacy under 18 month policy decision.

The Committee was apprised that based on the recommendations of the Committee, CDSCO has communicated all the firms regarding approval or otherwise in respect of the FDCs falling under category 'a', 'c' and 'd'. Committee was also apprised that 30 days timeline has been given to the companies for submitting their reply in respect of the FDCs falling under category 'a'. Further 4 months timeline has been assigned for submitting CT protocol in respect of FDCs falling under category 'd' which would be evaluated in consultation with SECs.

During the meeting, following issues including issues raised by IDMA in their representation were place before the Committee for deliberation:-

- 1. To provide 6 months time for submitting reply to the showcause notices issued.
- 2. To provide reasons for declaring certain FDCs as Irrational.
- 3. To give an opportunity to present their case for the FDCs declared irrational.
- 4. Not to insist for clinical trials, when product has already been consumed over years.
- 5. Not to reject FDCs on the ground that their availability leads to abuse potential.

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- Evaluators must be appropriately empowered with regulatory realties such that their assessment is scientific but balanced with current prescription practices.
  - FDCs combining ingredients, which are similar to DCG(I) approved formulations like vitamins preparations, Topical preparations etc. may be labeled as rational.
  - FDCs if seemingly doubtful, may be rationalized in view of they definitely 1/HG/not combining any obviously irrelevant blend of ingredients.
  - Not being available in any overseas market should not be a guiding criterion to determine the suitability of FDC being categorized as rational.
  - Additionally, a combination of drugs not being recommended by any worldwide scientific body, or a medical association need not form the basis of judging rationality of the FDC.
  - For antimicrobial combinations the same should be considered permitting if: (a) a particular pathogen that needs to be eliminated has a known incidence of frequent resistance; (b) a disease gas reported incidence of Multidrug Resistant (MDR) pathogens prevalent. Permitting the use of combination for such situations would, contrary to prevailing worries, eliminate the bacteria more assuredly and, in fact, avoid making them resistant. The examples of antimicrobial combinations for tuberculosis, HIV, campylobacter infections, etc. are all widely known and for such diseases it is a norm to combine antibacterial with the very
- 7. To discuss the information required from the companies in respect of FDCs which have been categorized under category 'b'.
- 8. To discuss various modalities to be followed for further examination of applications falling under category 'a' after receipt of reply to showcause notices from the firms.
- To finalize the recommendations in respect of certain FDCs as certain discrepancies have been observed among the recommendations. List of such FDCs is attached herewith for discussion and further finalization.
- 10. To decide any other issues of relevance for early disposal of proposals of such FDCs

Committee went through the representations and opined to decide on the basis of rationality, safety and efficacy and also shown its willingness to consider the methods or criteria proposed by the IDMA while ensuring the safety of patients.

Secondly, as regard to the extension of time for submitting reply to the various showcause notices issued by CDSCO, Committee opined that further time for reply is justifiable and may be given based on representation. However, Committee opined that instead of giving six months, a further period of 3 months may be given for submission of reply to the showcause notices issued as the sufficient opportunity is needed to submit proper scientific data.

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Committee was apprised that Ministry while approving the report of the Committee has suggested to seek information from industry in respect of FDCs categorized under category 'b' and to place the same before the Committee in which other experts will be associated on as required basis. Committee after detailed deliberation suggested that asking further information from the industry at this point of time for these FDCs is not required, as such as it will not serve any additional purpose. As suggested by the Ministry, Committee opined that subject experts can be invited to the meetings of Committee for detailed deliberation and further categorization of these FDCs. It was decided that the meetings can take place as per therapeutic category, if required and 2 subject experts of that therapeutic area can be invited to deliberate. The subject experts will be from the list of experts already available in Subject Expert Committees, Technical Committees or other committees, any other suitable experts from Govt. institutes as proposed by the Chairman, FDC Committee.

As it will take time to receive reply, collate and compilation of FDCs falling under category 'a' for which showcause notices have been issued by CDSCO, Committee desired that further meetings shall be conducted with subject experts with respect to FDCs falling under category 'b' so that these FDCs can be categorized appropriately. Committee opined that FDCs falling under "Medicine" therapeutic area can be discussed during next meeting and two subject experts can be invited to participate in the meeting.

As regard to the various discrepancies observed among the recommendations with respect to certain FDCs, these FDCs were examined again by the Committee and accordingly final recommendations made by the Committee are annexed herewith as Annexure A. Committee opined that CDSCO can issue letters with respect to these FDCs accordingly.

The meeting ended with the vote of thanks to the chair.

(Dr. E. L. Kaul)

(Dr. R.K. Khar)

(Dr. Bikash Medhi)

(Dr. C.D. Tipathi)

(Prof. Sanjay Singh

(Dr. Sanjeev Sinha)

(Prof. Chandrakant Kokate)

|  | List of FDCs where dis   | crepancy observed among recommendations.  |
|--|--|---|
| S.No   | 1  | Final Recommendations by Expert committee   |
| 1  | Beclomethasone + Clotrimazole + Neor   |   |
|  | 1901   | 1 8   |
|  |  | Pharmacodynamically irrelevent  |
| 2  | Calcium Orotate 740 mg + Zinc Sulpl  |   |
|  | mg + Folic acid 50 mcg+ Cyanggabala  | min 0.5 Due to subtherapeutic dose of Vit-B12   |
|  | mcg tablet   | Due to subtherapeutic dose of Vit-B12   |
| 31   | Propanolol + Clonazenom  |   |
| 4 /  | Aluminium + Magnesium + Simet  | thicone Already discussed by the earlier Committee  |
| 5 I  | Suspension per 10ml  | have discussed by the earlier Committee   |
| 3 1  | Paracetamol + Phenylephrine + Caffeine   | a,  |
|  |  | Pharmacodynamically irrelevent  |
| 6 L  | Protaverine +Clidinium + Chlordiazepox   |   |
|  |  | ide Already discussed by the earlier Committee  |
|  |  |   |
| 7 L  | evocetirizine + Phenylephrine + Ambro  | xol + a   |
|  |  |   |
| 8 A  | ginine Acid + Sodium Bicarbonat  | Pharmacodynamically irrelevent te + Already discussed by the earlier Committee  |
| AI<br>LI   | uminium Hydroxide + Magne  | sium sium   |
| 9 Ce   | (ULDXIDE Tablet  |   |
| 0.1  | 2pm cream  | wine Already discussed by the earlier Committee   |
| 0 Tai  | urine + Acetylcysteine tablet  |   |
| 1 Par  | acetamol + Dicyclomine   | b   |
|  |  | C,  |
| 2 Bec  | lomethasone + Gentamicin + Clotrimazo  | if PCM dose is 500 mg   |
|  |  |   |
| Dex  | tromethorphan + Chlorpheniramine   | Pharmacodynamically irrelevent  |
| Pher   | nylephrine   |   |
| Acec   | clofenac + Paracetamel + S.  |   |
|  | elofenac + Paracetamol + Serratiopeptida   | se Subjudice  |
| Atory  | vastatin + Metformin   |   |
| Napr   | oxen + Domperidone   | Already discussed by the earlier Committee  |
| rapi   | etamol + Phenylephrine   | Subjudice   |
| Parac  |  | + 3   |
| Parac<br>Chlor   | pheniramine + Caffeine   | Pharmacodura vi ii  |
| Parac<br>Chlor   | pheniramine + Caffeine   | Pharmacodynamically irrelevent  |
| Parac<br>Chlor<br>Flunii   | pheniramine + Caffeine<br>rizine + Paracetamol + Domperidone   | Pharmacodynamically irrelevent a,   |
| Parac<br>Chlor<br>Flunin<br>Benfo  | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin   | Pharmacodynamically irrelevent a, PK and PD irrelevant  |
| Parac<br>Chlor<br>Flunin<br>Benfo<br>Silyma  | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid   | Pharmacodynamically irrelevent a,   |
| Parac<br>Chlor<br>Flunin<br>Benfo<br>Silyma  | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b   |
| Parac<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro  | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorobeniramine   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee   |
| Parac<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro  | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c,                         |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace   | thiamine + Caffeine thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine tamol 650mg + Diclofenac 50mg   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg   |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace   | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine stamol 650mg + Diclofenac 50mg mphenicol + Dexamethasone eye drop   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg   |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace<br>Chlorar  | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine etamol 650mg + Diclofenac 50mg mphenicol + Dexamethasone eye drop cenac + Paracetamol + Trypein +   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg   |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace<br>Chlorar<br>ceclof                                      | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine etamol 650mg + Diclofenac 50mg  mphenicol + Dexamethasone eye drop  Tenac + Paracetamol + Trypsin + trypsin   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg c |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace<br>Chlorar<br>ceclof<br>hymo<br>iphent                    | pheniramine + Caffeine rizine + Paracetamol + Domperidone  thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine etamol 650mg + Diclofenac 50mg  mphenicol + Dexamethasone eye drop  tenac + Paracetamol + Trypsin + trypsin mydramine + Ammichlorido + Section   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg c |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace<br>Chlorar<br>ceclof<br>hymo<br>iphent                    | pheniramine + Caffeine rizine + Paracetamol + Domperidone  thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine etamol 650mg + Diclofenac 50mg  mphenicol + Dexamethasone eye drop  tenac + Paracetamol + Trypsin + trypsin mydramine + Ammichlorido + Section   | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg c |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace<br>Chlorar<br>ceclof<br>hymo<br>iphent<br>trate<br>rup/su | pheniramine + Caffeine rizine + Paracetamol + Domperidone thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine etamol 650mg + Diclofenac 50mg mphenicol + Dexamethasone eye drop fenac + Paracetamol + Trypsin + trypsin nydramine + Ammichloride + Sodium + Terpine Hydrate + Menthol spension  | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg c |
| Parace<br>Chlor<br>Flunin<br>Benfo<br>Silyma<br>Fapent<br>Dextro<br>Parace<br>Chlorar<br>ceclof<br>hymo<br>iphent<br>trate<br>rup/su | pheniramine + Caffeine rizine + Paracetamol + Domperidone  thiamine + Metformin arin + Urosochlorodoxy acid tadol + Paracetamol methorpahn + Chlorpheniramine etamol 650mg + Diclofenac 50mg  mphenicol + Dexamethasone eye drop  ienac + Paracetamol + Trypsin + trypsin nydramine + Ammichloride + Sodium + Terpine Hydrate + Menthol spension  thaosne + Miconazole + Nearoni thaosne + Miconazole + Nearoni thaosne + Miconazole + Nearoni | Pharmacodynamically irrelevent a, PK and PD irrelevant Already discussed by the earlier Committee b Already discussed by the earlier Committee c c, if PCM dose is 325 mg c |

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| 2  | 8 Calcium Citrate 1000mg + Element<br>Magnesium 100mg (as magnesium hydrate)<br>Elemental Zinc 4mg (as zinc Sulphate<br>+vitamin D3 200 IU | +  |
|----|--|--|
| 29 | Paracetamol + Chlorpheniramine   | b  |
| 30 | Amlodipine + Hydrochlorothiazide + Losartan  | d  |
| 31 | Mometasone + Hydroquinone + Tretinoin cream  | С  |
| 32 | Beclomethasone + Gentamicin + Miconazole   | a,   |
| 33 | Lornoxical +Paracetamol + Tramadol   | Pharmacodynamically irrelevent   |
| 34 | Chlorpheniramine Maleate IP 3 mg+Ammonium Chloride IP 130 mg+Sodium Citrate IP65 mg+Menthol IP 0.5 mg oral liquid                          | Already discussed by the earlier Committee  a, there is a potential of misuse in peadiatric population |
|    | Lactic acid bacillus 180 million +Folic acid   | b  |

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