Recommendations of the SEC (Cardiovascular & Renal) made in its 73th meeting held on 06.02.2020 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm's Name	Recommendation
New Drugs Division			
1.	12-73/10-DC (Pt. G) Azelnidipine 8mg	M/s Ajanta Pharma	The firm presented their proposal for the additional lower strength of Azelnidipine 8mg Tablets. Azelnidipine 16mg Tablets has been approved in India. Azelnidipine 8mg is approved and marketed in Japan & China. After detailed deliberation the committee recommended for grant of permission to manufacture Azelnidipine 8mg tablets for treatment of Stage I Hypertension as subsequent new drug.
2.	12-73/10-DC (Pt. B) Azelnidipine 8mg	M/s Precise Chemipharma	The firm presented their proposal for the additional lower strength of Azelnidipine 8mg Tablets. Azelnidipine 16mg Tablets has been approved in India. Azelnidipine 8mg is approved and marketed in Japan & China. After detailed deliberation the committee recommended for grant of permission to manufacture Azelnidipine 8mg tablets for treatment of Stage I Hypertension as subsequent new drug.
3.	12-38/15-DC (Pt-C) Azelnidipine 8mg/8 mg + Telmisartan 20/40 mg Tablets	M/s Ajanta Pharma	The firm presented the BE study report and clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial with the FDC.
4.	12-21/16-DC SucrofericOxyhydroxide Chewable tablet	M/s Emcure	In light of earlier recommendation dated 20.02.2019 the firm presented the BE study report before the committee. After detailed deliberation committee recommended that the proposal should be deliberated further in the next meeting in presence of Nephrologist.
Subsequent New Drugs Division			
5.	SND/IMP/19/000087 Dapagliflozin 10mg Film Coated Tablet (Additional indication)	M/s AstraZeneca	The firm presented their proposal for additional indication heart failure with reduced EF along with global clinical trial data. After detailed deliberation the committee opined that the firm should update about the current approval status of the drug in other countries for this indication for further consideration.
6.	12-29/2009-DC (Pt-Bayer-SND) II Rivaroxaban tablets 2.5mg	M/s Bayer	The firm presented justification for sample size of 250 instead of 1000 in the structured PMS study.

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			The committee after detailed deliberation agreed for the sample size of 250 in the present scenario.
7.	SND/MA/19/000125 Phenylephrine Injection 50mcg/ml	M/s Neon Laboratories	The firm presented their proposal for manufacture and marketing of Phenylephrine Injection 50mcg/ml as additional lower strength. The committee noted that the existing formulation of 10 mg/ ml is administered either as a bolus or in a dilute solution as continuous infusion. 50mcg/ml is approved in UK. The Committee after detailed deliberation recommended for grant of permission for manufacture and marketing of Phenylephrine Injection 50mcg/ml.
FDC Division			
8.	04-03/15-DC Metoprolol Succinate ER+Telmisartan+Chlorthalidone (25mg/50mg+40mg+12.5mg) Tablets	M/s. Sun Pharma Laboratories	The firm presented the BE and CT report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC of Metoprolol Succinate ER +Telmisartan+Chlorthalidone (25mg/50mg+40mg+12.5mg) Tablets.
9.	FDC/MA/19/000105 BenidipineHydrochloride+Chlorthalidone IP (4mg/4mg + 6.25mg/12.5mg) Film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented Phase III CT and BE protocol before the committee. After detailed deliberation, committee recommended for grant of permission to conduct BE and Phase-III- CT study as per the protocol. Before initiation of the clinical trial, BE report should be submitted to CDSCO.
10.	FDC/MA/19/000104 Efonidipine Hydrochloride Ethanolate+Chlorthalidone (20mg/20mg/40mg/40mg+6.25mg/12.5mg/6.25mg/12.50mg) Tablets	M/s. Zuventus Healthcare Ltd.	The firm presented Phase III CT protocol for the FDC of Efonidipine Hydrochloride Ethanolate 40mg + Chlorthalidone 12.5mg tablet in one strength only and changes in BE Protocol for proposed FDC. However, the firm has submitted their application in four strengths. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study with approved changes. The committee also recommended that the firm should submit the revised CT protocol as per the suggestions such as minimum sample size of 240 patients, investigations like CBP, CUE, ECG, X-ray Chest, fasting blood sugar to be included as baseline, electrolytes & RFT to be done in all the visits etc. Accordingly, the firm should submit revised Phase III CT protocol for review by the committee.

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11.	FDC/MA/19/000106 04-02/2018-DC 1. Efonidipine Hydrochloride Ethanolate +Telmisartan IP (20mg/20mg/40mg+20 mg/40mg/40mg) uncoated bilayered tablet	M/s. Zuventus Healthcare Ltd	The firm presented Phase III CT protocol for the FDC of Efonidipine Hydrochloride Ethanolate 40mg + Telmisartan IP 40mg uncoated bilayered tablet in one strength only and changes in BE Protocol for proposed FDC. However, the firm has submitted their application in three strengths. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study with approved changes. Further, the committee also recommended that the firm should submit the revised CT protocol as per the suggestions such as minimum sample size of 240 patients, investigations like CBP, CUE, ECG, X-ray Chest, fasting blood sugar to be included as baseline, electrolytes & RFT to be done in all the visits etc. Accordingly, the firm should submit the revised Phase III CT protocol for review by the committee.
12.	Efonidipine Hydrochloride Ethanolate+Telmisartan (20mg+40mg)Tablets	M/s Ajanta Pharma.	The firm presented Phase III CT and BE report before the committee. After detailed deliberation, committee recommended for grant of permission to manufacture and market the proposed FDC.
13.	FDC/IMP/19/000061 Glucose Monohydrate E.P 1.100gm+Magnesium Chloride Hexahydrate E.P 0.1.17gm+Calcium Chloride Dihydrate E.P. 0.2205gm+Sodium Hydrogen Carbonate E.P. 2.940gm+Sodium Chloride E.P. 6.136gm solution for haemodialysis/haemofiltration (multiBic Potassium free)	M/s. Fresenius Medical Care India Pvt. Ltd.	Firm presented their proposal before the committee with request of Phase-III CT waiver. After detailed deliberation the committee opined that the proposal should be deliberated in the next meeting in presence of Nephrologist.
14.	FDC/IMP/19/000062 For 2mmol/Potassium Chloride E.P. 01491gm+Sodium Chloride E.P. 6.136gm+Sodium Hydrogen Carbonate E.P. 2.940gm+Calcium Chloride Dihydrate E.P. 0.2205gm+Magnesium	M/s. Fresenius Medical Care India Pvt. Ltd.	Firm presented their proposal before the committee with request of Phase-III CT waiver. After detailed deliberation the committee opined that the proposal should be deliberated in the next meeting in presence of Nephrologist.

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	Chloride Hexahydrate E.P. 0.1017gm+Glucose Monohydrate E.P. 1.100gm For 4 mmol/l Potassium Chloride E.P. 0.2982gm+Sodium Chloride E.P. 6.136gm+Sodium Hydrogen Carbonate E.P. 2.940gm+Calcium Chloride Dihydrate E.P. 0.2205gm+Magnesium Chloride Hexahydrate E.P. 0.1017gm+Glucose Monohydrate E.P. 1.100gm solution for haemodialysis/haemofiltration		
15.	FDC/MA/19/000150 Fimasartan potassium trihydrate Eq. toFimasartan potassium 60mg/120mg + Chlorthalidone IP 12.5mg/12.5mg film coated tablet	M/s. Synokem	The firm presented Phase III CT and BE protocol before the committee. After detailed deliberation, committee recommended for grant of permission to conduct BE and Phase-III- CT study as per the protocol. Before initiation of the clinical trial, BE report should be submitted to CDSCO.
GCT Division			
16.	CT/69/18 Online Submission (7504) EdoxabanTosylate	M/s. IQVIA	The firm presented the protocol amendment. After detail deliberation the committee recommended for approval for the Protocol amendment (version-4.0).
17.	CT/96/19 Online Submission (17514) Lumasiran	M/s. Medpace	Firm did not turn up for presentation.
Medical Device Division			
18.	CI/MD/2019/16718 CRD_907 (OCT Guided Coronary Angioplasty)	M/s. St. Jude Medical India Pvt. Ltd.	The firm presented their protocol to conduct the global clinical investigation with the product. Committee noted that the proposed study is a post marketing trial which is already approved in countries like USA. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to condition that the study devices should be supplied free of cost

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			to the all the study subjects and all conditions of clinical investigation are applicable.
19.	MFG/MD/2019/16738 Drug (Sirolimus) Coated balloncather	M/s Bio India International Technologies Pvt Ltd	The firm presented the results of clinical investigation of the product with six months (Interim) follow-up. Committee noted that the product used in clinical investigation was manufactured in Switzerland, However, firm had applied for manufacturing permission in India. The firm is yet to submit the approval status of the product in country of origin/EU. After detailed deliberation, the committee recommended that the firm should submit the approval status of the product from other country along with one year follow-up data from the clinical investigation.