1. APPLICATIONS FOR INVESTIGATIONAL NEW DRUGS (INDs)

(Reference: Appendix I of Schedule – Y to Drugs and Cosmetics Rules, 1945)

#	Documents required to be submitted			Status	
				Yes	No
1	**Application for (permission for manufacture /import /clinical trial – purpose should be clearly mentioned)**				
2	**Name of the applicant**				
3	**Name of the New Drug**				
	a. Composition of the New Drug				
	b. Dosage Form				
	c. Proposed indication for the New Drug				
4	**Application in Form 44 complete in all respect duly signed and stamped by authorized person of the firm**				
5	**Treasury Challan of INR 50,000 (for Phase I) or INR 25,000 (for Phase II / III)**				
8	**Copy of valid manufacturing license in Form 25/28.**				
9	**Source of bulk drug.**				
10.	**Chemical and Pharmaceutical Information**				
	10.1	**Information on active ingredients**			
		10.1.1	Drug information (Generic name, Chemical name, or INN)		
	10.2	**Physicochemical Data**			
		10.2.1	Chemical name and structure, Empirical formula, Molecular weight.		
		10.2.2	Physical properties:- Description, Solubility, Rotation, Partition coefficient, Dissociation constant.		
	10.3	**Analytical Data**:- Elemental analysis, Mass spectrum, NMR spectra, IR spectra, UV spectra, Polymorphic identification.			
	10.4	**Complete monograph specification including**:- Identification, Identity/quantification of purities, Enantiomeric purity, Assay.			
	10.5	**Validations**:- Assay method, Impurity estimation method, Residual solvent/other volatile impurities (OVI) estimation method.			
	10.6	**Stabilities Studies** (for details refer Appendix IX of Schedule Y):- Final release specification, Reference standard characterization, Material safety data sheet			

	10.7	**Data on Formulation:-** Dosage form, Composition, Master manufacturing formula, Details of the formulation (Including inactive ingredients), Inprocess quality control check, Finished product specification, Excipient compatibility study, Validation of analytical method. Comparative evaluation with international brand(s) or approved Indian brands, if applicable:- Pack presentation, Dissolution, Assay, Impurities, Content uniformity, pH, Force degradation study, Stability evaluation in market intended pack at proposed storage conditions, Packing specifications, Process validation.			
11	**Animal Pharmacology** (as per Appendix IV of schedule Y)**:**				
	11.1	Summary			
	11.2	Specific pharmacological actions			
	11.3	General Pharmacological actions			
	11.4	Follow-up and supplemental safety Pharmacology Studies			
	11.5	Pharmacokinetics: absorption, distribution, metabolism, excretion			
12	**Animal toxicology data** (as per Appendix III of schedule Y):				
	12.1	**General Aspects**			
	12.2.	**Systemic Toxicity Studies,**			
	12.3	**Male Fertility Study**			
	12.4	**Female Reproduction and Developmental Toxicity Studies** (for all drugs proposed to be studied or used in women of child bearing age)			
	12.5	**Local toxicity** (as applicable)			
		12.5.1	**Dermal toxicity** (for products meant for topical (dermal) application)		
		12.5.2	**Ocular toxicity** (for products meant for ocular instillation)		
		12.5.3.	**Inhalation toxicity** (conducted with the formulation proposed to be used via inhalation route)		
		12.5.4	**Vaginal toxicity** (for products meant for topical application to vaginal mucosa)		
		12.5.5	**Photoallergy or dermal phototoxicity** (required if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential)		
		12.5.6	**Rectal tolerance test** (For all preparations meant for rectal administration)		
	12.6	**Genotoxicity**			
	12.7	**Allergenicity/Hypersensitivity**			

	12.8	**Carcinogenicity** (Carcinogenicity studies should be performed for all drugs that are expected to be clinically used for more than 6 months as well as for drugs used frequently in an intermittent manner in the treatment of chronic or recurrent conditions. However, completed rodent carcinogenicity studies are not needed in advance of the conduct of large scale clinical trials, unless there is a special concern for the patient population)		
	Reports of following toxicity studies should be submitted along with clinical trial applications of different Phases for INDs:			

For Phase I Clinical Trials

- Systemic Toxicity studies

  (i) Single dose toxicity studies

  (ii) Dose Ranging Studies

  (iii) Repeat-dose systemic toxicity studies of appropriate duration to support the duration of proposed human exposure.
- Male fertility study
- In-vitro genotoxicity tests
- Relevant local toxicity studies with proposed route of clinical application (duration depending on proposed length of clinical exposure)
- Allergenicity/Hypersensitivity tests (when there is a cause for concern or for parenteral drugs, including dermal application)
- Photo-allergy or dermal photo-toxicity test (if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential)

For Phase II Clinical Trials

- Provide a summary of all the non-clinical safety data (listed above) already submitted while obtaining the permissions for Phase I trial, with appropriate references.
- In case of an application for directly starting a Phase II trial - complete details of the non-clinical safety data needed for obtaining the permission for Phase I trial, as per the list provided above must be submitted.
- Repeat-dose systemic toxicity studies of appropriate duration to support the duration of proposed human exposure
- In-vitro and In-vivo genotoxicity tests.
- Segment II reproductive/developmental toxicity study (if female patients of child bearing age are going to be involved)

For Phase III Clinical Trials

- Provide a summary of all the non-clinical safety data (listed above) already submitted while obtaining the permissions for Phase I and II trials, with appropriate references.
- In case of an application for directly initiating a Phase III trial - complete details of the non-clinical safety data needed for obtaining the permissions for Phase I and II trials, as per the list provided above must be provided.
- Repeat-dose systemic toxicity studies of appropriate duration to support the duration of proposed human exposure
- Reproductive/developmental toxicity studies
- In-vitro and In-vivo genotoxicity tests.
- Segment I (if female patients of child bearing age are going to be involved), and
- Segment III (for drugs to be given to pregnant or nursing mothers or

	where there are indications of possible adverse effects on foetal development). • Carcinogenicity studies (when there is a cause for concern or when the drug is to be used for more than 6 months).				
13	**Human / Clinical pharmacology (Phase I) including summary of the study and reports**				
	13.1	Summary			
	13.2	Specific Pharmacological effects			
	13.3	General Pharmacological effects			
	13.4	Pharmacokinetics, absorption, distribution, metabolism, excretion			
	13.5	Pharmacodynamics / early measurement of drug activity			
14	**Therapeutic exploratory trials (Phase II)**				
	14.1	Summary			
	14.2	Study report(s) as given in Appendix II			
15	**Therapeutic confirmatory trials (Phase III)**				
	15.1	Summary			
	15.2	Individual study reports with listing of sites and Investigators.			
16	**Special Studies**				
	16.1	Summary			
	16.2	Bio-availability / Bio-equivalence			
	16.3	Other studies e.g. geriatrics, paediatrics, pregnant, or nursing women.			
17	**Regulatory status in other countries:-**				
	17.1	**Countries where the drug is**			
		17.1.1	Marketed		
		17.1.2	Approved		
		17.1.3	Approved as IND		
		17.1.4	Withdrawn, if any, with reasons.		
	17.2	Restrictions on use, if any, in countries where marketed / approved.			
	17.3	Free sale certificate or COPP, as appropriate.			
18	**Prescribing Information:-**				
	18.1	Proposed full prescribing information.			
19	**Samples and Testing Protocol/s**				
	19.1	Samples of pure drug substance and finished product (an equivalent of 50 clinical doses, or more number of clinical doses if prescribed by the Licensing Authority), with testing protocols, full impurity profile and release specifications.) (To be submitted to the laboratory as directed by the Licensing Authority)			

20. STRUCTURE, CONTENTS AND FORMAT FOR CLINICAL TRIAL PROTOCOL

(Reference: Appendix- X of Schedule – Y to Drugs and Cosmetics Rules, 1945)

#	Documents required to be submitted	Status	
		Yes	No
1.	Title Page		
2.	Table of Contents		
3.	Study Objective(s) (primary as well as secondary) and their logical relation to the study design.		
4.	Study Design		
5.	Study Population		
6.	Subject Eligibility - Inclusion Criteria and Exclusion Criteria		
7.	Study Assessments		
8.	Study Treatment		
9.	Adverse Events		
10.	Ethical Considerations		
11.	Study Monitoring and Supervision		
12.	Study Monitoring and Supervision		
13.	Investigational Product Management		
14.	Data Analysis		
15.	Undertaking by the Investigator as per Appendix VII of Schedule Y:- (Ethics Committee should be of same area where the site is located and details of the committee should be mentioned).		

16.	**Informed Consent Documents:-** Patient Information Sheet (PIS) / Informed consent form (ICF) as per revised Appendix V of Schedule Y including the following clauses. A. Statement describing the financial compensation and medical management as under:- a) In the event of an injury occurring to the clinical trial subjects, such subjects shall be provided free medical management as long as required. b) In the event of a trial related injury or death, the sponsor or his representative, whosoever has obtained permission from licensing authority for conduct of clinical study shall provide financial compensation for the injury or death. B. In serial no. 02 of an Appendix V, the following shall be included: Address of the subject: Qualification: Occupation: Student/Self=employed/service/Housewife/Other. (Please tick as appropriate) Annual income of Subject: Name and Address of nominee and his/her relation to the subject. (for the purpose of compensation in case of trial related death) C. After the name of witness occurring at the end, the following shall be inserted: "Copy of the patient information sheet and duly filled ICF shall be handed over to the subject or his/her attendant"		
17.	Undertaking by the Sponsor/Sponsors representative/applicant to the licensing authority to provide medical management and compensation in case of clinical trial related injury or death for which subjects are entitled to compensation as required under rule 122DAB(6).		
18.	Declaration regarding financial status of the applicant vis-à-vis medical management and compensation to be paid to the trial participants (in case of injury or death in clinical trial)		
19.	List of Investigators including site address (es).		
	(a) Trial site details (whether it is equipped with super specialty or multi-specialty facilities and emergency facilities with Institutional ethics committee.		
	(b) Furnish details on the total number of trials being undertaken currently by the proposed Investigator.		
20.	Ethics Committee approvals, if available:- (Institutional Ethics Committee should be in same area where the site is located).		
21.	As per the protocol, whether the subjects will receive the standard care. (Give declaration)		

22.	Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.		

21. STRUCTURE, CONTENTS AND FORMAT FOR CLINICAL STUDY REPORTS

(Reference: Appendix- II of Schedule – Y to Drugs and Cosmetics Rules, 1945)

#	Documents required to be submitted	Status	
		Yes	No
1.	Title Page		
2.	Study Synopsis		
3.	Statement of compliance with the 'Guidelines for Clinical Trials on Pharmaceutical Products in India		
4.	List of Abbreviations and Definitions		
5.	Table of contents		
6.	Copy of Ethics Committee approval		
7.	Study Team		
8.	Introduction		
9.	Study Objective		
10.	Investigational Plan		
11.	Trial Subjects		
12.	Efficacy evaluation		
13.	Safety Evaluation		

14.	Discussion and overall Conclusion		
15.	List of References		

Note:

1. All items mentioned above may not be applicable to all drugs. The items not relevant to a particular new drug should be marked with “Not Applicable (NA)”.

2. In case the application is for clinical trial permission :-

(a) adequate chemical and pharmaceutical information should be provided to ensure the proper identity, purity, quality & strength of the investigational product, the amount of information needed may vary with the Phase of clinical trials, proposed duration of trials, dosage forms and the amount of information otherwise available

(b) In case of applications for protocol amendments of already approved studies, applicants should submit copy of approval of protocol, amended new protocol, summarized list of all the new changes incorporated alongwith justification / reasons for the change.

(c) **Ethics Committee Approval:** Ethical approval should be obtained from Ethics Committee located in the same area where the clinical trial site is located.

(d) The proposed clinical trial study centers should be geographically distributed in the country and should also include clinical sites which have their own Institutional Ethics Committee.

2. CHECKLIST FOR ACCEPTABILITY OF APPLICATION PERTANING TO GRANT OF PERMISSION TO IMPORT OR MANUFACTURE NEW DRUGS GOING TO BE INTRODUCED FOR THE FIRST TIME IN THE COUNTRY FOR SALE OR TO UNDERTAKE CLINICAL TRIALS

(Reference: Appendix I of Schedule – Y to Drugs and Cosmetics Rules, 1945)

#	Documents required to be submitted			Status	
				Yes	No
1	**Application for (permission for manufacture /import/clinical trial – purpose should be clearly mentioned)**				
2	**Name of the applicant**				
3	**Name of the New Drug**				
	a. Composition of the New Drug				
	b. Dosage Form				
	c. Proposed indication for the New Drug				
4	**Application in Form 44 complete in all respect duly signed and stamped by authorized person of the firm**				
5	**Treasury Challan of INR 50,000 (for Phase I) or INR 25,000 (for Phase II / III)**				
8	**Copy of valid manufacturing license in Form 25/28 along with copy of**				
9	**Source of bulk drug.**				
10.	**Chemical and Pharmaceutical Information**				
	10.1	**Information on active ingredients**			
		10.1.1	Drug information (Generic name, Chemical name, or INN)		
	10.2	**Physicochemical Data**			
		10.2.1	Chemical name and structure, Empirical formula, Molecular weight.		
		10.2.2	Physical properties:- Description, Solubility, Rotation, Partition coefficient, Dissociation constant.		
	10.3	**Analytical Data**:- Elemental analysis, Mass spectrum, NMR spectra, IR spectra, UV spectra, Polymorphic identification.			
	10.4	**Complete monograph specification including**:- Identification, Identity/quantification of purities, Enantiomeric purity, Assay.			
	10.5	**Validations**:- Assay method, Impurity estimation method, Residual solvent/other volatile impurities (OVI) estimation method.			
	10.6	**Stabilities Studies** (for details refer Appendix IX of Schedule Y):- Final release specification, Reference standard characterization, Material safety data sheet			

	10.7	**Data on Formulation:-** Dosage form, Composition, Master manufacturing formula, Details of the formulation (Including inactive ingredients), Inprocess quality control check, Finished product specification, Excipient compatibility study, Validation of analytical method. Comparative evaluation with international brand(s) or approved Indian brands, if applicable:- Pack presentation, Dissolution, Assay, Impurities, Content uniformity, pH, Force degradation study, Stability evaluation in market intended pack at proposed storage conditions, Packing specifications, Process validation.			
11	**Animal Pharmacology** (as per Appendix IV of schedule Y)**:**				
	11.1	Summary			
	11.2	Specific pharmacological actions			
	11.3	General Pharmacological actions			
	11.4	Follow-up and supplemental safety Pharmacology Studies			
	11.5	Pharmacokinetics: absorption, distribution, metabolism, excretion			
12	**Animal toxicology data** (as per Appendix III of schedule Y)				
	12.1	**General Aspects**			
	12.2.	**Systemic Toxicity Studies,**			
	12.3	**Male Fertility Study**			
	12.4	**Female Reproduction and Developmental Toxicity Studies** (for all drugs proposed to be studied or used in women of child bearing age)			
	12.5	**Local toxicity** (as applicable)			
		12.5.1	**Dermal toxicity** (for products meant for topical (dermal) application)		
		12.5.2	**Ocular toxicity** (for products meant for ocular instillation)		
		12.5.3.	**Inhalation toxicity** (conducted with the formulation proposed to be used via inhalation route)		
		12.5.4	**Vaginal toxicity** (for products meant for topical application to vaginal mucosa)		
		12.5.5	**Photoallergy or dermal phototoxicity** (required if the drug or a metabolite is related to an agent causing photosensitivity or the nature of action suggests such a potential)		
		12.5.6	**Rectal tolerance test** (For all preparations meant for rectal administration)		
	12.6	**Genotoxicity**			
	12.7	**Allergenicity/Hypersensitivity**			

	12.8	**Carcinogenicity** (Carcinogenicity studies should be performed for all drugs that are expected to be clinically used for more than 6 months as well as for drugs used frequently in an intermittent manner in the treatment of chronic or recurrent conditions. However, completed rodent carcinogenicity studies are not needed in advance of the conduct of large scale clinical trials, unless there is a special concern for the patient population)			
13	**Human / Clinical pharmacology (Phase I) including summary of the study and reports**				
	13.1	Summary			
	13.2	Specific Pharmacological effects			
	13.3	General Pharmacological effects			
	13.4	Pharmacokinetics, absorption, distribution, metabolism, excretion			
	13.5	Pharmacodynamics / early measurement of drug activity			
14	**Therapeutic exploratory trials (Phase II)**				
	14.1	Summary			
	14.2	Study report(s) as given in Appendix II			
15	**Therapeutic confirmatory trials (Phase III)**				
	15.1	Summary			
	15.2	Individual study reports with listing of sites and Investigators.			
16	**Special Studies**				
	16.1	Summary			
	16.2	Bio-availability / Bio-equivalence			
	16.3	Other studies e.g. geriatrics, paediatrics, pregnant, or nursing women.			
17	**Regulatory status in other countries:-**				
	17.1	**Countries where the drug is.**			
		17.1.1	Marketed		
		17.1.2	Approved		
		17.1.3	Approved as IND		
		17.1.4	Withdrawn, if any, with reasons.		
	17.2	Restrictions on use, if any, in countries where marketed / approved.			
	17.3	Free sale certificate or COPP, as appropriate.			
18	**Prescribing Information:-**				
	18.1	Proposed full prescribing information. : The prescribing information (package insert) shall comprise the following sections: generic name; composition; Ddosage form/s, indications;dose and method of administration; use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.); contra- indications; warnings; precautions; drug interactions; undesirable effects; overdose; pharmacodynamic and pharmacokinetic properties; incompatibilities; shelf-life; packaging information; storage and handling instructions.			

19	**Samples and Testing Protocol/s**			
	19.1	Samples of pure drug substance and finished product (an equivalent of 50 clinical doses, or more number of clinical doses if prescribed by the Licensing Authority), with testing protocols, full impurity profile and release specifications.) (To be submitted to the laboratory as directed by the Licensing Authority)		
20	**Proposed Draft specimen of the label and carton.** The drafts of label and carton texts should comply with provisions of Rules 96 and 97.			
21	If the study drug is intended to be imported for the purposes of examination, test or analysis, the application for import of small quantities of drugs for such purpose should also be made in Form 12.			

22. STRUCTURE, CONTENTS AND FORMAT FOR CLINICAL TRIAL PROTOCOL

(Reference: Appendix - X of Schedule – Y to Drugs and Cosmetics Rules, 1945)

#	Documents required to be submitted	Status	
		Yes	No
1.	Title Page		
2.	Table of Contents		
3.	Study Objective(s) (primary as well as secondary) and their logical relation to the study design.		
4.	Study Design		
5.	Study Population		
6.	Subject Eligibility - Inclusion Criteria and Exclusion Criteria		
7.	Study Assessments		
8.	Study Treatment		
9.	Adverse Events		
10.	Ethical Considerations		
11.	Study Monitoring and Supervision		
12.	Study Monitoring and Supervision		
13.	Investigational Product Management		
14.	Data Analysis		
15.	Undertaking by the Investigator as per Appendix VII of Schedule Y:- (Ethics Committee should be of same area where the site is located and details of the committee should be mentioned).		

16.	**Informed Consent Documents:-** Patient Information Sheet (PIS) / Informed consent form (ICF) as per revised Appendix V of Schedule Y including the following clauses. D. Statement describing the financial compensation and medical management as under:- c) In the event of an injury occurring to the clinical trial subjects, such subjects shall be provided free medical management as long as required. d) In the event of a trial related injury or death, the sponsor or his representative, whosoever has obtained permission from licensing authority for conduct of clinical study shall provide financial compensation for the injury or death. E. In serial no. 02 of an Appendix V, the following shall be included: Address of the subject: Qualification: Occupation: Student/Self=employed/service/Housewife/Other. (Please tick as appropriate) Annual income of Subject: Name and Address of nominee and his/her relation to the subject. (for the purpose of compensation in case of trial related death) F. After the name of witness occurring at the end, the following shall be inserted: "Copy of the patient information sheet and duly filled ICF shall be handed over to the subject or his/her attendant"		
17.	Undertaking by the Sponsor/Sponsors representative/applicant to the licensing authority to provide medical management and compensation in case of clinical trial related injury or death for which subjects are entitled to compensation as required under rule 122DAB(6).		
18.	Declaration regarding financial status of the applicant vis-à-vis medical management and compensation to be paid to the trial participants (in case of injury or death in clinical trial)		
19.	List of Investigators including site address (es).		
	(c) Trial site details (whether it is equipped with super specialty or multi-specialty facilities and emergency facilities with Institutional ethics committee.		
	(d) Furnish details on the total number of trials being undertaken currently by the proposed Investigator.		
20.	Ethics Committee approvals, if available:- (Institutional Ethics Committee should be in same area where the site is located).		
21.	As per the protocol, whether the subjects will receive the standard care. (Give declaration)		

22.	Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.		

23. Protocol of Bioequivalence study along with Informed Consent document and undertaking by Investigator in case of Oral Dosage Forms having systematic absorption. In case of biowaiver, justification should be submitted.

24. Structure, Contents and Format for Clinical Study Reports:

(Reference: Appendix II of Schedule – Y to Drugs and Cosmetics Rules, 1945)

#	Documents required to be submitted	Status	
		Yes	No
1.	Title Page		
2.	Study Synopsis		
3.	Statement of compliance with the 'Guidelines for Clinical Trials on Pharmaceutical Products in India		
4.	List of Abbreviations and Definitions		
5.	Table of contents		
6.	Copy of Ethics Committee approval		
7.	Study Team		
8.	Introduction		
9.	Study Objective		
10.	Investigational Plan		
11.	Trial Subjects		

12.	Efficacy evaluation		
13.	Safety Evaluation		
14.	Discussion and overall Conclusion		
15.	List of References		

Note:

1. All items mentioned above may not be applicable to all drugs. The items not relevant to a particular new drug should be marked with “Not Applicable (NA)”.

2. Application for both bulk as well as formulation is required to be submitted. Proposal for grant of permission to manufacture only bulk drug will be considered after approval of it’s formulation.

3. In case the application is for clinical trial permission:

a. Adequate chemical and pharmaceutical information should be provided to ensure the proper identity, purity, quality & strength of the investigational product, the amount of information needed may vary with the Phase of clinical trials, proposed duration of trials, dosage forms and the amount of information otherwise available.

b. In case of applications for protocol amendments of already approved studies, applicants should submit copy of approval of protocol, amended new protocol, summarized list of all the new changes incorporated along with justification / reasons for the change.

c. Ethics Committee Approval: Ethical approval should be obtained from Ethics

Committee located in the same area where the clinical trial site is located.

d. The proposed clinical trial study centres should be geographically distributed in the country and should also include clinical sites which have their own Institutional Ethics Committee.

3.CHECKLIST FOR ACCEPTABILITY OF APPLICATION PERTANING TO GRANT OF PERMISSION TO IMPORT OR MANUFACTURE NEW PHYTOPHARMACEUTICAL DRUGS GOING TO BE INTRODUCED FOR THE FIRST TIME IN THE COUNTRY FOR SALE OR TO UNDERTAKE CLINICAL TRIALS

#	Documents required to be submitted		Status	
			Yes	No
1	**Application for permission to import or manufacture new drugs for sale or to undertake clinical trials -** Purpose should be clearly mentioned.			
	a. Name of the applicant			
	b. Name of the Drug			
	c. Composition of the Drug with bio active constituents and Phytopharmaceuticals (qualitatively and quantitatively assessed)			
	d. Proposed indication			
2	**Application in Form 44** should be complete in all respect and signed by the authorized person of the firm with name and designation			
3	**Treasury Challan of Rs.50,000 and** should mention the name of the New Drug including correct head of the account, payable at, bank clearance, etc.			
4	**Copy of valid manufacturing license in Form 25/28 along with copy of Form 29**			
5	**Source of bulk drugs** a) In-house b) Other than in-house**.** If source is other than in-house, a copy of consent letter from manufacturer of the bulk drug should be submitted and the manufacture of the bulk drug should also file application for the bulk drug.			
6	**Data to be submitted by the applicant:**			
	6.1	A brief description or summary of the phytopharmaceutical drug giving the botanical name of the plant (including vernacular or scriptural name, wherever applicable), formulation and route of administration, dosages, therapeutic class for which it is indicated and the claims to be made for the phytopharmaceutical product.		
	6.2	Published literature including information on plant or product or phytopharmaceutical drug, as a traditional medicine or as an ethno medicine and provide reference to books and other documents, regarding composition, process prescribed, dose or method of usage, proportion of the active ingredients in such traditional preparations per dose or per day's consumption and uses.		
	6.3	Information on any contraindications, side effects mentioned in traditional medicine or ethno medicine literature or reports on current usage of the formulation.		
	6.4	Published scientific reports in respect of safety and pharmacological studies relevant for the phytopharmaceutical drug intended to be marketed,-		

		a)	where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and		
		b)	where process or usage is different from that known in traditional medicine or ethno medicine.		
	6.5	Information on any contraindications, side effects mentioned or reported in any of the studies, information on side effects and adverse reactions reported during current usage of the phytopharmaceutical in the last three years, wherever applicable.			
	6.6	Present usage of the phytopharmaceutical drug, – to establish history of usages, provide details of the product, manufacturer, quantum sold, extent of exposure on human population and number of years for which the product is being sold.			
7.	**Human or clinical pharmacology information:**				
	7.1	Published scientific reports in respect of pharmacological studies including human studies or clinical studies or epidemiological studies, relevant for the phytopharmaceutical drug intended to be marketed,-			
		a)	where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and		
		b)	where process or usage is different from that known in traditional medicine or ethno medicine.		
	7.2	Pharmacodynamic information (if available).			
	7.3	Monographs, if any, published on the plant or product or extract or phytopharmaceutical. (Copies of all publications, along with english translation to be attached.)			
	Data generated by applicant				
8.	Identification, authentication and source of plant used for extraction and fractionation:				
	8.1	Taxonomical identity of the plant used as a source of the phytopharmaceutical drug giving botanical name of genus, species and family, followed by the authority citation (taxonomist's name who named the species), the variety or the cultivar (if any) needs to be mentioned.			
	8.2	Morphological and anatomical description giving diagnostic features and a photograph of the plant or plant part for further confirmation of identity and authenticity. (Furnish certificate of confirmation of botanical identity by a qualified taxonomist).			
	8.3	Natural habitat and geographical distribution of the plant and also mention whether the part of the plant used is renewable or destructive and the source whether cultivated or wild.			
	8.4	Season or time of collection.			
	8.5	Source of the plant including its geographical location and season or time of collection.			

	8.6	A statement indicating whether the species is any of the following, namely:-			
		a)	determined to be endangered or threatened under the Endangered Species Act or the Convention on International Trade in Endangered species (CITES) of wild Fauna and Flora;		
		b)	entitled to special protection under the Biological Diversity Act, 2002 (18 of 2003);		
		c)	any known genotypic, chemotypic and ecotypic variability of species.		
	8.7	A list of grower or supplier (including names and addresses) and information on the following items for each grower or supplier, if available or identified already, including information of primary processing, namely:-			
		a)	harvest location;		
		b)	growth conditions;		
		c)	stage of plant growth at harvest;		
		d)	harvesting time;		
		e)	collection, washing, drying and storage conditions;		
		f)	handling, garbling and transportation;		
		g)	grinding, pulverising of the plant material; and		
		h)	sieving for getting uniform particle size of powdered plant material.		
	8.8	Quality specifications, namely:-			
		a)	foreign matter;		
		b)	total ash;		
		c)	acid insoluble ash;		
		d)	pesticide residue;		
		e)	heavy metal contamination;		
		f)	microbial load;		
		g)	chromatographic finger print profile with phytochemical reference marker;		
		h)	assay for bio-active or phytochemical compounds; and		
		i)	chromatographic fingerprint of a sample as per test method given under quality control of the phytopharmaceutical drug		
	8.9	An undertaking to supply specimen sample of plant duly labeled and photocopy of the certificate of identity confirmation issued by a qualified taxonomist along with drawings or photographs of the diagnostic morphological and histological features of the botanical raw material used for the confirmation of authenticity.			

9	Process for extraction and subsequent fractionation and purification:				
	9.1	Quality specifications and test methods for starting material.			
	9.2	Steps involved in processing.			
		a)	details of solvent used, extractive values, solvent residue tests or limits, physico-chemical tests, microbial loads, heavy metal contaminants, chromatographic finger print profile with phytochemical reference markers, assay for active constituents or characteristic markers, if active constituents are not known;		
		b)	characterisation of final purified fraction;		
		c)	data on bio-active constituent of final purified fraction;		
		d)	information on any excipients or diluents or stabiliser or preservative used, if any.		
	9.3	Details of packaging of the purified and characterized final product, storage conditions and labeling.			
10	**Formulation of phytopharmaceutical drug applied for:**				
	10.1	Details of the composition, proportion of the final purified fraction with defined markers of phytopharmaceutical drug per unit dose, name and proportions of all excipients, stabilisers and any other agent used and packaging materials.			
	10.2	Test for identification for the phytopharmaceutical drug.			
	10.3	Quality specifications for active and inactive phytopharmaceutical chromatographic finger print profile with phytochemical reference marker and assay of active constituent or characteristic chemical marker.			
11	**Manufacturing process of formulation:**				
	11.1	The outline of the method of manufacture of the dosage form, along with environmental controls, in-process quality control tests and limits for acceptance.			
	11.2	Details of all packaging materials used, packing steps and description of the final packs.			
	11.3	Finished product's quality specifications, including tests specific for the dosage form, quality and chromatographic finger print profile with phytochemical reference marker and assay for active constituent or characteristic marker, if active constituents are not known.			
12	**Stability data:**				
	12.1	Stability data of the phytopharmaceutical drug described at 4 above, stored at room temperature at 40 +/- 2 deg. C and humidity at 75%RH +/- 5%RH for 0, 1, 2, 3 and 6 months.			

	12.2		Stability data of the phytopharmaceutical drug in dosage form or formulation stored at room temperature at 40 +/- 2 deg. C and humidity at 75%RH +/- 5%RH for 0, 1, 2, 3 and 6 months, in the pack intended for marketing.		
13	**Safety and pharmacological information:**				
	13.1		Data on safety and pharmacological studies to be provided		
	13.2		Animal toxicity and safety data:		
		a)	28 to 90 days repeat dose oral toxicity on two species of animals;		
		b)	In-vitro genotoxicity data (Ame's test and Chromosomal aberration test as per Schedule Y);		
		c)	dermal toxicity tests for topical use products;		
		d)	teratogenicity study (only if phytopharmaceutical drug is intended for use during pregnancy).		
14	**Human studies:**				
	14.1		Clinical trials for phytopharmaceutical drugs to be conducted as per applicable rules and guidelines for new drugs.		
	14.2		For all phytopharmaceutical drugs data from phase I (to determine maximum tolerated dose and associated toxicities) and the protocols shall be submitted prior to performing the studies.		
	14.3		Data of results of dose finding studies performed and the protocols shall be submitted prior to performing the studies: Provided that in the case of phytopharmaceutical drug already marketed for more than five years or where there is adequate published evidence regarding the safety of the phytopharmaceutical drug, the studies may be abbreviated, modified or relaxed.		
15	**Confirmatory clinical trials:**				
	15.1		Submit protocols for approval for any specific or special safety and efficacy study proposed specific to the phytopharmaceutical drug.		
	15.2		Submit proposed protocol for approval for human clinical studies appropriate to generate or validate safety and efficacy data for the phytopharmaceutical dosage form or product as per applicable rules and guidelines.		
	15.3		Submit information on how the quality of the formulation would be maintained during the above studies.		
16	**Regulatory status:** Status of the phytopharmaceutical drug marketed in any country under any category like functional food or dietary supplement or as traditional medicine or as an approved drug.				
17	**Marketing information:**				
	17.1		Details of package insert or patient information sheet of the phytopharmaceutical drug to be marketed.		

	17.2	Draft of the text for label and carton.		
18	**Post marketing surveillance (PMS):**			
	18.1	The applicant shall furnish periodic safety update reports every six months for the first two years after approval the drug is granted.		
	18.2	For subsequent two years the periodic safety update reports need to be submitted annually.		
19	**Any other relevant information:** Any other relevant information which the applicant considers that it will help in scientific evaluation of the application.			

