DCGI REQUIREMENTS TO CONDUCT CLINICAL TRIALS IN INDIA

Table 1 Documentation requirements by DCGI

Sr No.	Documents	Documents required for conducting new trials, import, or manufacture of new drugs Note: Enlisted items may not be applicable for all drugs. (Y/N)	Documents required for grant of permission for import or manufacture of approved new drug (Y/N)	Documents for conducting a clinical trial or for importing or to manufacture an approved new drug with new claims (new dosage form, new route of administration, new strength, or new indication) (Y/N)
1	Introduction and brief description of the drug and the therapeutic class	Y	Y	N
2	Chemical composition and pharmaceutical data	Y	Y	Y
3	Animal pharmacology and toxicology (for details refer clause 3 and clause 2 of Second Schedule)	Y	N	Y
4	Phase I, Phase II, and Phase III trial data	Y	N	Y
5	Global clinical trial data	Y	N	Y
6	New Chemical Entity Data	Y	Not Applicable	Not Applicable
7	Special studies, if any, after approval from Central Licensing Authority	Y	Y	N
8	Regulatory status in other countries	Y	N	Y
9	Prescribing information	Y	N	N
10	Samples and testing protocol (s)	Y	N	N
11	In case of sale of new drug, a copy of drug license issued by State Licencing Authority	Y	N	Not Applicable
12	Marketing data	N	Y	Y
13	In case of approved new drug, number and date of permission or number and date of license granted	Not Applicable	Not Applicable	Y
14	Therapeutic data for new indication claim/new dosage form/new route of administration	Not Applicable	Not Applicable	Y

(Y- Yes; N-No)

Table 2 Documentation for conducting clinical trials, import, or manufacture a phytopharmaceutical drug in India

Data to be submitted by applicant	Data to be generated by applicant per New Drugs and Clinical Trials Rules 2019
Summary: Botanical name of the plant (vernacular or scriptural name), formulation and manufacturing details, route of administration, dosages, therapeutic indication. Details on the history of usage, product details, details of the manufacturer, quantum of product sold, the period for which the product has been in the market, and the extent of exposure of human population to the drug.	**1. Identification, authentication and plant source used for extraction and fractionation** **2. Process of extraction, fractionation, and purification** **3. Formulation of phytopharmaceutical drug** **4. Manufacturing process** **5. Stability data** **6. Safety and pharmacological data** **7. Human studies: This criterion may be modified or relaxed in case the phytopharmaceutical drug has been in the market for more than five years or where there is sufficient published evidence of the safety and efficacy of the phytopharmaceutical drug.** **8. Confirmatory clinical trials** **9. Regulatory status** **10. Marketing information** **11. Post marketing surveillance(PMS)** **12. Any other relevant information**
Published literature and book references: Information on the plant or the phytopharmaceutical drug, and its use in traditional systems of medicine or ethnomedicine as well as its current therapeutic usage	
Any known **contraindications or side effects** mentioned in classic literature or traditional systems of medicine or in any clinical studies. **Adverse events or serious adverse events** reported during post-marketing surveillance of the phytopharmaceutical drug in the past three years, wherever applicable.	
Published safety studies and pharmacological studies of the phytopharmaceutical drug intended to be marketed in cases where the process and usages are similar or same as the product known in traditional medicine or in ethno medicine; also in cases where process or usage are different from that known in traditional medicine or in ethno medicine	

Table 3 Timelines for DCGI approval of clinical trials

Documents/meeting that require DCGI review or approval	Data to be generated by applicant per New Drugs and Clinical Trials Rules 2019
Application for clinical trial of a new drug or an investigational product (IP) as part of drug discovery and research as well as drug manufacture in India	**Within 30 working days** from the date of receipt of application
Application for clinical trial of a new drug already approved outside India	**Within 90 working days** from the date of receipt of application
Frequency of Subject Expert Committee (SEC) Review Meeting	Monthly or once in two months depending on the indication and nature of trial

Table 4 Documents to be submitted for import license by sponsors

- Port of loading of Investigational Products (Test & Reference), preferably country name
- GMP compliance statement/certificate for test formulation
- Sponsor's authorization letter on company letter head
- Sponsor's undertaking on company letter head
- Name and address(es) of drug product manufacturer; details of manufacturing site, formulation site, primary and secondary packaging site, batch release site, dispatch site, and testing site
- Pack presentation details of the drug (bottle/ampoule/vial/injection/bottles/drums/blisters/ strips/others) and pack size of the drug (tablets per bottle/mL of ampoule/others)

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