veeda clinical research

DCGI REQUIREMENTS TO CONDUCT BIOAVAILABILITY/BIOEQUIVALENCE (BA/BE) STUDIES IN INDIA

Documents	Signature and date on company letter head (Y/N)
Chemical and pharmaceutical data	Y
Complete certificate of analysis (CoA) of test and reference formulation	Y
Stability data for test formulation	Y
Comparative dissolution data in tabular column with related graphs for test & reference formulations	Y
Good manufacturing practice (GMP) compliance statement/certificate for test formulation	N
Port of loading of investigational products (for test & Reference) with country name and full address	N
Sponsor's authorization letter	Y
Sponsor's undertaking cum indemnification letter	Y
Name and address(es) of drug product manufacturer (test product), manufacturing site, formulation site (primary and secondary packaging site, batch release site, dispatch site, testing site)	N
Name and full address of manufacturing site with telephone, fax and e-mail address for reference and test products	N
Pack presentation details of the drug (bottle/ampoule/vial/injection/drums/blisters/strips/others) and pack size of the drug (tablets per bottle/mL of ampoule/Others)	N
Qualitative & quantitative difference of test product if there are more than one test products in the study	N
Pharmaceutical composition of reference and test product. (Test product composition usually present in CPS data and Reference product composition usually present in prescription leaflet)	N
Published literatures for all new drug applications	N
Published clinical and non-clinical data for unapproved molecules	N

Table 1 Stability data for test formulation

Study	Study conditions	Duration of study
Long-term	30°C ± 2°C/75% RH ± 5% RH	6 months or 12 months
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months

Note: Per the New Drugs and Clinical Trials Rules 2019, a minimum of 3 months stability data is required for long term and accelerated studies from the most recently manufactured batch of the test product. For CoA, long term stability data, accelerated stability data, and comparative dissolution data, data should be from the same batch. In addition, data of the provided batch should be valid during DCGI application (Batch data older than 2-3 years will not be accepted by CDSCO)

If the stability conditions are other than those presented in Table 1, relevant justification and stability guidelines can be attached along with the data. This data should cover at least the following points:

- Batch number
- Batch size
- Study initiation date
- Manufacturing date
- Stability condition
- Stability duration
- Proposed shelf life

Table 2 Timelines for DCGI approval of BA/BE trials

Documents/meeting that require DCGI review or approval	Timeline
Application for BA/BE No Objection Certificate (NOC) and Test license (TL)	**90 days*** ***The official timeline provided by CDSCO is 90 days but approval can be sought in 45-50 days if no queries have been raised by DCGI.**
BA/BE application for an old drug where only TL is required	**Within 7 days**
BA/BE application for old drug approved in Indian Pharmacopoeia (IP) 2010	**Approximately 15 days**
Frequency of Subject Expert Committee (SEC) Review Meeting	**Monthly or once in two months depending on the indication and nature of trial**

Table 2 Documents required for import license

- 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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