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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 (Refer Table 1)	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, 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 Drug 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 Drug product if there are more than one Drug 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

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
- Stability condition
- Study initiation date
- Stability duration
- Proposed shelf life
- Manufacturing date

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)	**1-2 weeks for application process and 3-4 weeks for approval if no queries have been raised by DCGI.**
BA/BE application for an old drug where only TL is required	**Within 1-2 weeks**
Frequency of Subject Expert Committee (SEC) Review Meeting	**Monthly or once in two months depending on the indication and nature of trial**

Table 3 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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