Documents to be submitted for grant of permission to conduct Bioequivalence studies for export purpose.

A large number of applications are being filed to the office of DCG (I) at CDSCO (HQ) by Pharmaceutical companies, both manufacturers and importers as well as CRO's on behalf of them, requesting for the approval to carry out BE studies with various pharmaceutical dosage formulations on Indian subjects.

In light of the above, for easy processing of such applications and to bring uniformity in decision making all stake holders of the afore mentioned activities are hereby advised to submit their applications with following documents. All applications should accompany the documents with proper index & page number.

Requirements for BE study of a new molecule not approved in India but approved in the other countries.

1. Application in Form-44 duly signed, by the competent authority with name and designation.
2. Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval granted to the BE study centre by CDSCO.
5. Sponsor's Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. The study synopsis
8. Pre-clinical single dose data and repeated dose toxicity data.
9. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers/patients data published in reputed journals.
10. Regulatory status of the drug.
11. Names of the countries where the drug is currently being marketed (to be mentioned in the covering letter also).
12. Package literature on the international product
13. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
14. In the case of multiple dose BE study adequate supporting safety data should be submitted.
15. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
16. Depending on the nature of the drug like cytoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

New Drugs approved in India within period of 1 year:-

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 25000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed by the competent authority on their letterhead.
6. The study protocols.
7. Clinical study data and published report of pharmacokinetic and pharmacodynamic study carried out in healthy volunteers data published in reputed journals.
8. Package literature on the international product.
9. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
10. In the case of multiple dose BE study adequate supporting safety data should be submitted.
11. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
12. Depending on the nature of the drug like cytoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

New Drugs approved within period of more than 1 year & less than 4 years:-

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 15000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed on their letterhead by the competent authority.
6. The study protocols.
7. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
8. In the case of multiple dose BE study adequate supporting safety data should be submitted.
9. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
10. Depending on the nature of the drug like cytoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

BE NOC for all the drug products in modified release form irrespective of their approval status:-

1. Application in Form-44 duly signed, by the competent authority with name and designation
2. Treasury Challan of Rs. 15000/- as per Drugs & Cosmetic Rules.
3. Undertaking by the Principal Investigator (PI) as per appendix VII of schedule "Y" of Drugs and Cosmetic Rules.
4. A copy of the approval of the BE study centre from CDSCO.
5. Sponsor's Authorization letter duly signed on their letterhead by the competent authority.
6. The study protocols.
7. Complete Certificate of Analysis of same batches (both test & reference formulations) to be used in the BE study.
8. In the case of multiple dose BE study adequate supporting safety data should be submitted.
9. In the case of Injectable preparation the sub-acute toxicity should be submitted on the product of the sponsor, generated in two species for adequate duration.
10. Depending on the nature of the drug like cytoxic agent, hormonal preparations etc. Proper justification for conducting studies on healthy volunteers/patients or male/ female should be submitted.

    All above requirements are general in nature, however depending on the nature of the drug, disease and studies further specific information may also be required to be furnished by the firm.

(A.K. Pradhan)
Asstt. Drugs Controller (India)