FAQs on BA/BE study for Export Application

1. **How to obtain permission for conduct of BA/BE study for Export purpose?**

Any person/sponsor or investigator who intends to conduct BA/BE study for Export of new drug or investigational new drug in human subjects should submit application in Form CT-05 to CLA along with necessary documents specified under Table 2 of fourth schedule and fees as specified under sixth schedule to obtain permission in Form CT-07.

Note: No fee shall be payable for conducting a bioavailability or bioequivalence study in human subjects by an institution or organization owned or funded wholly and partially by the Central Government or a State Government.

2. **What is the validity period of permission granted in Form CT-07?**

The permission to conduct bioavailability or bioequivalence study granted under rule 34 in Form CT-07 shall remain valid for a period of one year from the date of its issue, unless suspended or cancelled by the Central Licensing Authority.

In exceptional circumstances, where the Central Licensing Authority is satisfied about the necessity for an extension beyond one year, the said authority may, on the request of the applicant made in writing, extend the validity of permission granted for a further period of one year.

3. **What is the time line for grant of permission to conduct bioavailability or bioequivalence study for a new drug or investigational new drug in Form CT-07?**

The existing timeline for processing of applications for grant of BE permission and Import Licence will be followed if application is found complete in all aspects. Query will be raised against observed deficiencies. The query reply shall be submitted within 30 days from receipt of such query.

4. **Can I initiate study in human beings at any time after the approval of the CLA?**

The BA/BE study for Export shall be initiated by enrolling the first subject within a period of 1 year from the date of grant of permission, failing which, prior permission from the CLA shall be required before initiation of study.

5. What is the stability study conditions to be submitted while filing application for permission to conduct BA/BE study for Export?

A minimum of 3 months Accelerated and Long term stability data at the condition specified in Second schedule of New Drugs and Clinical Trials Rules, 2019 to be submitted along with application in Form CT-05.

6. What is the time line for intimation of protocol approval granted by Ethics committee to the Central Licensing Authority.

The Central Licensing Authority shall be informed about the approval granted by the registered Ethics Committee within a period of 15 working days of the grant of such approval.

7. In case of termination of BA/BE study for Export, should I inform CLA about the same?

Yes, in case of termination of any BA/BE study for Export, the detailed reasons for such termination shall be communicated to the CLA within 30 working days of such termination.

8. In case of SAE or study related death, should I have to inform CLA?

(i) In case of an injury during BA/BE study for Export of new drug or Investigational New Drug (IND) to the subject of such study, complete medical management and compensation shall be required to be provided in accordance with the Chapter VI of the Rules and details of compensation provided in such cases shall be intimated to the CLA within 30 days of the receipt of order the CLA.

(ii) In case of study related death or permanent disability of any subject, compensation shall be required to be provided in accordance with Chapter VI and

the same shall be intimated to CLA within thirty days of receipt of the order of the CLA.

9. What action can be taken for non-compliance to the rules in conduct of BA/BE study for Export?

Any sponsor or investigator to whom permission has been granted fails to comply with any provision of the Act and the rules, the CLA can execute one or more following actions:

(i) issue warning in writing describing the deficiency or defect observed during inspection or otherwise, which may affect adversely the rights, or well- being of a subject enrolled in the study or the validity of bioavailability or bioequivalence study conducted;

(ii) reject the results of BA/BE study for Export, as the case may be;

(iii) suspend for such period as considered appropriate or cancel the permission

(iv) debar the investigator or the sponsor including his representatives, to conduct any BA/BE study in future for such period as considered appropriate by the CLA.

10. How to apply for permission to manufacture new drug or investigational new drug for BA/BE study for Export?

Any person who intends to manufacture a formulation of new drug for BA/BE study for Export shall submit application in CT-10/CT-12 (as applicable), for obtaining permission from the respective Zonal offices to manufacture such new drug.

11. Where should I submit my application for obtaining permission to manufacture new drug or investigational new drug only for examination, test and analysis and not for CT or BA/BE study for Export?

Such application is required to be submitted to the respective Zonal offices of CDSCO.

12. What is the validity period of permission granted in Form CT-11 /CT-14 to manufacture a formulation or API of a new drug or an investigational new drug to conduct BA/BE study for Export?

The permission granted in Form CT-11/CT-14 to manufacture a formulation of a new drug or an investigational new drug to conduct BA/BE study for Export shall remain valid for a period of three years from the date of its issue, unless suspended or cancelled by CLA.

13. What I should do if a new drug manufactured under Form CT-11 /CT-14 crosses the specified shelf life?

If the new drug manufactured for purposes of CT or BA/BE study or for examination, test and analysis is left over or remains unused or gets damaged or its specified shelf life has been crossed or has been found to be of sub- standard quality, the same shall be destroyed and action taken in respect thereof shall be recorded.

14. How to apply for grant of licence to manufacture new drugs or investigational new drugs for CT or BA/BE study or for examination, test and analysis by SLA?

After obtaining permission in CT-11 or CT-14 as the case may be, the person, who intends to manufacture the new drug or investigational new drugs for CT or BA/BE study or for examination, test and analysis of new drugs or investigational new drugs, shall make an application for grant of licence to manufacture the new drug or investigational new drugs to the respective SLA in accordance with the provisions of the Act and the Drugs and Cosmetics Rules, 1945.

15. What is the labelling a new drug or investigational new drug manufactured under Form CT-11,CT-14?

Any new drug or investigational new drug manufactured under Form CT-11 & Form CT-14 shall be kept in containers bearing labels, indicating the name of the drug or code number, batch or lot number, wherever applicable, date of manufacture, use before date, storage conditions, name of the institution or organization or the center where the BA/BE study for Export is proposed to be conducted, name and address of the manufacturer, and the purpose for which it has been manufactured.

16. How to import a new drug for conducting BA/BE study for Export?

Any person or institution or organization who intends to import a new drug or any such substance for BA/BE study for Export shall make an application in Form CT-16 to the CLA. The application shall be accompanied by a fees specified in the Sixth Schedule and such other information and documents as specified in Form CT-16.

17. What is the fee required for Form CT-16 application?

The application shall be accompanied by fees of Rs. 5000/- for each product along with such other information and documents as specified in Form CT-16.

18. Where an application should be submitted for import of new drugs for BA/BE study or for examination, test and analysis?

In case of import of such drugs for BA/BE study, the application in Form-CT-16 should be submitted to the CDSCO, HQ. However, in case of import of such drugs only for examination, test and analysis and not for any CT, BA/BE study, the application in CT-16 should be submitted to the respective Zonal offices of CDSCO.

19. What is the validity period of licence granted in Form CT-17?

The licence granted under rule 68 in Form CT-17 shall remain valid for a period of 3 years from the date of its issue, unless suspended or cancelled by CLA.

20. Whether changes can be made after obtaining BE permission and Test Licence.

Applicant shall apply for amendment if there is any change in proposed study, for which permission to conduct BA/BE Study in Form CT-07 & Licence to import New Drugs/ Investigational New Drug in Form CT-17 has already been issued by this Directorate

Firm shall obtain amendment for approval for Major Changes and acknowledgement letter for the Minor Changes issued by Licensing Authority, before initiation of the study.

21. What is meant by a single application for BA/BE for Export purpose.

A single application for BA/BE studies for Export purpose means an application for conduct of Bioequivalence study accompanied by either single protocol or two

protocols i.e., Fasting and Fed study of same drug, same strength, same dosage form and same study design.