Central drugs Standard Control Organization
(BA BE Division for export)

FAQs on Prior Intimation Application for BA/BE study for Export Purpose under the New Drugs and Clinical Trial Rules, 2019 ammended as per G.S.R 50(E) dated 21.01.2026.

1. What is the amendment to the New Drugs and Clinical Trial Rules, 2019 under G.S.R 50(E) dated 21.01.2026?

The amendment allows an applicant to submit the application for single-dose, two-period, two-sequence, two-treatment BA-BE study design / protocol for **export purpose only** through a simplified prior intimation-based process which will be acknowledged by the CLA for conducting BA/BE studies in healthy adult volunteers, under specified conditions.

2. What types of BA/BE study design are covered under this amendment?

Single-dose, two-period, two-sequence, two-treatment BA/BE studies of oral dosage form of drugs in normal healthy adult human volunteers (for export purpose only).

3. What category of drugs is eligible under this prior intimation application process?

Test product must be Oral dosage forms of a drug (other than drugs of Cytotoxic, Hormone, Narcotic and Psychotropic substances categories and not a drug of Narrow Therapeutic Index or a drug having highly variable pharmacokinetics) and already approved in India or in any one of the following countries, namely, USA, EU, Japan, Australia, Canada, UK.

4. Whether such application is accepted for banned drugs or prohibited for manufacture/sale in any country for human use?

NO.

5. What is the role of the Ethics Committee (EC) under G.S.R 50(E) dated 21.01.2026.

In addition to the functions of ethics committee defined under NDCT Rules, 2019-

- The Ethics Committee shall review the study protocol and other related documents for the proposed BA/BE study for the Prior Intimation and upload the approval letter in the online portal.
- The Ethics Committee shall maintain separate records of review and approval of all such studies.

- These records are subject to review by the CLA at the time of EC registration renewal or at the time of any inspection or whenever required by the Central Licensing Authority.

6. Is there a limit on the sample size for such studies?

YES. The sample size shall be more than or equal to 18 healthy adult human volunteers.

7. Which form is to be used for submitting such prior intimation application?

The applicant shall submit online application as prior intimation in Form CT-05.

8. Is any fee applicable for such prior intimation based studies?

YES. A fee as specified in the Sixth Schedule of the NDCT Rules, 2019 must be submitted along with the application.

9. What documents and information need to accompany the application?

The application should include all information and documents as specified in Table 2 & Table 3 of the Fourth Schedule of the NDCT Rules, 2019.

10. How does this process differ from the existing BA/BE study approval?

- BA/BE studies for Export purpose only, under this amendment require only prior intimation and acknowledgment from CLA before initiation of the study.

- For all other purposes or categories not covered under the amended rules, the system of prior approval shall remain applicable.

11. Can studies on cytotoxic or hormonal drugs be notified under this rule?

NO. Drugs of Cytotoxic, Hormone, Narcotic and Psychotropic substances categories and a drug of Narrow Therapeutic Index or a drug having highly variable pharmacokinetics are excluded from this prior intimation application process and needs to be submitted through existing process of application.

12. Whether this prior intimation process is applicable to study designs such as three-period, three-sequence, and three-treatment, parallel, partial replicate or fully replicate designs, Multiple dose studies, etc.?

NO. The prior intimation process is restricted to **"single-dose, two-period, two-sequence, two-treatment**" bioavailability or bioequivalence studies conducted in normal healthy adult human volunteers, as per the provisions under the relevant amendment to the New Drugs and Clinical Trials (NDCT) Rules, 2019.

13. Who is the approving authority for such studies?

The Central Licensing Authority (CLA), i.e., the Drugs Controller General of India (DCGI) is the approving authority for such studies.

14. Is this process applicable to BA/BE studies for India submission?

NO. This prior intimation system applies only to studies conducted for export purposes.

15. What is the validity period of acknowledgement of prior intimation for such studies?

The acknowledgement of prior intimation under the proviso of Rule 31 (2) shall remain valid for a period of one year from the date of issue, unless suspended or cancelled by the CLA.

Further, 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 period of permission granted or the acknowledgment of prior intimation under the proviso to sub-rule (2) of rule 31 for a further period of one year.

16. Whether such application must only be accepted for the product approved in India or anyone of countries namely, USA, EU, Japan, Australia, Canada and UK?

YES. The application must only be accepted for the product approved in India or anyone of countries namely, USA, EU, Japan, Australia, Canada and UK.

17. Whether any changes shall be applicable post notification?

No changes shall be accepted after acknowledgement of prior intimation.

18. Whether the proposed provisions are applicable for modified release (MR), sustained release (SR), extended release (ER) formulations etc. as well as liquid oral dosage forms such as suspensions and emulsions?

YES. The provisions are applicable to all oral dosage forms, including modified release (MR), sustained release (SR), extended release (ER) formulations, as well as liquid oral dosage forms such as suspensions and emulsions, *etc*. except drugs of Cytotoxic, Hormone, Narcotic and Psychotropic substances categories and drug of Narrow Therapeutic Index or a drug having highly variable pharmacokinetics.

19. Whether this prior intimation application process is applicable to parenteral, transdermal, topical, or inhalation dosage forms?

NO. The prior intimation process is limited to oral dosage forms only and shall not applicable for parenteral, transdermal, topical, inhalation, or other non-oral routes of administration.

20. 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 Bioavailability or 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.

21. Whether for such studies, Test product of sponsor and Reference product/RLD should contain same active pharmaceutical ingredient, same dose, dosage form, strength, *etc.*?

YES.

22. How to import a new drug for conducting such studies?

Any person or institution or organization who intends to import a new drug or any substance for such studies shall make a separate application in Form CT-16 to the CLA through online portal and the existing system of prior approval shall remain applicable for import of such drugs.

Note: The FAQs are aimed only for creating public awareness about Prior Intimation of Application for BA/BE study for Export under the New Drugs and Clinical Trial Rules, 2019 and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules there under and respective Guidelines / Clarifications issued by CDSCO from time to time for their entire professional needs.