File No.: DC-DT-11013(11)/1/2025-eoffice-Part (3)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
O/o Drugs Controller General (I)

FDA Bhawan, New Delhi
Date: 20 APR 2026

CIRCULAR

Subject: Implementation of Prior intimation System for Form CT-05 application (for export purpose only) *w.e.f 21.04.2026* in pursuance of G.S.R 50(E) dated 21.01.2026-reg.

In pursuance of Gazette Notification **G.S.R. 50(E) dated 21st January 2026**, amendments have been made to the New Drugs and Clinical Trials Rules, 2019, introducing a system of **prior intimation**, which shall come into force after ninety (90) days from the date of its publication in the Official Gazette. Whereas, the aforesaid period of 90 days from the date of publication will be completed on **21.04.2026**, it is hereby notified that the provisions of said G.S.R. 50(E) shall come into force ***w.e.f* 21.04.2026**.

Accordingly, it is hereby informed that all stakeholders shall submit online application (for export purpose only) that are complying with requirements and provisions mentioned in the aforesaid Gazette Notification as **prior intimation** in Form CT-05 on Sugam portal.

It is hereby informed that as mentioned in Gazette Notification, the **Prior Intimation** System shall be applicable to following:

1. Single-dose, two-period, two-sequence, two-treatment, bioavailability or bioequivalence studies in normal healthy adult human volunteers (for export purpose only).
2. Oral dosage form of a drug, other than drugs of Cytotoxic, Hormone, Narcotic and psychotropic substances categories and Drugs with narrow therapeutic index or Drugs having highly variable pharmacokinetics.
3. Already approved in India or any one of the countries, namely, United States of America, European Union, Japan, Australia, Canada and United Kingdom.
4. The application of the **prior intimation** shall be accompanied with approval of the Ethics Committee registered with the Central Licensing Authority under rule 8 under New Drugs and Clinical Trials Rules, 2019.
5. The samples size shall be **more than or equal to eighteen (18)**.
6. Ethics Committee shall maintain a separate record of review and approval of such bioavailability or bioequivalence studies being conducted on the basis of the acknowledgement of **prior intimation**, which shall be reviewed by the Central Licensing Authority at the time of renewal of the Registration of the Ethics Committee or any inspection or whenever required by the Central Licensing Authority.

It may also be noted that once the application in Form CT-05 is submitted in online Sugam portal, the acknowledgment of application submission received from the portal may be treated as **"prior intimation"** and the concerned applicant can accordingly use this intimation for further use as required. ***For all other purposes or categories not covered under the amended rules, the existing system of prior approval shall remain applicable.***

This circular is issued for information and compliance by all stakeholders.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Copy for information and necessary action to:

1. All Divisions, Zonal/Sub-Zonal offices of CDSCO.
2. All State/UT Drug Controllers.
3. US (DR) Section
4. Office of JS (DR)
5. All stake holders though CDSCO website.