April 20, 2026

CDSCO

Some export BA/BE studies need only prior intimation from April 21

CDSCO's circular of April 20, 2026 brings in prior intimation in Form CT-05 on Sugam for certain export-only BA/BE studies from April 21, under G.S.R. 50(E).

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Office of the Drugs Controller General (India), Directorate General of Health Services, issued a circular under File No. DC-DT-11013(11)/1/2025-eoffice-Part (3), with a date stamp of April 20, 2026. Its subject is the implementation of the prior intimation system for Form CT-05 applications (for export purpose only) from April 21, 2026, under G.S.R. 50(E) dated January 21, 2026. It is signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) and Central Licensing Authority, and is issued for information and compliance by all stakeholders.

KEY FACTS

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The circular says G.S.R. 50(E) amended the New Drugs and Clinical Trials Rules, 2019 to bring in a system of prior intimation, which comes into force after ninety (90) days from the date of its publication in the Official Gazette. It states that this 90-day period will be completed on April 21, 2026, and notifies that the provisions of G.S.R. 50(E) come into force from that date. From then, stakeholders are to submit online applications (for export purpose only) that meet the notification's requirements as prior intimation in Form CT-05 on the Sugam portal.

As the circular lists them, the prior intimation system applies to: (1) single-dose, two-period, two-sequence, two-treatment bioavailability or bioequivalence (BA/BE) studies in normal healthy adult human volunteers, for export purpose only; (2) the oral dosage form of a drug, other than drugs of the cytotoxic, hormone, narcotic and psychotropic substances categories, drugs with a narrow therapeutic index and drugs with highly variable pharmacokinetics; (3) drugs already approved in India or in any one of the United States, European Union, Japan, Australia, Canada and United Kingdom; (4) applications accompanied by the approval of an Ethics Committee registered with the Central Licensing Authority under rule 8 of the rules; (5) a sample size of more than or equal to eighteen (18); and (6) the Ethics Committee keeping a separate record of its review and approval of studies conducted on the basis of the acknowledgment of prior intimation, which the Central Licensing Authority reviews at the renewal of the committee's registration, at any inspection, or whenever it requires.

Once a Form CT-05 application is submitted on the Sugam portal, the portal's acknowledgment of the submission may be treated as the "prior intimation", and the applicant can use it as required. For all other purposes or categories not covered under the amended rules, the existing system of prior approval remains applicable. Copies went to all CDSCO divisions and zonal and sub-zonal offices, all State and UT Drug Controllers, the US (DR) Section and the Office of JS (DR).

The circular does not state the fee or how long the acknowledgment stays valid; for the requirements, it points applicants to G.S.R. 50(E). It does not deal with importing the drug to be used in these studies.

Issued by	Central Drugs Standard Control Organization, Office of the Drugs Controller General (India), Directorate General of Health Services
Document	Circular, File No. DC-DT-11013(11)/1/2025-eoffice-Part (3)
Dated	April 20, 2026 (date stamp)
Takes effect	April 21, 2026, when, as the circular states, the 90 days from the publication of G.S.R. 50(E) are completed
Amending rules	G.S.R. 50(E), the New Drugs and Clinical Trials (Second Amendment) Rules, 2026, dated January 21, 2026; Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 50, January 22, 2026 (CG-DL-E-27012026-269595)
Applies to	Single-dose, two-period, two-sequence, two-treatment BA/BE studies in normal healthy adult human volunteers, for export purpose only
Drugs covered	Oral dosage forms, other than cytotoxic, hormone, narcotic and psychotropic drugs, narrow therapeutic index drugs and drugs with highly variable pharmacokinetics, already approved in India, the United States, European Union, Japan, Australia, Canada or United Kingdom
Conditions	Approval of an Ethics Committee registered under rule 8; a sample size of 18 or more; a separate Ethics Committee record, reviewed by the Central Licensing Authority at renewal of registration, at inspection or whenever it requires
How to file	Online application in Form CT-05 on the Sugam portal; the portal's acknowledgment may be treated as the prior intimation
Everything else	The existing system of prior approval
Related	CDSCO notice of May 22, 2026 (F.No. DC-DT-15011(11)/125/2025-eoffice): a standalone Form CT-16 application on the NSWS portal to import the reference or investigational drug for these studies
Related	Draft G.S.R. 790(E), September 3, 2026: would omit "(for export purpose only)" from the proviso to rule 31(2) of the NDCT Rules, 2019; no final rule on CDSCO's list of Gazette notifications, read October 28, 2026
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Central Licensing Authority

The circular (PDF, 3.9 MB)

Source: CDSCO's own copy.

Checked against the official copy on October 28, 2026.

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Read online: indusdesk.com/cdsco/insights/some-export-ba-be-studies-need-only-prior-intimation-from-april-21/