November 8, 2026

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Clinical trial approval in India: CT-04, CT-06, new drug permission

Clinical trial approval in India comes from the Central Drugs Standard Control Organization (CDSCO). The sponsor files Form CT-04 and gets permission on Form CT-06. The rules give ninety working days, or thirty for a drug discovered in India, and silence past that means deemed approval. Importing a new drug for sale needs Form CT-18.

YOU APPLY TO THE Central Licensing Authority at CDSCO on Form CT-04, with the data the Second Schedule lists and the fee (rule 21). The authority grants permission on Form CT-06, tells you about gaps you can fix, or rejects the application with reasons (rule 22(1)). A registered ethics committee must also approve the protocol (rule 19).

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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How is a clinical trial approved in India?

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1. Send the protocol to CDSCO and the ethics committee together

CDSCO's advisory of May 11, 2026 asks committees to review it without waiting for CDSCO's approval.

2. File Form CT-04 on SUGAM

A trial by a body the central or a state government funds or owns, wholly or partly, pays no fee (rule 21(2)).

3. Fix any gaps CDSCO points out

CDSCO then decides within ninety days of your reply (rule 22(3)).

4. Receive Form CT-06, or record a deemed approval

After a deemed approval, you tell CDSCO on Form CT-06A before the trial starts (rule 22(2A)).

5. Ask for reconsideration or appeal if refused

Ask within sixty working days of a rejection, or appeal to the Ministry of Health and Family Welfare within forty-five days (rule 22(3) and (4)).

For who decides what, start with CDSCO and how India regulates drugs, medical devices and cosmetics. See also our summary of parallel review.

How long does clinical trial approval in India take?

The rules give CDSCO ninety working days to decide a trial application (rule 22(2)). For a drug discovered in India, or researched here to be made and marketed here, the limit is thirty working days (rule 23). If you hear nothing in that time, the permission is deemed granted. These are outer limits in the rules, not promised dates.

Time limits in the New Drugs and Clinical Trials Rules, 2019

What CDSCO decides	Time limit	If there's no reply in time	Rule
Permission to run a clinical trial (CT-04 to CT-06)	90 working days	Deemed granted (Form CT-06A)	Rule 22(2) and (2A)
Trial of a drug discovered or researched in India	30 working days	Deemed granted (Form CT-4A)	Rule 23
Trial of a new drug approved in a rule 101 country	90 working days	Deemed granted	Rule 24
Making a new drug for a trial, a bioavailability and bioequivalence (BA/BE) study or testing (CT-10 to CT-11)	45 working days	Deemed granted	Rule 53, as amended by G.S.R. 46(E)
Importing a new drug for a trial, BA/BE study or testing (CT-16 to CT-17)	90 days	No deemed grant	Rule 68(1)
Importing a new drug for sale (CT-18 to CT-19 or CT-20)	90 working days	No deemed grant	Rule 76(1)

Some news reports said a January 2026 amendment halved the time to approve a clinical trial. It didn't. G.S.R. 46(E) cut the limits for making trial and test batches, in rules 53 and 60, from ninety to forty-five working days. Trial permission in rule 22 stays at ninety working days.

Can a local clinical trial be waived?

Sometimes. Under rule 75(7), an application to import a new drug for sale may go without a local clinical trial. The main route is a drug approved and marketed in a country CDSCO names under

rule 101, with no major unexpected serious adverse events reported. Other conditions apply, and the rule says the trial "may not be required": CDSCO decides.

- **Approval abroad:** approved and marketed in a rule 101 country (rule 75(7)(i)), or approved there while a global trial CDSCO permitted runs in India (rule 75(7)(ii)). Rule 101 countries are named by order: check the one in force.
- **No known difference in Indian patients:** no evidence that Indians differ in the enzymes, genes or other factors that affect how the drug works (rule 75(7)(iii)).
- **A Phase IV commitment:** a written undertaking to run a Phase IV trial on a design CDSCO approves (rule 75(7)(iv)).

The permission is Form CT-19 for an active ingredient or CT-20 for a formulation (rule 76(1)). A drug that is no longer new needs a Form 41 registration and a Form 10 licence instead: see drug import licences in India.

What changed for BA/BE studies in 2026?

Since April 21, 2026, some bioavailability and bioequivalence (BA/BE) studies done for export only can start on a prior intimation. You file Form CT-05 on SUGAM and begin once the portal acknowledges it, with no wait for permission. G.S.R. 50(E) of January 21, 2026 added this to rule 31(2). Every other BA/BE study still needs permission first.

- **The study:** single-dose, two-period, two-sequence, two-treatment, in healthy adult volunteers, with at least eighteen subjects and a registered ethics committee's approval (G.S.R. 50(E)).
- **The drug:** an oral dosage form of a drug already approved in India, the US, the EU, Japan, Australia, Canada or the UK. It can't be cytotoxic, a hormone, narcotic or psychotropic, a narrow therapeutic index drug or highly variable.

CDSCO's circular of April 20, 2026 set the start date (our summary of the CT-05 route). Importing the test product needs a standalone Form CT-16 on the National Single Window System, an interim step under CDSCO's notice of May 22, 2026 (our note on the standalone CT-16).

A draft of September 2026, G.S.R. 790(E), would delete "for export purpose only" from that rule. It is a draft, not law (our summary of the draft).

Which licence lets you import a new drug for a trial or test?

You need a licence in Form CT-17 to import a new or investigational drug for a clinical trial, a BA/BE study, or examination, test and analysis. You apply on Form CT-16, and CDSCO decides within ninety days (rules 67 and 68). Making trial batches in India instead takes a CT-10 application and a CT-11 permission (rules 52 and 53).

Since G.S.R. 46(E), batches only for analytical and non-clinical testing start on an acknowledged CT-10 prior intimation (rule 52(1), proviso). Sex hormones, cytotoxic drugs, beta lactams, biologics with live microorganisms, and narcotic and psychotropic drugs still need permission. No batch may be sold (rule 55).

What else changed for sponsors in 2026?

Three more 2026 changes touch sponsors. Applications to import and market new drugs approved nowhere, backed by Phase III global trials with Indian subjects, go to CDSCO's IND Division. Safety update reports run from the date of actual marketing. And CDSCO rejects long-pending global trial, BA/BE and ethics committee files on SUGAM left unanswered after three reminders.

- **The IND Division:** since CDSCO's circular of August 10, 2026 (our summary).
- **Safety update reports:** from launch, not approval, under CDSCO's advisory of April 21, 2026 (our summary).
- **Long-pending applications:** unanswered after three reminders, a fourth notice rejects the file and forfeits the fee, under CDSCO's notice of May 4, 2026.

New CDSCO notices on trials appear in our CDSCO tracker.

How IndusDesk helps with clinical trial approval

We help sponsors and CROs pick the route, prepare CT-04, CT-05, CT-16 and CT-18 files and replies to CDSCO, and follow new notices. The sponsor files the application, and every permission is CDSCO's to grant.

Public policy & advocacy →

Regulatory & trade advisory →

Talk to our desk about clinical trial approval Message us on WhatsApp

Frequently asked questions

Does time spent fixing gaps count toward the ninety working days?

No. Once you fix the gaps CDSCO points out, it decides within ninety days of your reply (rule 22(3)). The first limit is ninety working days from a Form CT-04 application, or thirty for a drug discovered in India (rules 22(2) and 23 of the New Drugs and Clinical Trials Rules, 2019).

What is deemed approval for a clinical trial in India?

If CDSCO doesn't reply within the time limit, the trial permission is deemed granted and legally valid. Before starting, you inform CDSCO on Form CT-06A, which goes on its record as the deemed approval (rule 22(2) and (2A)).

Can a new drug be approved in India without a local trial?

Yes, if rule 75(7)'s conditions are met, including approval and marketing in a country named under rule 101 and a Phase IV undertaking. CDSCO decides. See the conditions above.

What is Form CT-05?

Form CT-05 is the application to run a BA/BE study (rule 33). Since April 21, 2026, it is also the prior intimation for some export-only BA/BE studies, which start once SUGAM acknowledges it.

Sources

- New Drugs and Clinical Trials Rules, 2019 (G.S.R. 227(E)), CDSCO's compilation as amended to G.S.R. 778(E) of October 14, 2022: rules 19, 21 to 24, 31, 33, 52, 53, 55, 59, 67, 68, 75, 76 and 101 (PDF, 1.7 MB)
- G.S.R. 46(E), January 20, 2026: New Drugs and Clinical Trials (Amendment) Rules, 2026, paragraphs 1 to 5, 9 and 10 (prior intimation for test batches; 45 working days in rules 53 and 60) (PDF, 733 KB)
- G.S.R. 50(E), January 21, 2026: New Drugs and Clinical Trials (Second Amendment) Rules, 2026, paragraphs 1 to 3 (prior intimation in Form CT-05 for some export BA/BE studies) (PDF, 809 KB)
- CDSCO circular DC-DT-11013(11)/1/2025-eoffice-Part (3), April 20, 2026: the CT-05 prior intimation system from April 21, 2026 (PDF, 3.9 MB)
- CDSCO notice DC-DT-15011(11)/125/2025-eoffice, May 22, 2026: standalone Form CT-16 on the NSWS portal for export BA/BE imports (PDF, 3.5 MB)
- G.S.R. 790(E), September 3, 2026 (Gazette of September 9): draft amendment to rule 31, prior intimation beyond studies for export (PDF, 681 KB)
- CDSCO advisory ETHICS-11011/5/2026-e-office, May 11, 2026: parallel submission of trial applications to CDSCO and ethics committees (PDF, 345 KB)
- CDSCO circular ND-11011(13)/2/2026-eoffice, August 10, 2026: new drugs not approved anywhere, with Phase III global trials in India, go to the IND Division (PDF, 400 KB)
- CDSCO advisory PSUR/4/2026-eoffice, April 21, 2026: PSURs run from the date of actual marketing (PDF, 341 KB)
- CDSCO public notice IT-11011(11)/16/2026, May 4, 2026: rejection of long-pending SUGAM applications, extended to global trial, BA/BE and ethics committee files (PDF, 779 KB)

IndusDesk

hello@indusdesk.com · +91 11 4141 3939

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

Read online: indusdesk.com/cdsco/clinical-trial-approval/