CDSCO New Drug Pathway Worksheet

Classify the product under the NDCT Rules, pick the category, and settle the local trial position.

Step 1. Is it a new drug? Rule 2(1)(w) self-check

Tick every limb that applies. One tick makes the product a new drug and the CDSCO permission applies.

- ☐ (i) Substance (API or phytopharmaceutical) not used in India to any significant extent and not approved by the CLA for the proposed claims
- ☐ (ii) Approved drug proposed for a new indication, route, dosage form, strength or patient population
- ☐ (iii) Fixed-dose combination: approved drugs combined for the first time in a fixed ratio, or an approved combination with a changed ratio or ingredients
- ☐ (iv) Modified-release, sustained-release or delayed-release form, or a novel drug delivery system, of an approved drug
- ☐ (v) Vaccine, rDNA product, living modified organism, monoclonal antibody, stem cell derived product, gene therapeutic product or xenograft
- ☐ Four-year check: the molecule's first Indian approval is less than four years old, so it is still a new drug for every applicant

Step 2. Category

- ☐ Investigational New Drug: not approved for marketing in any country; trial applications in Form CT-04, permission in CT-06
- ☐ New Drug: new to India, seeking marketing permission in Form CT-18 (import) or CT-21 (manufacture)
- ☐ Subsequent New Drug: new claim, form, strength, route or population on an approved drug, or a second applicant inside the four-year window

Step 3. Local clinical trial position (Rule 101)

Approved in the US, UK, Japan, Australia, Canada or the EU, and in one of the five waiver categories of the August 2024 order:

- ☐ Orphan drug for a rare disease
- ☐ Gene therapy or cell therapy product
- ☐ New drug for use in a pandemic situation
- ☐ New drug for special defense purposes
- ☐ Significant therapeutic advance over the current standard of care

- ☐ Both waiver conditions hold: no evidence of a relevant difference in Indian metabolism or response, and a Phase IV study in India is committed
- ☐ Outside the categories: position prepared for the SEC (global data sufficiency, a bridging study, or an Indian Phase III trial)

Filing Checklist and CT Forms

Run the checks before Form CT-18 or CT-21 is filed. Tick as each item closes.

Regulatory status

- ☐ Indian and global approvals mapped with dates, indications and conditions
- ☐ SEC minutes for the molecule and therapeutic area reviewed
- ☐ Prior CDSCO correspondence and decisions collected

Evidence

- ☐ Clinical package mapped to the proposed Indian indication
- ☐ Non-clinical abbreviation claimed and justified where allowed
- ☐ Zone IVb stability (30 °C / 75% RH) for the proposed shelf life
- ☐ Bioequivalence data for a subsequent-applicant or new-form filing

Application

- ☐ CT-18 or CT-21 matched to the import or manufacturing model
- ☐ Dossier in CTD format against the NDCT Second Schedule
- ☐ Cross-module consistency check done (indication, specification, label, classification)
- ☐ SEC presentation and question bank prepared with clinical input

Post-approval plan

- ☐ PSUR cadence resourced: six-monthly for 2 years, then annual for 2 years
- ☐ Phase IV commitment scoped where a waiver or accelerated route is used
- ☐ Downstream import or State manufacturing license sequenced

CT forms at a glance

Purpose	Apply	Permission
Clinical trial	CT-04	CT-06
BA/BE study	CT-05	CT-07
Manufacture for trial / test and analysis	CT-10	CT-11
Import new drug for sale	CT-18	CT-19 (API) / CT-20 (formulation)
Manufacture new drug for sale	CT-21	CT-22 (API) / CT-23 (formulation)

Review targets: 90 working days for applications with SEC review and for CT-04; 30 working days with deemed approval for a drug discovered or developed in India (Rule 23).

Notes and open gaps

Get the classification, the waiver position and the gap list before drafting.

EvySaif is a clinician-led regulatory and medical writing consultancy for CDSCO, GCC and EU submissions.

evysaif.com | info@evysaif.com | +91 94135 73253