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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Drug import licence in India: Form 41 registration and Form 10

A drug import licence in India comes in two parts. The foreign factory and its drugs need a registration certificate in Form 41, applied for on Form 40. The importer needs an import licence in Form 10 (10A for Schedule X), applied for on Form 8. Each lasts three years, and imported drugs need a year of shelf life left.

IMPORTING A DRUG FOR sale needs two approvals under the Drugs Rules, 1945. A registration certificate in Form 41 covers the foreign factory and its drugs (rules 21(e) and 27A). An import licence in Form 10 then lets the importer bring them in (rule 23). Schedule X drugs take Form 10A instead.

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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What two approvals does a drug import licence in India need?

Importing a drug for sale needs two approvals under the Drugs Rules, 1945. A registration certificate in Form 41 covers the foreign factory and its drugs (rules 21(e) and 27A). An import licence in Form 10 then lets the importer bring them in (rule 23). Schedule X drugs take Form 10A instead.

1. Register the factory and its drugs

Apply on Form 40 with the information in Schedules D-I and D-II (rule 24A(1)). The certificate is Form 41.

2. Apply for the import licence

Apply on Form 8 (8A for Schedule X), with a copy of the Form 41 and the maker's undertaking in Form 9 (rule 24).

3. Have the licence decided

The licensing authority weighs your storage premises and your line of business (rule 25A).

4. Repeat for each factory

Factories in different places each need their own certificate and licence (rules 25 and 25B).

The role of the Central Drugs Standard Control Organization (CDSCO) is in our guide to CDSCO and how India regulates drugs. A drug new to India first needs import permission under the New Drugs and Clinical Trials Rules, 2019, applied for on Form CT-18 (rules 75 and 76): see clinical trial approval and new drug permission.

Who can apply for Form 41 and Form 10?

The foreign maker can apply itself if it holds an Indian wholesale drug licence. Otherwise its authorized agent in India applies, holding an Indian licence to make drugs for sale or a wholesale licence. The same applies to Form 40 for the certificate and Form 8 for the import licence (rules 24A(1) and 24(1)).

The maker's factory must be approved by its own country's regulator, with a free sale approval there or in other major countries (rule 21(d)).

The agent holds the maker's power of attorney, authenticated before a First-Class Magistrate in India, or abroad before an equivalent authority with Indian Embassy attestation (rule 24A(2)). The applicant pays for any inspection of the factory, and pays testing fees straight to the laboratory (rule 24A(5) and (6)). For devices, see our guide to the Indian authorized agent.

Which drug imports need no Form 41 registration certificate?

An inactive bulk substance used to make a formulation needs no Form 41 registration certificate (rule 24A(8)). Rule 24(2) also exempts in vitro diagnostic (IVD) kits and reagents, except kits notified as drugs, and lets the authority issue Form 10 without one in an emergency, with central government approval.

IVD kits now follow the device rules

IVDs are medical devices under the Medical Devices Rules, 2017 (rule 3(zb)), which override the Drugs Rules (rule 96). Their import licence is MD-15: see medical device import licences.

How long does a Form 41 take, and how long are Form 41 and Form 10 valid?

A Form 41 registration certificate issues within nine months of a complete application, extendable by three months in exceptional cases (rule 27A). The certificate and the Form 10 import licence each last three years (rules 28 and 28A). Apply for fresh ones nine and three months before expiry.

Time limits and validity in the Drugs Rules, 1945

Approval	Time to issue	Valid for	Apply for a fresh one	Rule
Registration certificate (Form 41)	Nine months, plus up to three in exceptional cases	Three years	Nine months before expiry	Rules 27A and 28A
Import licence (Form 10 or 10A)	None set in rule 27	Three years	Three months before expiry	Rules 27 and 28

Applied for on time, the old approval stays in force until a decision. These are limits in the rules, not a forecast.

How much shelf life must an imported drug have?

An imported drug needs at least one year of shelf life left on the date of import, or 60% of its labeled shelf life for biological drugs and radiopharmaceuticals. G.S.R. 951(E) of October 16, 2026 set this in rule 31, in force from its Gazette publication on October 28. The old rule required 60% for every drug.

G.S.R. 951(E) followed the draft G.S.R. 505(E) of June 22, 2026. CDSCO's compiled Drugs Rules still print the old 60% rule.

Shipments already ordered get no transition period, because G.S.R. 951(E) took effect on publication. The licensing authority may still allow a shorter shelf life in exceptional cases, with reasons in writing, but never past the expiry date (rule 31, third proviso). See our insight on the final shelf life rule.

Through which ports and airports can drugs be imported into India?

Drugs may enter India only through the places listed in rule 43A of the Drugs Rules: named seaports, inland container depots, land border crossings and twelve airports, the newest Navi Mumbai since July 2026. A draft of October 28, 2026 would add Noida International Airport and more depots.

Airports for drug imports under rule 43A

Airport	Status	Instrument
Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa, Bengaluru and Visakhapatnam	On the list	Rule 43A
Cochin and Thiruvananthapuram	In force May 28, 2024	G.S.R. 293(E)
Navi Mumbai	In force July 3, 2026 (notified July 2)	G.S.R. 561(E)
Noida International Airport	Proposed in a draft of October 28, 2026	Draft G.S.R. 954(E)

The same draft would add inland container depots in Haryana, Uttar Pradesh, Gujarat, Hyderabad and Bengaluru, and a special economic zone in Karnataka. It is a draft (our insight on the draft).

On October 7, 2025, CDSCO asked Customs to send bills of entry on ICEGATE to its port offices, and to admit drugs, devices and cosmetics only at notified ports. Clearance itself is in our guide to customs in India, and import rules in our guide to India's import policy.

What happens if an imported drug consignment fails testing?

If the government laboratory finds a consignment not of standard quality and the fault can't be remedied, Customs sends you the report. Within two months you must re-export the drugs to their country of manufacture or forfeit them for destruction (rule 41(1)). You may contest the report within fifteen days.

Customs may sample a doubtful consignment and hold it until the report, or release it on your written undertaking not to dispose of it; asked to return it, you have ten days (rule 40).

Can you import drugs for tests, for a patient or for personal use?

Yes, in small amounts. A Form 11 licence covers drugs for examination, test or analysis. A Government hospital may import a new drug not yet approved in India for patients with life-threatening disease, on a Form CT-25 licence. A traveler may carry up to one hundred average doses of a drug for personal use.

Imports outside the Form 10 route

Purpose	Application	Permission and limit	Rule
Examination, test or analysis	Form 12	Licence in Form 11, small quantities	Drugs Rules, rules 33 and 34
Patients at a Government hospital or Government medical institution	Form CT-24, by a medical officer, certified by the hospital or institution head	Licence in Form CT-25, for a drug approved in its country of origin; up to 100 average doses per patient	New Drugs and Clinical Trials Rules, 2019, rules 86 and 87
Personal use, in baggage	None; declare to Customs if asked	Up to 100 average doses of a drug; more only by sanction	Drugs Rules, rule 36
Personal use, not in baggage	Form 12A, with a prescription	Permit in Form 12B	Drugs Rules, rule 36

A draft of June 23, 2026, G.S.R. 509(E), would let you import drugs for analytical and non-clinical testing on an acknowledged prior intimation instead of a Form 11 licence, with some drug classes left out. It is a draft (our insight on the draft).

What can stop a drug import into India?

A drug banned in its country of origin can't be imported under any name, except for examination, test or analysis (rule 30B). Since August 2026, an applicant who files misleading, fake or

fabricated documents may be debarred (rule 29B). And the Act bars misbranded, adulterated or spurious drugs (section 10).

Rule 29B came in with G.S.R. 706(E) of July 30, 2026, after a notice to show cause, with an appeal to the central government within thirty days (our insight on debarment).

The central government may also ban a drug's import in the public interest (section 10A). A broken condition can suspend or cancel a licence or certificate (rules 29 and 29A). New bans and notices appear on our CDSCO tracker. Drug prices are NPPA's work, not CDSCO's: see our NPPA insights.

How IndusDesk helps with a drug import licence

We watch the authorities, tell you what each change means for your products and plans, represent you while a decision is still open, and carry the work through, with every step on record in your workspace.

We work out which approvals each drug needs, prepare the Form 40 and Form 8 files for the maker or its agent to submit, and track renewals and notices. We aren't anyone's authorized agent or importer, and never promise a licence: CDSCO decides.

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Frequently asked questions

Can I import a drug with less than a year of shelf life?

Only in exceptional cases, with the licensing authority's reasons in writing (rule 31). Biological drugs and radiopharmaceuticals may come in with 60% of labeled shelf life.

Do IVD kits need a Form 41?

No. Rule 24(2) exempts them, except kits notified as drugs. IVDs are medical devices under the Medical Devices Rules, 2017, imported on an MD-15 licence.

How much medicine can a traveler bring into India?

Up to one hundred average doses of any single drug, in personal baggage for the traveler's own use (rule 36). More needs the licensing authority's sanction, in an exceptional case.

Sources

- The Drugs Rules, 1945 (CDSCO compilation, as amended by G.S.R. 360(E) of July 1, 2024), Part IV: rules 21, 23 to 25B, 27 to 31, 33, 34, 36, 40, 41 and 43A (PDF, 7.1 MB)
- G.S.R. 951(E), Drugs (Thirteenth Amendment) Rules, 2026, October 16, 2026 (Gazette of October 28, 2026): rule 31, second proviso (PDF, 572 KB)
- G.S.R. 505(E), draft amendment of rule 31 (residual shelf life), June 22, 2026 (PDF, 692 KB)
- G.S.R. 293(E), Drugs (Third Amendment) Rules, 2024, May 28, 2024: Cochin and Thiruvananthapuram added to rule 43A (PDF, 717 KB)
- G.S.R. 561(E), Drugs (Ninth Amendment) Rules, 2026, July 2, 2026: Navi Mumbai added to rule 43A (PDF, 1.1 MB)
- G.S.R. 954(E), draft amendment of rule 43A, October 28, 2026 (a draft) (PDF, 616 KB)
- CDSCO letter IMP-12018(19)/13/2025-eoffice, October 7, 2025: mapping of ICEGATE with CDSCO-notified ports (PDF, 2.3 MB)

- G.S.R. 509(E), draft amendment of rules 33 to 35 (prior intimation for test imports), June 23, 2026 (a draft) (PDF, 1.2 MB)
- G.S.R. 706(E), Drugs (Eleventh Amendment) Rules, 2026, July 30, 2026 (Gazette of August 5, 2026): rule 29B (PDF, 759 KB)
- The Drugs and Cosmetics Act, 1940 (CDSCO copy): sections 10 and 10A (PDF, 686 KB)
- The Medical Devices Rules, 2017 (CDSCO compilation): rules 3(zb), 36 and 96 (PDF, 1.6 MB)
- The New Drugs and Clinical Trials Rules, 2019 (CDSCO compilation): rules 75, 76, 86 and 87 (PDF, 1.7 MB)

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