

GMP Certification for Supplements, Ayurveda and Medicines From India

Yash Khatri

Founder, SourcingFrom

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GMP means different things depending on who stamped it. An Indian state licence under revised Schedule M, a WHO-GMP certificate or CoPP from CDSCO, a Schedule T licence for Ayurveda and US cGMP under 21 CFR 111 are four separate things, and the US version is never "certified" by the FDA at all. This guide shows importers what to ask for and how to check it, and walks Indian makers through the steps.

The Short Version

- The FDA does not issue GMP certificates for supplements. A US importer is responsible for buying from a maker that follows 21 CFR 111.
- A WHO-GMP certificate or CoPP from India is issued by the regulator after a joint inspection, and it names products. Check the product is on it.
- 110 of the 469 firms on the US drug GMP import alert (66-40) were Indian on 23 Sep 2026. Check the list before you order.
- GMP covers the process. It is not a batch test. Test heavy metals yourself.
- Ayurvedic makers work under Schedule T, and a CoPP for an Ayush product is issued by CDSCO in consultation with the Ministry of Ayush.

What does "GMP certified" on an Indian supplier's brochure actually mean? Honestly, it could mean four different things, and only one of them might be what your regulator expects.



India is one of the world's biggest makers of generic medicines, herbal extracts and Ayurvedic products, so the question comes up constantly. This guide is part of our [certifications hub](#). It covers the GMP layer. The product-level rules for ashwagandha and other botanicals are on our [Ayurvedic supplements page](#).

1. Four Kinds of GMP You Will See From India

Revised Schedule M. This is India's legal GMP for medicines, in the Drugs Rules, 1945. A drug manufacturing licence from the state licensing authority depends on it. Larger makers had to comply first, and the health ministry extended the deadline to 31 December 2025 for MSME makers with turnover up to Rs 250 crore that applied for it (G.S.R. 127(E), 11 Feb 2025, as reported). From 2026 it applies to everyone making drugs.

Schedule T. This is the GMP for Ayurvedic, Siddha and Unani medicines in the same Drugs Rules, alongside Schedule M-I for homoeopathy (Parliament answers on Ayush quality). An Ayush manufacturing licence depends on it.

WHO-GMP and the CoPP. A Certificate of Pharmaceutical Product is the WHO-format certificate that a buying country's regulator can ask for. In India CDSCO issues it after a joint inspection by its zonal office and the state licensing authority (CDSCO GMP inspection list, 2025). For Ayush products, CDSCO issues the CoPP in consultation with the Ministry of Ayush. CDSCO's published Ayush CoPP list shows a validity of three years from issue, or the manufacturing licence's validity if that ends first (CDSCO, 16 Jun 2020).

US cGMP (21 CFR 111) for dietary supplements. This is a US rule, not a certificate. Anyone who makes, packs, labels or holds a supplement for the US market must follow it. The FDA inspects but doesn't certify. When an Indian brochure says "US FDA GMP certified" for a supplement, what it usually means is a private audit against 21 CFR 111 by a commercial body, which can be useful, or a registration number, which proves nothing about GMP at all.

What you see	Who issues it	What it proves
Schedule M licence	State drug regulator	Legal right to make drugs in India
Schedule T licence	State Ayush licensing authority	Legal right to make Ayush medicines
WHO-GMP / CoPP	CDSCO with the state (and Ayush ministry)	Regulator inspected the site to WHO GMP, named products
"21 CFR 111 compliant"	Nobody official, often a private auditor	Only as good as the auditor's report

2. What Your Market Wants

- **US, supplements.** No certificate is required, but you as the importer must buy from a maker following 21 CFR 111, and the FDA can refuse goods made under conditions that don't meet it. For a supplement that makes a disease claim, the FDA treats it as an unapproved new drug – that was the charge on 945 of 1,277 refused Indian supplement lines in our count of FDA refusal data.
- **US, drugs.** The site needs FDA drug establishment registration and is inspected by the FDA. Import Alert 66–40 (drug GMPs not met) held 110 Indian firms out of 469 on 23 Sep 2026, about a quarter of the list.
- **EU and UK, medicines.** A non-EU site needs a GMP certificate from an EU or UK inspection, or coverage under a mutual recognition agreement. India has no such agreement with the EU, so check the EudraGMDP database or the MHRA for the site.
- **EU and UK, food supplements.** Treated as food. GMP is not a legal certificate. The buyer usually asks for a food safety scheme (see [food safety certifications](#)).
- **Australia.** Medicines and listed complementary medicines go through the TGA, which assesses overseas makers' GMP. Check the current pathway with the TGA.
- **Gulf, Africa, Southeast Asia.** Many regulators ask for the CoPP when registering a product. That's where WHO-GMP from India does the most work.

3. What an Importer Should Check

Step 1 – Ask which GMP, from whom. Get the actual document, not the brochure line. A Schedule M or Schedule T licence, a CoPP or WHO-GMP certificate, or a named third-party audit report.

Step 2 – Check the product is named. A CoPP lists products. A WHO-GMP certificate may name dosage forms. If your ashwagandha capsule isn't on it then the certificate doesn't cover it.

Step 3 – Check the dates against the licence. The CoPP can't outlive the manufacturing licence. Ask for the licence too.



Step 4 – Check the FDA lists. Search the maker on the FDA import alerts for India, especially 66–40 (drug GMPs), 66–41 (unapproved new drugs promoted in the US) and 99–42 (heavy metals). Our count found 26 Indian firms on 99–42, all added since 2021 (FDA pages, 23 Sep 2026). How to read them is in our [FDA import alerts guide](#).

Step 5 – Check for warning letters. Search the maker's name in the FDA warning letter database. A closed letter with a fix is a good sign. An open one isn't.

Step 6 – Test the batch yourself. GMP covers the process, not the batch. US buyers of Indian botanicals have long retested heavy-metal certificates of analysis, and a user on r/Ayurveda put it plainly back in 2017 – GMP is for the manufacturing process and "technically it should cover QC part but legally it is not so" (forum signal FS-CAT-082). Choose the lab and have an independent person draw the sample.

Red flags

- "FDA approved factory" for a supplement maker. There's no such thing.
- A CoPP with no product list.
- A trader quoting a GMP certificate that belongs to the contract maker. Contract manufacturing is normal and often the right model, but know whose site it is and who answers for quality.
- A heavy-metals result with no lab name or accreditation number.

4. How an Indian Maker Gets WHO-GMP or a CoPP

This half is for Indian manufacturers of medicines and Ayush products. Check every current form, fee and timeline on the CDSCO and SUGAM portals and your state drug controller's site.

Who issues what

- **State licensing authority.** The manufacturing licence and the Schedule M or Schedule T compliance behind it.
- **CDSCO** (Central Drugs Standard Control Organisation). The WHO-GMP certificate and CoPP, through joint inspection with the state.
- **Ministry of Ayush.** Consulted on CoPP for Ayurvedic, Siddha and Unani products.

- **Quality Council of India.** Runs the voluntary Ayush Mark scheme for third-party quality certification of Ayush products (Parliament answers).

Eligibility

You need a valid manufacturing licence, a site that meets revised Schedule M (or Schedule T for Ayush), products already licensed, and stability and validation data. If you are an MSME that relied on the 2025 extension, finish the upgrade first. A WHO-GMP inspection on a site still mid-upgrade wastes a slot.

The steps

Step 1 – Gap check against revised Schedule M or Schedule T. Walk the plant against every clause, including the pharmaceutical quality system, quality risk management, validation and the computer systems that hold your records. About four to eight weeks.

Step 2 – Fix and document. Close the gaps, write the site master file, validate the processes and cleaning, and qualify the equipment. This is the long step, often three to nine months for an older plant.

Step 3 – Apply. File the application for WHO-GMP or CoPP through the CDSCO process (for Ayush products, the Ayush CoPP route), with the site master file, product list, licences and product data. Check the current fee on the portal.

Step 4 – Joint inspection. CDSCO's zonal or sub-zonal office and the state authority inspect together. Under the CDSCO procedure as reported, processing runs about 21 working days without a joint inspection and 28 with one, and the CoPP issues within about 5 days of a positive recommendation. Check current timelines with CDSCO.

Step 5 – Close the observations. Send evidence for each observation. The certificate issues once they're closed.

Step 6 – Add products later. Sites inspected and found compliant within the last two years can usually add products to the CoPP on product data alone, without a fresh inspection (as reported from the CDSCO procedure).

For US supplement buyers specifically

There's no Indian or US certificate to apply for. Write your quality system to 21 CFR 111 (identity testing of every dietary ingredient, specifications, batch records, complaint handling), register the facility with the FDA as a food facility (see [FDA food facility registration](#)) and expect the buyer to send an auditor or ask for a third-party audit. Read the current text of Part 111 on eCFR yourself. I couldn't read it at source for this guide.

Validity and renewal

The CoPP runs three years or until the manufacturing licence ends, whichever is first (CDSCO Ayush list). Renewal means another joint inspection, and CDSCO's 2025 inspection list shows renewals going through the same joint teams.

Common reasons for refusal

- Data integrity gaps, like backdated records and shared logins on lab instruments.
- No validation for cleaning between products.
- Water systems not qualified.
- Ayurvedic products with claims that read as drug claims in the buyer's country.
- Heavy metals in raw herbs with no supplier testing.

What to send the buyer

The licence, the CoPP or WHO-GMP certificate with the product list, the latest inspection outcome, batch certificates of analysis from an accredited lab, and your FDA registration number if they sell in the US.

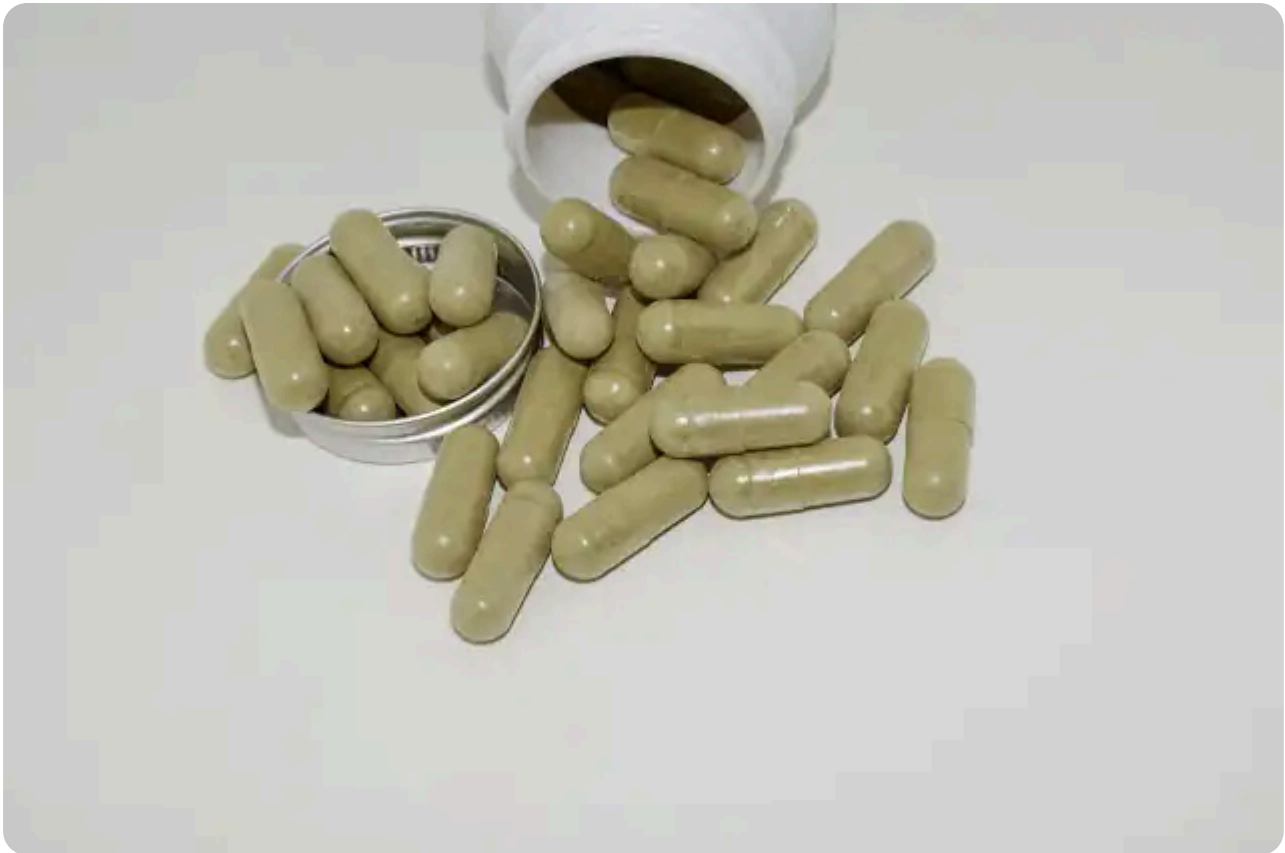
Getting a plant through Schedule M and a joint inspection is months of work. If you need someone to run the readiness and keep the observations moving, [SourcingSync](#) does that.

5. A Worked Example With Ashwagandha Capsules for the US

This example is an illustration built from the rules above, not a real firm.

Say you're a US brand buying ashwagandha root capsules from a maker in Gujarat. The maker sends a WHO-GMP certificate, an Ayush licence and a CoPP.

That's a good start, but the CoPP is a document for regulators that ask for it, and the FDA doesn't. So you check the maker against the FDA alerts for India, look at the 99-42 heavy-metals list and 66-41, and search for warning letters. You confirm "root only" in the spec and the extraction solvent. You then commission identity and heavy-metal testing on the first batch in a lab you choose, because under 21 CFR 111 the responsibility for identity sits with the supply chain, and the FDA will ask you, not the maker in Gujarat.



6. Frequently Asked Questions

Does the FDA certify GMP for Indian supplement makers? No. The FDA inspects. It doesn't issue GMP certificates for supplements.

Is WHO-GMP the same as US cGMP? No. They overlap a great deal, but they're different rule sets with different inspectors.

Is a CoPP needed for food supplements? Usually not, because most markets treat supplements as food. It's needed where the product is registered as a medicine.

What is the Ayush Mark? A voluntary quality certification for Ayurvedic, Siddha and Unani products run by the Quality Council of India. Check its current scope with QCI.

7. Next Steps

- All certificate guides in the [certifications hub](#).
- Ashwagandha and herbal products from India on [Ayurvedic supplements](#).
- Check makers against [FDA import alerts](#).
- Register for the US with [FDA food facility registration](#).
- Food scheme certificates in [food safety certifications](#).
- Test before you ship with [food import testing](#).