

CDSCO Submission Guide

Healthcare

Document type: Licence / statutory filing · Generated 15 Oct 2026

This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Guides an India CDSCO submission — the application type, relevant forms and SUGAM-portal route, documents required and approximate timelines. Use this for the filing route; for the regulatory narrative sections use the Pharma Regulatory Writing tool.

Purpose of this tool & output

Guide an India drug/device filing

How the output is used

Use the guide to prepare an India drug/device filing to CDSCO with the right dossier and process.

Who receives it

The Central Drugs Standard Control Organisation (CDSCO), via the SUGAM portal.

How to submit / file it

File on SUGAM with the application form, dossier and fees for your category (drug/device/clinical trial).

Fees & charges

Application fees vary by category and application type, as notified by CDSCO.

Who should vet it

A regulatory-affairs consultant experienced with CDSCO submissions.

Important cautions

AI-generated guide; CDSCO requirements are detailed and change; use a regulatory expert.

Companion documents

- Pharma Regulatory Writing
- Study Protocol Synopsis
- Patient Information Leaflet
- Pharmacovigilance / AE Narrative
- Product Monograph Draft

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and

processes vary by state and change over time — confirm with your state authority.