

Product Permission / Registration

Pharma, Chemicals & Life Sciences

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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

Explains product permission and registration — product permission from the licensing authority, new drug approval if applicable, and the documents (formulation, specs, stability, method) — with a note on when central approval is needed. Use this to register a product for manufacture. Requirements depend on the product category; confirm with a regulatory expert.

Purpose of this tool & output

Register your product for manufacture

How the output is used

Use it to prepare a product permission or registration for a formulation you want to make, with the data and documents the authority expects.

Who receives it

The State Licensing Authority for standard products, or CDSCO (DCGI) for new drugs and specified categories.

How to submit / file it

File the product permission application with the formulation, specifications and labels through the state portal or SUGAM (CDSCO); new drugs need clinical or bioequivalence data.

Fees & charges

A per-product government fee that varies by category and authority.

Who should vet it

A regulatory affairs professional; new-drug work needs a CDSCO-experienced consultant.

Important cautions

AI-generated guide; requirements depend on product category, confirm with a regulatory expert.

Companion documents

- [CDSCO Regulatory Primer](#)
- [Drug Manufacturing Licence Guide](#)
- [Regulatory Dossier Structure](#)
- [Drug Labeling Compliance](#)
- [Regulatory Strategy Planner](#)
- [Import Licence & Registration](#)

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.