

Registration of Indian drug product in overseas market

Procedure for Export of Pharmaceutical Products from India

Key Regulatory Bodies Involved:

- **CDSCO** – Central Drugs Standard Control Organization
- **DGFT** – Directorate General of Foreign Trade
- **Pharmexcil** – Pharmaceutical Export Promotion Council of India
- State Drug Licensing Authorities
- Indian Customs Department

Step-by-Step Export Process:

Step 1: Obtain Manufacturing License

- Must have a valid manufacturing license issued by the State Drug Authority.
 - **Form 25** – For non-sterile products
 - **Form 28** – For sterile products

Step 2: Obtain Import Export Code (IEC)

- Required for any exporter.
- Issued by DGFT.

Step 3: Product Registration in Importing Country

- Required by the drug regulatory authority of the importing country.
- Examples: FDA (USA), EMA (Europe), PMDA (Japan), etc.

Step 4: Prepare Regulatory Dossier

- Documentation in CTD, eCTD, or ACTD format.
- Includes quality data, bioequivalence studies, and DMF references.

Step 5: Obtain WHO-GMP Certification

- Issued by CDSCO or State FDA to demonstrate compliance with Good Manufacturing Practices.

Step 6: Apply for Export NOC (if applicable)

- Some APIs or formulations may need a No Objection Certificate (NOC) from CDSCO before export.

Step 7: Customs Clearance and Shipment

- Provide required documents at the port of export:
 - Commercial Invoice

- Packing List
- Certificate of Analysis (CoA)
- Certificate of Pharmaceutical Product (COPP)
- Certificate of Origin (COO)
- Shipping Bill

Export of Drugs from India – Key Labelling Rules

Rule 94: Packing and Labelling (Non-Homeopathic Drugs)

- Labels for export must comply with the importing country's laws and include:
 - Drug name
 - Manufacturer's name, address, and license number
 - Batch/lot number
 - Expiry date
- Additional label details:
 - Supplier's name and address
 - Patient's name and quantity
 - Prescription entry number
 - Dose (if for internal use)
 - **"FOR EXTERNAL USE ONLY"** (if applicable)

Rule 95: Sale/Distribution Prohibited Without Proper Labelling

- Drugs must not be sold or distributed unless labelled as per these rules.

Rule 96: Mandatory Label Details

- Drug labels must be in indelible ink and clearly visible on all packaging, including:
- Proper drug name (more prominent than trade name)
- Based on classification:
- Depending on classification, the label should comply with:
 - Schedule F / F1
 - Indian Pharmacopoeia or Rule 124 standards
 - National Formulary of India (N.F.I.)
 - International Nonproprietary Names (INN) or WHO descriptive names

Technical Documentation for Export and Product Registration

Common Technical Document (CTD)

A harmonized format adopted by many global regulatory bodies.

Divided into five modules:

Module 1 – Regional Information

- Cover letter
- Application form
- Product Information (labeling, package inserts)
- Certificates:
 - GMP
 - Certificate of Pharmaceutical Product (CPP or CoPP)
- Product Registration Certificates
- Legal documents (Power of Attorney, Manufacturing Agreement)
- Site Master File
- Fee Payment Proof

Module 2 – Summary Documents

- Overall Summary
- Quality Overall Summary
- Nonclinical Overview
- Clinical Overview

Module 3 – Quality

A. Drug Substance

- Name, structure, general properties
- Manufacturer information
- Manufacturing process and controls
- Specifications
- Analytical procedures and validation
- Stability data

B. Drug Product

- Composition of the product
- Pharmaceutical development report



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