IV

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PHARMACEUTICAL EXPORT-IMPORT COMPLIANCE

US-FDA Inspections, WHO-GMP Certification, EU-GMP, and the D&C Import Rules for the Indian Pharmaceutical Exporter

Pharmaceutical Export-Import Compliance

US-FDA Inspections, WHO-GMP Certification, EU-GMP, and the D&C; Import Rules for the Indian Pharmaceutical Exporter

A Practitioner's Handbook for the Pharmaceutical Industry

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FOREWORD

India exported US$ 30.47 billion in pharmaceutical products in FY 2024-25, a 9.4% increase over FY 2023-24. Indian pharmaceutical products reach over 200 countries, with the United States absorbing approximately 34% of exports. India supplies over 60% of the world's vaccines and 20% of global generic medicines. The domestic market stands at approximately US$ 60 billion (FY25), projected to reach US$ 130 billion by 2030.

Yet behind this commercial success lies a demanding multi-jurisdictional regulatory architecture. A single US-FDA warning letter can close an export facility. An EU-GMP non-compliance finding can block access to the entire European market. A WHO prequalification lapse can exclude a manufacturer from global tender procurement. This handbook maps the complete export-import compliance framework for the Indian pharmaceutical manufacturer.

PART I — THE EXPORT REGULATORY ARCHITECTURE

Chapter 1: Overview of Indian Pharmaceutical Exports

1.1 Market Structure

1.2 Regulatory Agencies Governing Indian Pharma Exports

PART II — US-FDA COMPLIANCE

Chapter 2: The FDA Inspection Framework

2.1 Types of FDA Inspections

2.2 FDA Form 483 — Observations

Form 483 is issued at the conclusion of an inspection when the FDA investigator observes conditions that may constitute violations of the FD&C; Act and regulations. A Form 483 is not a final FDA determination — it is an opportunity for the manufacturer to respond.

Response timeline: The manufacturer should respond within 15 business days of the inspection closeout. There is no statutory deadline, but delay significantly increases the likelihood of escalation to a Warning Letter.

Best practices for Form 483 response:

Acknowledge each observation specifically

Provide a detailed corrective action plan with timelines

Include documentary evidence of actions already taken

Identify root causes, not just symptoms

Commit to CAPA (Corrective and Preventive Action) completion dates

Engage experienced US regulatory counsel for drafting

2.3 Warning Letters

A Warning Letter is a formal FDA communication indicating that the agency has identified significant violations. It is published on the FDA website and becomes a public record.

Impact of a Warning Letter:

All pending ANDA applications from the facility may be placed on hold

Import Alert / Import Detention may be issued

The facility is effectively blocked from US market access until remediation is accepted

Remediation typically requires a re-inspection and a satisfactory outcome

2.4 FDA Enforcement on Indian Sites — 2024-2025 Data

In FY 2025, US-FDA conducted approximately 212 drug-facility inspections globally, down from 284 in 2024. Official Action Indicated (OAI) outcomes for Indian facilities dropped to 11 in 2025 from 20 in 2024, suggesting improving compliance across the industry.

Major 2024-2025 FDA enforcement actions involving Indian facilities included Warning Letters to facilities of several major manufacturers for data integrity failures, cross-contamination risks, and inadequate laboratory controls. The most common Form 483 observations at Indian facilities continue to be: data integrity (ALCOA+ principles); inadequate investigation of OOS results; cross-contamination controls; and equipment cleaning validation.

PART III — WHO-GMP AND INTERNATIONAL CERTIFICATION

Chapter 3: WHO Prequalification

3.1 The WHO-PQ Process

WHO Prequalification is essential for manufacturers seeking to supply medicines to UN procurement agencies (UNICEF, UNDP, Global Fund). The process involves product dossier assessment (based on WHO guidelines equivalent to ICH CTD format), site inspection (WHO-GMP compliance), and ongoing surveillance.

3.2 Certificate of Pharmaceutical Products (CoPP)

The CoPP is issued by CDSCO and certifies that a drug product is approved for marketing in India and that the manufacturing facility complies with GMP requirements. It follows the WHO Certification Scheme format and is accepted by most importing countries as evidence of regulatory oversight.

PART IV — EU-GMP COMPLIANCE

Chapter 4: EU Market Access

4.1 EU-GMP Certification

For Indian manufacturers seeking to export to the European Union, a valid EU-GMP certificate issued by an EU Member State authority following an on-site inspection is mandatory. The inspection covers compliance with EU-GMP guidelines (Eudralex Volume 4), including Annexes specific to sterile manufacturing, biological products, and APIs.

4.2 Qualified Person (QP) Requirements

Every batch of medicinal product imported into the EU must be certified by a Qualified Person. The QP must verify that the product has been manufactured and tested in accordance with EU-GMP requirements.

PART V — IMPORT COMPLIANCE

Chapter 5: The D&C; Import Framework

5.1 Import Licence

Import of drugs into India requires a licence under the Drugs and Cosmetics Rules, 1945. The key forms are:

5.2 CDSCO Registration for Imported Drugs

All imported drugs must be registered with CDSCO. The registration process requires: a valid manufacturing licence from the country of origin; a Certificate of Pharmaceutical Products (CoPP) or equivalent; product dossier including stability data, bioequivalence studies (where applicable); and a Free Sale Certificate from the country of origin.

PART VI — PRACTICAL COMPLIANCE TOOLS

Chapter 6: The Export Compliance Checklist

Pre-Export:

- Manufacturing licence (Form 25/28) valid and current
- WHO-GMP certificate current (or EU-GMP as applicable)
- Product registered in the destination country
- CoPP obtained from CDSCO for the specific product
- Pharmexcil Registration Certificate of Exporter (RCMC) valid
- Export NOC from CDSCO (for Schedule H1/X drugs)
- Country-specific labelling requirements met
- Stability data compliant with destination-country climate zone (Zone I-IV)
- Batch documentation (BMR, CoA, analytical records) archived
- Cold chain documentation prepared (for temperature-sensitive products)

Post-FDA Inspection Response Protocol:

- Day 0: Receive Form 483 — assign response team immediately
- Day 1-3: Categorise each observation (critical/major/minor)
- Day 3-7: Draft preliminary CAPA for each observation
- Day 7-10: Internal review by QA Head, Production Head, and Legal
- Day 10-13: Engage US regulatory counsel for review
- Day 15: Submit Form 483 response to FDA investigator and FDA District Office
- Day 15-90: Implement CAPA; document every step
- Day 90+: Prepare for re-inspection readiness

REFERENCES

Drugs and Cosmetics Rules, 1945 (Import provisions — Part X, Forms 40-42)

CDSCO — CoPP Guidance (cdsco.gov.in)

US FDA — Inspection Guides and Form 483 Process

WHO Prequalification Programme (extranet.who.int/prequal)

Eudralex Volume 4 — EU GMP Guidelines

Pharmexcil — Export Statistics FY 2024-25

IBEF — Indian Pharmaceutical Industry Report 2025

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