D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 12

CDSCO and IPC



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

IDENTTTY

Central Drugs Standard Control Organization (CDSCO) is India's Central Drug Authority for functions assigned to the Central Government under the Drugs and Cosmetics Act, 1940 and the rules made under it.

MINISTRY OF HEALTH & FAMILY WELFARE

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Directorate General of Health Services (DGHS)

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CDSCO

→ HEADQUARTERS: NEW DELHI
HEAD: DCGI

ADMINISTRATIVE POSITION

MINISTRY OF HEALTH & FAMILY WELFARE

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Directorate General of Health Services (DGHS)

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CDSCO

CENTRAL FUNCTIONS

CENTRAL / CDSCO

- Approval of new drugs and clinical trials.
- Regulatory control over import of drugs.
- Laying down drug standards and control over quality of imported drugs.
- Approval of specified licences and coordination of uniform enforcement.

COORDINATION

STATE DRUG REGULATORS

STATE DRUG REGULATORS

- Primarily license and inspect manufacture, sale and distribution within the State, subject to the Act and Rules.
- Enforce requirements through State Licensing Authorities and inspectors.

FIELD NETWORK

CDSCO works through headquarters, zonal and sub-zonal offices, port offices and central drug-testing laboratories. Office counts may change as the network is reorganised.


Zonal Offices


Sub-zonal Offices


Port Offices


Central Drug-testing Laboratories

KEY IDEA

Drug regulation in India is a shared Central-State responsibility, not the work of one office alone.

MAIN FUNCTIONS OF CDSCO



NEW DRUGS

Evaluates data on quality, safety and efficacy before granting permission to import or manufacture a new drug for sale.



IMPORT CONTROL

Registers eligible foreign manufacturing sites and products, grants prescribed import permissions and works through port offices to control imported drugs.



QUALITY AND SAFETY

- Coordinates inspections, sampling and testing through field offices and laboratories.
- Uses post-marketing surveillance, safety information and recalls / alerts when required.
- Regulates notified medical devices under the applicable law and Medical Devices Rules, 2017.



CLINICAL TRIALS

Scientifically and regulatorily reviews clinical-trial applications and oversees trials under the New Drugs and Clinical Trials Rules, 2019.



SPECIFIED LICENCES AND PRODUCTS

Performs central approval functions for specified categories such as vaccines, sera, blood and blood products, large-volume parenterals and certain other products, as provided by law.



NATIONAL COORDINATION

Convenes or supports expert and statutory bodies, coordinates with State Drug Regulatory Authorities and promotes uniform implementation.





ABOUT DRUG SCHEDULES

Schedules such as H, H1 and X are parts of the Drugs Rules. Amendments are made through the legal notification process; CDSCO provides regulatory and technical support.

REGULATORY LIFECYCLE

APPLICATION → REVIEW → PERMISSION / LICENCE → MONITORING → CORRECTIVE ACTION, when needed.

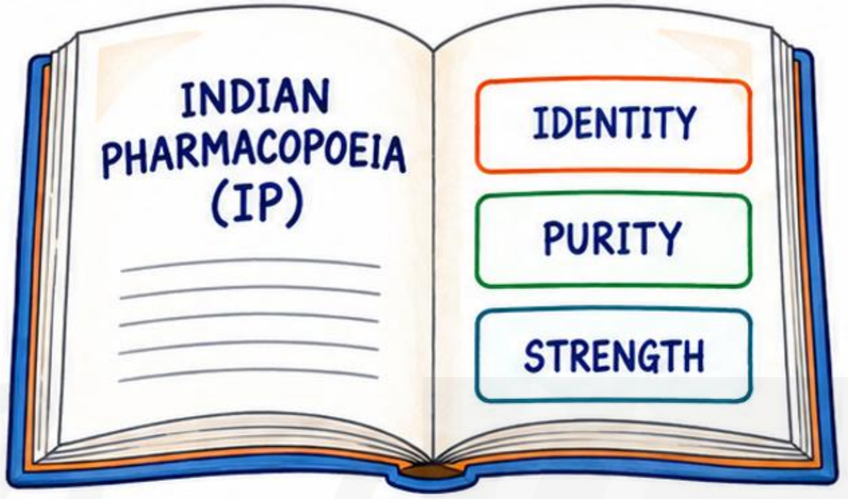
INDIAN PHARMACOPOEIA COMMISSION (IPC)

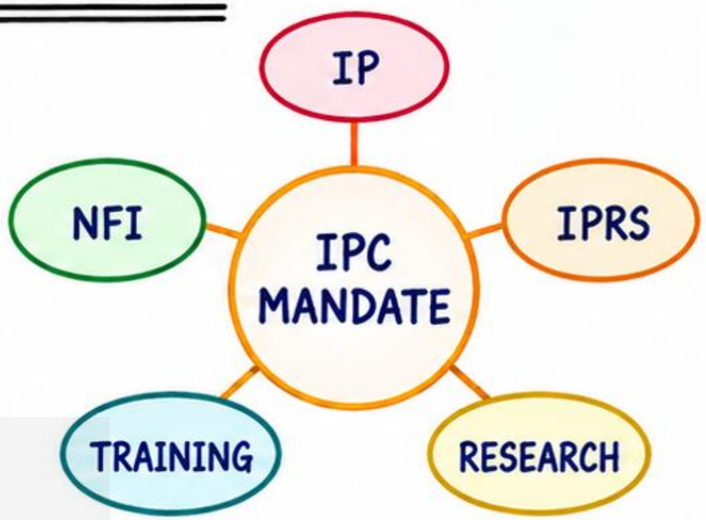
IDENTITY

Indian Pharmacopoeia Commission (IPC) is an autonomous institution under the Ministry of Health & Family Welfare, Government of India. It is located at Ghaziabad, Uttar Pradesh.

Ghaziabad, Uttar Pradesh







INDIAN PHARMACOPOEIA (IP)

- IP is the official book of drug standards in India.
- Under the **Second Schedule** to the Drugs and Cosmetics Act, IP standards specify requirements such as identity, purity and strength.
- Regulatory authorities enforce these authoritative quality standards for drugs imported, manufactured for sale, stocked, exhibited for sale or distributed in India.

MONOGRAPHS AND GENERAL CHAPTERS

IPC prepares and revises:

- Monographs for active pharmaceutical ingredients, pharmaceutical aids / excipients, dosage forms, biologicals, herbal products and relevant medical devices.
- General analytical methods, tests, reagents and other common requirements.

IP REFERENCE SUBSTANCES — IPRS

- Authentic reference materials issued by IPC for the purpose stated in an IP monograph.
- Used to identify an article and assess purity or assay by comparison.
- Official standards in cases of arbitration; working standards may be used routinely after standardisation against IPRS.

OTHER MANDATES

IPC regularly publishes the National Formulary of India (NFI), supplies IPRS, conducts training and research, and collaborates with other pharmacopoeias.

QUALITY-CONTROL FLOW



NOTE

Pharmacopoeial compliance demonstrates specified quality; clinical efficacy is evaluated separately by the regulator.

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