

Easy to Learn...



PHARMACEUTICAL JURISPRUDENCE

For Pharma Competitive Examination



GPAT



NIPER



PHARMACIST



D.I.

Theory & Practice Book



GDC PUBLICATION



Easy to Learn

PHARMACEUTICAL JURISPRUDENCE

Theory & Practice Book

GPAT | NIPER | DRUG INSPECTOR | PHARMACIST

Authors

Dr. Pravin Kawtikwar

M.Pharm., PhD.
Professor and Principal,
Sudhakar Rao Naik Institute of Pharmacy,
Pusad, Maharashtra

Dr. Dama Ganesh Yogiraj

M.Pharm., PhD.
Professor and Principal,
Saradchandra Pawar, College of Pharmacy,
Pune

Dr. Man Singh

M.Pharm., PhD.
Professor & Head,
Department of pharmacy, MLN Government Medical College,
Prayagraj, UP

Dr. Abhishek Tripathi

M.Pharm., PhD.
HOD,
GPAT Discussion Center,
Bilaspur

Dr. Snehamayee Mohapatra

M.Pharm., PhD.
Associate Professor,
Faculty of Pharmacy, SOA Deemed to be University,
Bhubaneswar, Odisha

Mrs. Ahilya Kanwar

B.Pharm, M.Pharm.
Pharma Associate,
GPAT Discussion Center,
Bilaspur



GDC Publication.

3rd Floor, Shiv Hari Tower, Ashok Nagar,
Sarkanda, Bilaspur (C.G.),
Pin code : 495001

A Text Book of Pharmaceutical Jurisprudence

ISBN : 978-81-968577-1-4

Copyright © 2025, By the GDC Publication.

All rights are reserved. No part of this publication may be reproduced, stored in or introduced into a retrieval system, or transmitted in any form or by any means (electronic, mechanical, photo-copying, recording or otherwise), without the prior written permission of the above mentioned publisher of this book.

GDC PUBLICATION has taken due care in collecting the data and providing the solutions, before publishing this book. In spite of this, if any inaccuracy or printing error occurs then GDC PUBLICATION owes no responsibility. GDC PUBLICATION will be grateful if you could point out any such error. Your suggestions will be appreciated.

Any government or Private organization logo, posters, brand product name and image used in this book is for educational purposes only.

Typesetting by :

Team GDC

Composition by :

Vidyadhar Sahu and Chandranayan Sahu

Printed by :

GPAT Discussion Center Pvt. Ltd.
Bilaspur, 495001

Price : ₹ 399

Jurisdiction : All disputes with respect to this publication shall be subject to the jurisdiction of the Courts, Tribunals and Forums of Bilaspur Chhattisgarh, India only.

© All rights reserved by GDC PUBLICATION. No part of this book may be reproduced or utilized in any form without the written permission from the publisher.

for further Information about the products from GDC Publication

☎ +91-9343674693, +91-6263936320, +91-8810619859

🌐 www.gdclasses.com | www.gdconlinetest.in

✉ gdcgpat037@gmail.com

PREFACE

Pharmaceutical Jurisprudence is a branch of pharmacy that deals with the study of laws, rules, and regulations related to the manufacture, distribution, import, export, sale, and use of drugs and cosmetics in India. It provides the legal framework within which the pharmacy profession operates, ensuring safety, efficacy, and quality of medicines while safeguarding the rights of patients and healthcare providers.

We are delighted to introduce the publication entitled **"Easy to Learn - Pharmaceutical Jurisprudence"** to the esteemed Pharmacy students, in accordance with the latest guidelines and curriculum.

The book comprises 30 chapters and concludes with 500 MCQs, which are not only for practice but also designed to understand and remember the concepts, identify common mistakes, and make learning easier, in line with the book's goal of being 'Easy to Learn'. The distinctive feature of this book is its simple language, flowcharts and tables, making complex legal concepts easy to understand. It serves not only as a reliable study guide for pharmacy students and a useful reference for aspirants preparing for GPAT, NIPER, Drug Inspector, Pharmacist recruitment and other Pharma competitive examinations.

Our primary goal in preparing this book is to provide students with clarity, confidence, and practical knowledge of Pharmaceutical Jurisprudence. Laws and regulations often appear difficult or confusing, but when presented in an organized and student-friendly manner, they become meaningful tools that guide professional practice. Through this effort, we aim to cultivate a sense of responsibility and integrity among budding pharmacists, enabling them to uphold ethical standards and contribute effectively to public health.

We would like to extend our deepest gratitude to our team, whose tireless efforts and valuable insights were essential in shaping this book. Their dedication to making learning effortless is reflected on every page.

We sincerely hope that this textbook will become your trusted companion, a resource that not only helps you succeed in your examinations but also builds a strong foundation for a distinguished and ethical career in the field of pharmacy.

Thank you for choosing **"Easy to Learn - Pharmaceutical Jurisprudence."**

"Law is not just a set of rules, it is the foundation of professional integrity in pharmacy."

Authors

INDEX

Sl.	UNITS	PAGES
1.	Pharmaceutical Legislation in India	1-3
2.	Code of Pharmaceutical Ethics	4-6
3.	Pharmacy Act	7-14
4.	All India Council for Technical Education (AICTE) Act	15-18
5.	Drugs and Cosmetics Act and Rules	19-44
6.	Narcotic Drugs and Psychotropic Substances Act	45-52
7.	Medicinal and Toilet Preparations (Excise Duties) Act and Rules	53-63
8.	Drugs and Magic Remedies Act and Rules	64-67
9.	Drug Price Control Order (DPCO)	68-73
10.	Insecticides Act and Rules	74-78
11.	Poisons Act	79-80
12.	Medical Termination of Pregnancy Act and Rules	81-84
13.	Patents Act and Rules	85-89
14.	Designs Act and Rules	90-93
15.	Trade Marks Act	94-98
16.	Factories Act	99-104
17.	Industries (Development and Regulation) Act	105-108
18.	Minimum Wages Act	109-111
19.	Consumer Protection Act	112-117
20.	Prevention of Cruelty to Animals Act	118-123
21.	Right to Information Act	124-130
22.	International Council for Harmonisation (ICH) Guidelines	131-135
23.	World Health Organization (WHO)	136-140
24.	Pharmacopoeias	141-148
25.	Central Drug Standard Control Organization (CDSCO)	149-154
26.	Investigational New Drug Application (INDA)	155-159
27.	United States Food and Drug Administration (USFDA)	160-167
28.	Code of Federal Regulations (CFR)	168-177
29.	Organisation for Economic Co-operation and Development (OECD)	178-185
30.	International Organization for Standardization (ISO)	186-193
	PRACTICE MCQs	194-226

Pharmaceutical Legislation in India

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- Pharmaceutical legislation is a legislation which covers various laws enacted from time to time by the Government for the regulation of education, practice and pharmaceutical industry for promoting health care system and safeguarding public health. Thus, it is concerned with the social, economical and health aspects of the society.
- Jurisprudence is the study of fundamental legal principles. It includes the knowledge of law and technically it is the science of first principles of civil law.
- Pharmaceutical Jurisprudence is a branch of pharmacy which deals with the knowledge of laws relating to drugs and pharmaceuticals and about pharmacy profession.

OBJECTIVES

- To ensure that the patients receive drugs of required quality, tested and evaluated for safety and efficacy for their intended result.
- To promote the health care system by regulating the manufacture and supply of good quality drugs.
- To regulate the profession and profession of pharmacy.
- To safeguard the public from such advertisements of drugs that makes false claim for the drug or gives the misleading information about the drug.
- To promote the indigenous research technology.
- To control the prices of drugs.

DRUG ENQUIRY COMMITTEE (DEC)

- The Government of India responded to a strong public opinion on the subject of drugs, and in pursuance thereof, and that of the Resolution of 1927; appointed the Drugs Enquiry Committee (also known as the Chopra Committee) under the chairmanship of Col. R. N. Chopra and Dr. B. Mukherjee as its Assistant Secretary.
- Dr. Mukherjee was later appointed the Director of the Central Drugs Laboratory and subsequently of the Central Drugs Research Institute.
- The report of the Committee was published in 1931 and presented a picture of the state of affairs then prevalent.

RECOMMENDATIONS OF THE CHOPRA COMMITTEE

- There should be a central legislation to control drugs and pharmacy.
- Setting up of testing laboratories in all the states so as to control quality of production of drugs and pharmaceuticals and also imported drugs.
- Appointment of an Advisory Board to advise the Government in making Rules
- Registration of every patent and proprietary medicine of undisclosed formula manufactured in India or imported from outside the country.

Code of Pharmaceutical Ethics

SCAN ME

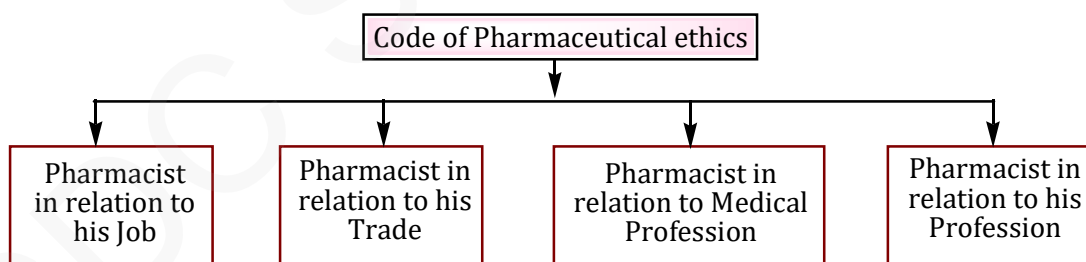
To Join FREE
Online Test

INTRODUCTION

- **Ethics:** It is referred as “the code moral principles” or as “the science of morals”. Ethics are rules by which a profession regulates actions and sets standard for all its members. If rule of ethics (professional conduct) is broken the professional body may subject the violator to loss of professional privileges.
- **Pharmaceutical ethics:** It means the moral principles to be followed by pharmacist as regards to his conduct, behavior and character. The ethics in relation to pharmacy profession is called pharmaceutical ethics.
- **Morality:** Morality means good conduct or behavior and consciousness.
- **Laws:** Law is defined as ‘Rules of human conduct binding all persons in a state or nation’.

CODE OF PHARMACEUTICAL ETHICS

- The code of pharmaceutical ethics is formulated by Pharmacy Council of India (PCI) for the guidance of Indian pharmacist.
- There was a statement by **Charaka** ancient Indian Philosopher. Physician and Pharmacist “**Even if your own life be in danger, you should not betray or neglect the interests of your patients.**”
- The code of pharmaceutical ethics helps to guide the pharmacist as to how he should conduct himself in relation to: His job, His trade, His profession, His fellow Pharmacist and with medical profession and other health professionals.



PHARMACIST IN RELATION TO HIS JOB

1.	Pharmaceutical Services	Pharmacist provides efficient and reasonably comprehensive pharmaceutical services should be provided. This involves ✓ Supply of commonly required medicine without delay. ✓ Willingness to furnish emergency supplies at all times.
2.	Conduct of pharmacy	Precaution should be taken by the pharmacist to avoid risk or error of accidental contamination in the preparation, dispensing and supply of medicines

Pharmacy Act

SCAN ME

To Join FREE
Online Test

IMPORTANT DATE

Act passed	1948
Came into force	4 th March 1948
Amendment	Minor – 1976 & Major – 1959, 1981

PHARMACY (AMENDMENT) BILL, 2023

- The Pharmacy (Amendment) Bill, 2023 has been introduced in Lok Sabha on August 03, 2023.
- The Bill looks at the insertion of “**new section 32C**”, which provides a special provision relating to persons registered or qualified under the Jammu and Kashmir Pharmacy Act, 2011.
- The Bill specifies that anyone who is registered as a pharmacist under the Jammu and Kashmir Pharmacy Act, 2011 or possesses qualifications prescribed under the 2011 Act will be deemed to be registered as a pharmacist under the Pharmacy Act, 1948.

OBJECTIVES

- To regulate the pharmacy profession and practice of pharmacy.
- To regulates the pharmacy education for the purpose of registration as a pharmacist.
- To raising the status of pharmacy profession.
- To restoration of pharmacy profession in its due place in the health service.
- To frames the education and training of pharmacy professionals and governing control over their professional work.

CHAPTERS AND SECTIONS

The act has been divided into **5 chapters** and **46 sections**.

CHAPTERS	DESCRIPTION	SECTIONS
Chapter I	Introductory	1-2
Chapter II	Pharmacy Council of India (PCI)	3-18
Chapter III	State Pharmacy Councils (SPC)	19-28
Chapter IV	Registration of Pharmacists	29-40
Chapter V	Miscellaneous	41-46

IMPORTANT SECTION

Section 3	Constitution and composition of Central Council (PCI)
Section 10	Education Regulations
Section 12	Approved courses of study and examinations

ROLE OF CENTRAL COUNCIL

- Education regulation
- The equipment & facilities to be provided for student
- Approval to the course of study & examination
- Withdrawal of approval
- Central Council shall appoint registrar who shall act as secretary to the council & if need as its treasure too.
- Central council constitute executive committee consist president and vice president & other 5 members elected by central council from among its member.
- Rules are made by central govt. and regulation by state govt.

STATE PHARMACY COUNCIL

STATE PHARMACY COUNCIL

- State Pharmacy Councils and Joint State Councils are also constituted by the State Government
- Two or more States entering into an agreement may agree for the constitution of a Joint State Council for all the participating States.
- State Council may appoint a Registrar who may act as its secretary and also as Treasurer.
- President and Vice-President of the State Council shall be elected by the members from amongst themselves.
- President and Vice-President shall hold office as such for a term not exceeding five years.
- State and Joint Pharmacy Councils are constituted for 5 years.

CONSTITUTION OF STATE PHARMACY COUNCIL AND JOINT STATE COUNCIL

State Pharmacy Council is constituted of 15 members: 7 elected members, 5 nominated members and 3 elected members.

STATE COUNCIL	JOINT STATE COUNCIL
Elected member	
• 6 Registered pharmacists elected from amongst themselves • 1 member elected by members of the Medical Council of the state	• 3-5 Registered pharmacist of each of the participating state elected from amongst themselves • 1 member elected by the Medical Council of each state from amongst its members.
Nominated members	
• 5 members of whom at least 3 shall be possessing degree /diploma in pharmacy or pharmaceutical chemistry or be registered pharmacists nominated by the State Government.	• 2-4 members nominated by each participating State of whom more than half shall be possessing a degree or diploma in pharmacy or pharmaceutical chemistry or be registered pharmacists.
Ex-officio members	
• Chief administrative Medical Officer of the State. • Officer in Charge of Drugs and Cosmetics Act, 1940. • Government Analyst under the Drug and Cosmetics Act as State Government may appoint in this behalf.	• Chief Administrative Medical Officer of each of the participating states. • Officer in charge of Drug Control Organization of each participating state. • Government Analyst of each participating State.

All India Council For Technical Education (AICTE) Act

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The Act was enacted on 15th December, 1987.
- The Act came into force with effect from 28th March 1988.
- The statutory AICTE was established on 12 May 1988.
- AICTE established by Central Government
- Headquarter located at Delhi.



CHAPTERS AND SECTIONS

The act has been divided into **6 Chapters and 25 Sections**.

CHAPTERS	DESCRIPTION	SECTIONS
Chapter I	Introductory	1-2
Chapter II	Establishment of the council	3-9
Chapter III	Powers and functions of the council	10-11
Chapter IV	Bodies of the council	12-14
Chapter V	Finance, Accounts and Audit	15-19
Chapter VI	Miscellaneous	20-25

OBJECTIVES

- To provide for the establishment of an AICTE with a view to the proper planning and coordinated development of the technical education system throughout the country.
- The promotion of qualitative improvement of such education in relation to planned quantitative growth
- The regulation and proper maintenance of norms and standards in the technical education system and for matters connected therewith.

DEFINITION

1. **Commission:** means the University Grants Commission established under section 4 of the University Grants Commission Act, 1956.
2. **Council:** It means the All-India Council for Technical Education established under section 3.
3. **Fund:** It means the Fund of the Council constituted under section 16.
4. **Member:** It means a member of the Council and includes the Chairman and Vice-Chairman.
5. **Prescribed:** It means prescribed by rules made under this Act
6. **Regulations:** It means regulations made under this Act

Drugs and Cosmetics Act and Rules



INTRODUCTION

- The Drugs and Cosmetics Act was passed in 1940, (10th April 1940) and Rules passed in 1945.
- This Act was amended in 1955 by the Indian Parliament and Subsequently amended in 1960, 1962, 1964, 1972, 1982, 1986, 1995, 2008 and 2016.
- Major amendment was made in 1982 and latest amended up to the 31st December, 2016.

IMPORTANT AMENDMENTS

- Schedule E, I and L were deleted, Schedule G and H were revised and expanded and a new Schedule X was added in 1982.
- Schedule M (GMP) and Y were introduced in 1988.
- Schedules T of Ayurvedic Siddha and Unani medicines was introduced in 2000.
- Schedule HX, for curbing the misuse of antibiotics and other drugs in 2011.
- Good Laboratory Practices has been made as law by introducing it as Schedule L-1 which is a New Schedule under Drugs and Cosmetics Rules, 1945 vide Gazette notification no GSR 780 (E) 10-11-2008 with effect from 1-11-2010.
- The Drugs and Cosmetics Act, 1940 was indeed amended in 1964 to specifically include Ayurvedic, Siddha, and Unani drugs under its purview.

OBJECTIVES

- Act to regulate the import, manufacture, distribution and sales of drugs and cosmetics.
- The main objective of Drugs and Cosmetic Act, 1940 and subsequent amendments is to regulate the import manufacture distribution and sale of drugs and cosmetics of allopathy, Ayurveda, Siddha and Unani Tibbs.
- Act regulates the manufacture and sale of drugs and cosmetics through licensing so that these are manufactured, distributed and sold only by qualified persons.

CHAPTERS

This Act consist of five chapters and each chapter related to particular subject

CHAPTERS	DESCRIPTION
Chapter I	Introductory
Chapter II	Administrative Bodies: Drugs Technical Advisory Board, Central Drugs Laboratory and Drugs Consultative Committee
Chapter III	Import of Drugs and Cosmetics
Chapter IV	Manufacture, Sale and Distribution of Drugs and Cosmetics
Chapter IVA	Provisions relating to Ayurvedic, Siddha and Unani Drugs
Chapter V	Miscellaneous

Appendix I – Data required with application for permission to market new drug.

Appendix II – Format for submission of clinical trial reports.

Appendix III – Animal toxicity required for clinical trial report

Appendix IV – Number of animals for long time studies.

Appendix V – Patient consent form for participation in phase I clinical trial

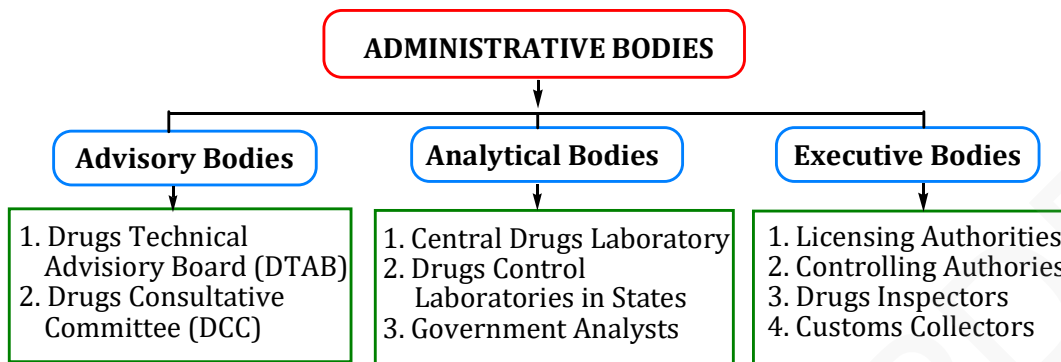
Appendix VI – Four group of fixed dose combinations and their data requirement

SCHEDULES TO THE RULES

SCHEDULES	SIGNIFICANCE	
A	Proforma for application for the licenses, issues and renewal of licenses, for sending memoranda under the act	
B	Rates of Fee for test or analysis by the CDL or state drugs laboratories	
B₁	Fees for the test or analysis by the Pharmacopoeia Laboratory for Indian Medicine (PLIM) or the Government Analyst	
C	List of Biological and special products (injectable/ parenteral) whose import, sale, distribution and manufacture are governed by special provision e.g. Surgical dressings and ophthalmic preparations etc.	
C₁	List of other special products (non-parenteral) whose import, sale, distribution and manufacture are governed by special provision e.g. Digitalis, Ergot, Adrenaline, Fish liver oil etc.	
D	List of drugs exempted from the provision of import of drugs.	
D₁	Information and undertaking required to be submitted by the manufacturer with the application form for a registration certificate	
D₂	Information required to be submitted by the manufacturer with the application form for registration of a bulk drug/formulation/special product for its import into India	
D₃	Information and undertaking required to be submitted by the manufacturer or his authorized importer/distributor/agent with the application form for a registration certificate	
E₁	List of Poisonous substances under ASU system of medicines.	
F	Part XII B	Requirement for the functioning and operation of blood bank and/ or for the preparation of blood component
	Part XII C I	Requirements for manufacture of blood products
	Part XII C II	Requirements for manufacture of blood products from bulk finished products
	Part XII D	Requirements for collection, processing, testing, storage, banking and release of umbilical cord blood derived stem cells
	Part XIII	General
F₁	Part IA	Production of bacterial vaccines
	Part IB	Production of viral vaccines
	Part II	Production of all sera from living animals
	Part III	Manufacture and standardization of diagnostic agents (bacterial origin)
	Part IV	General
F₂	Standards of surgical dressings	
F₃	Standards of sterilized umbilical tapes	
FF	Standards for ophthalmic preparations	
G	List of substances to be used under the medical supervision and which are to be labelled accordingly	
H	List of drugs to be sold on the prescription of an RMP/ List of prescription drugs	
J	Diseases and ailments which a drug may not purport to prevent or cure or make claims to prevent or cure	

CHAPTER II- ADMINISTRATIVE BODIES

Central government and State Government establish or appoint following bodies for efficient running of the Act

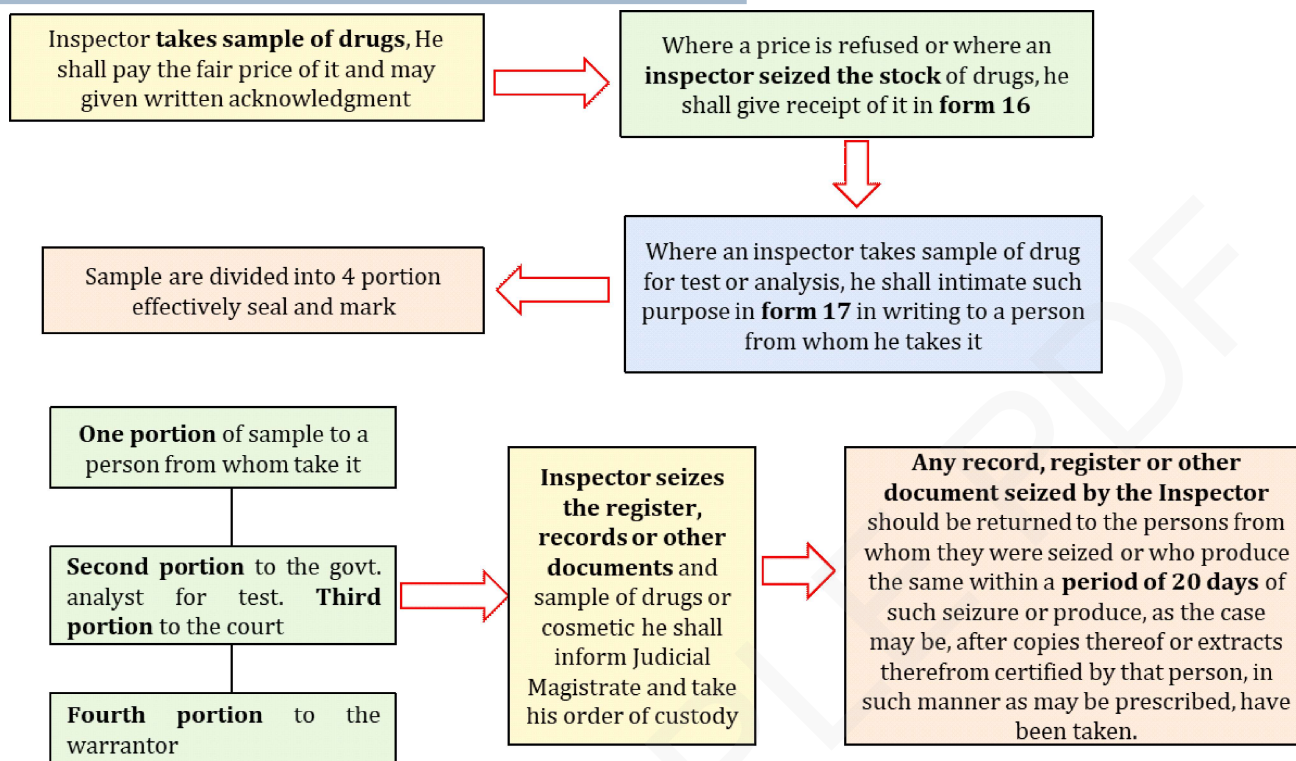
**DRUGS TECHNICAL ADVISORY BOARD (DTAB)**

- DTAB is constituted by the Central Government under the section 5 to advise the Central and State Governments on technical matters arising out of the administration of this Act
- Head office of the Drugs Technical Advisory Board (DTAB) is located in New Delhi.
- Nominated and elected members hold the office for three years but are eligible for re-nominated or re-election.
- Drugs Technical Advisory Board (Allopathy) consists of 18 members (Ex officio = 08, Nominated = 05, Elected = 05)]

MEMBERS OF DRUGS TECHNICAL ADVISORY BOARD (DTAB)

EX-OFFICIO MEMBERS (TOTAL = 8)	NOMINATED MEMBERS (TOTAL = 5)	ELECTED MEMBERS (TOTAL = 5)
1. Director General of Health Services – Chairman 2. Drug Controller of India 3. Director of Central Drug Laboratory, Kolkata 4. Director of Central research Institute, Kasauli 5. Director Indian Veterinary Research Institute, Izatnagar 6. Director of Central Drug Research Institute, Lucknow 7. President – Medical Council of India (MCI) 8. President – Pharmacy Council of India (PCI)	1. Two Person nominated by the central govt. amongst person who are incharge of Drug Control in States. 2. One person from pharmaceutical industry, nominated by central govt. 3. Two Government Analyst nominated by central govt.	1. A teacher in pharmacy or pharmaceutical chemistry or pharmacognosy, elected by executive committee of PCI 2. A teacher in medicine or therapeutics, elected by executive committee of MCI 3. One pharmacologist elected by Governing body of Indian Council of Medical Research 4. One person elected by the council of Central Medical Association 5. One person to be elected by the council of the Indian Pharmaceutical Association

PROCEDURE OF INSPECTION: SECTION 23



DUTIES OF DRUG INSPECTOR

❖ Duties of Inspectors of premises licensed for sale: Rule 51

1. To inspect not less than once a year all establishments licensed for the sale of drugs within the area assigned to him and to satisfy himself that the conditions of the licences are being observed.
2. To procure and send for test or analysis, if necessary, imported packages which he has reason to suspect contain drugs being sold or stocked or exhibited for sale in contravention of the provisions of the Act or Rules thereunder
3. To investigate any complaint in writing which may be made to him and to institute prosecutions in respect of breaches of the Act and Rules thereunder
4. To maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority
5. To make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act
6. When so authorized by the State Government, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

❖ Duties of Inspectors to inspect the manufacture of drugs or cosmetics: Rule 52

1. To inspect not less than once a year, all premises licensed for manufacture of drugs or cosmetics within the area allotted to him to satisfy himself that the conditions of the licence and provisions of the Act and Rules thereunder are being observed

OFFENCES & PENALTIES RELATING TO IMPORT OF DRUGS

OFFENCES	PENALTIES	
	First Conviction	Subsequent Conviction
1. Import of adulterated or spurious drugs or spurious cosmetic or any cosmetics containing any ingredient which may render it unsafe or harmful for use under the directions recommended.	3 years / Fine upto ₹ 5000	5 years / Fine upto ₹ 10,000 or both
2. Import of any drugs or cosmetic other than referred above, the import of which is prohibited	Fine upto ₹ 500/ 6 months or both	Fine upto ₹ 1000 / 1 year or both
3. Import of any drug or cosmetic in contravention of any notification issued under section 10A.	Fine upto ₹ 5000 / 3 years or both	

FORMS FOR IMPORT OF DRUGS

PURPOSE	DRUGS	APPLICATION FORM	LICENSE GRANTED FORM
IMPORT	i. Drugs specified in schedule C and C1 (excluding those specified in Schedule X)	8	10
	ii. Drugs specified in Schedule X	8A	10A
	iii. Drugs for the purposes of examination, test or analysis	12	11
	iv. Small quantity of drugs for personal use	12A	12B
	v. Small quantities of new drugs by a Govt. Hospital/ Autonomous Medical Institution	12AA	---

CHAPTER IV- MANUFACTURE OF DRUGS AND COSMETICS

MANUFACTURE OF DRUGS

- Manufacture in relation to any drug or cosmetic, includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale and distribution but does not include the compounding or dispensing of any drug or packing of any drug in the ordinary course of retail business.
- Following licences are provided for manufacturing of drugs under the Drugs and Cosmetics Act and Rules thereunder**
 - Drugs other than those specified in Schedule C, C1, and X
 - Drugs specified in Schedule C, C1 but not specified in Schedule X
 - Drugs specified in Schedule C and C1
 - Drugs specified in Schedule X but not in Schedule C and C1
 - Drugs specified in Schedule C, C1 and X
 - Drugs for the purpose of examination, test or analysis
 - Loan licences
 - Blood products

Narcotic Drugs and Psychotropic Substances Act and Rules



IMPORTANT DATES

Opium Act	1857, 1878
Dangerous Drugs Act	1930
Central Opium Rules	1934
Dangerous Drugs Rules	1957
Central Manufactured Drugs Rules	1962
Narcotic Drugs & Psychotropic Substances Act & Rules	1985
Narcotic Drugs & Psychotropic Substances Act came in force	14 November 1985
Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act	1988
Narcotic Drugs and Psychotropic Substances (Regulation of Controlled Substances) Order	1993 (Came into force on 15 th April 1993)

OBJECTIVES

- To consolidate and amend the law relating to narcotic drugs.
- To make stringent provisions for the control and regulation of operations relating to narcotic drugs and psychotropic substances.
- To provide for the forfeiture of property, derived from, or used in illicit traffic in narcotic drugs and psychotropic substances.
- To implement the provisions of the International Conventions on Narcotic Drugs and Psychotropic Substances and for matters connected therewith.

IMPORTANT POINTS

- Coca, Opium and Hemp comes under Dangerous Drugs Act
- Government Opium Factory – **Ghazipur (UP), Neemuch (MP)**
- Opium poppy for the production of opium or poppy straw can be cultivated only on behalf of the Central Government in states of **Madhya Pradesh (M.P.), Uttar Pradesh (U.P.) and Rajasthan** in accordance with the conditions of a licence issued by the District Opium Officer.
- District Opium Officer appoint one of the cultivators of opium poppy as Lambardar in each village where opium poppy is cultivated.
- Central Government shall appoint “Narcotic Commissioner” have all powers and perform all functions relating to the cultivation of the opium poppy and production of opium.
- Central Government have empowered to amend list of psychotropic substance.



- (b) The sale proceeds of any property forfeited.
- (c) Any grants that may be made by any person or institution.
- (d) Any income from investment of the amounts credited.
- The Fund shall be applied by the Central Government to meet the expenditure incurred in connection with the measures taken for
 - i. Combating illicit traffic in NDPS or controlled substances.
 - ii. Controlling the abuse of NDPS.
 - iii. Identifying, treating, rehabilitating addicts.
 - iv. Preventing drug abuse.
 - v. Educating the public against drug abuse.
 - vi. Supplying drugs to addicts.
- The Central Govt may constitute a Governing Body to advise that Govt and to sanction money out of the said Fund subject to the limit notified by the Central Govt
- The Governing Body shall consist of a Chairman and such other members not exceeding six as the Central Government may appoint

AUTHORITIES AND OFFICER

- Central govt shall appoint narcotic officer who have all power and perform all function relating to the opium.
- Central govt. constituent national fund for control of drug abuse.
- State government may appoint suitably designated officers deemed necessary to implement the provision of the act in their territories.

OFFENCES AND PENALTIES

OFFENCES		FIRST CONVICTION
1. In relation to poppy straw: To produces, possesses, transports, imports inter-State, exports inter-State, sells, purchases, uses or omits to warehouse poppy straw	Where contravention involves small quantity	6 Months/10,000 or both
	Lesser than commercial quantity but greater than small quantity	10 Years/Fine upto 1 lakh
	Commercial quantity	NLT 10-20 Years/Fine NLT 1-2 lakh
2. In relation to prepared opium: To manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses prepared opium	Where contravention involves small quantity	6 Months/10,000 or both
	Lesser than commercial quantity but greater than small quantity	10 Years/Fine upto 1 lakh
	Commercial quantity	NLT 10-20 Years/Fine NLT 1-2 lakh
3. In relation to opium poppy and opium: To cultivates the opium poppy or produces, manufactures, possesses, sells, purchases, transports, imports inter-State, exports inter-State or uses opium	Where contravention involves small quantity	6 Months/10,000 or both
	Commercial quantity	NLT 10-20 Years/Fine NLT 1-2 lakh
	In any case	10 Years/Fine upto 1 lakh

Medicinal and Toilet Preparations (Excise Duties) Act and Rules



INTRODUCTION

Medicinal And Toilet Preparations Act was passed	1955
Medicinal And Toilet Preparations Rules was passed	1956
Came into force	1 st April 1957

OBJECTIVES

- To provide for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol, narcotic drug or narcotics.
- To provide for uniformly in the rules and rate of excise duties leviable on such preparation throughout the country.

IMPORTANT POINTS

- License to manufacture in bonded laboratories is issued by Excise Commissioner.
- A non- bonded manufacturer shall be inspected by the other officer at least once in a month.
- Alcoholic preparations can be stored in a warehouse for a maximum period of 3 years
- Dutiable goods cannot be delivered from a bonded manufactory or a bonded warehouse before 6 a.m. and after 6 p.m. nor at any hour on Sundays or other holidays.
- Rules and regulation: All over India except Jammu and Kashmir.
- State government may appoint desired number of excise officers.
- Excise commissioner may issue written instruction providing for any supplementary arising out of these rules.

SCHEDULES

- Schedule to Act** - Description of dutiable goods.
- Schedule to Rules** - List of Medicinal and Toilet Preparations Containing Alcohol which are Capable of Being Consumed as Ordinary Alcohol Beverages

DEFINITIONS

Alcohol	Ethyl alcohol of any strength and purity having the chemical composition C_2H_5OH
Dutiable goods	The medicinal and toilet preparations specified in the Schedule as being subject to the duties of excise levied under this Act
Excise officer	An officer of the excise Department of any state and any person empowered to exercise all or any of the powers of the excise officer under this Act

Exporter should present entire consignment to excise officer	Exporter Should give separate application for different means of export
Excise officer take samples and send for analysis on the basis of it permit for export	
All goods should contain serial no., owners name & mark, total qty of dutiable goods, alcoholic strength, name & address of consignee, gross wt. of each package	
Excise officer puts his official seal on each package	
Excise officer return the duplicate copy of application to exporter	

OFFENCES AND PENALTIES

S. NO.	OFFENCES	PENALTIES
1.	Non-compliance with conditions of the license and failure to pay duty	6 months / fine upto ₹ 200 or both
2.	Failure to supply information asked or giving false information	
3.	Attempting or committing or abetting commission of any offence	
4.	Connivance of offences by owners or occupiers of land	6 months / fine up to ₹ 500 or both
5.	Vexatious search, seizure etc. by Excise Officer	Fine upto ₹ 2000
6.	Failure of Excise Officer on duty	3 months
7.	Improper maintenance of stocks or accounts	Fine upto ₹ 100
8.	Making false entries or tearing pages from stock book	Fine upto ₹ 2000
9.	Sale of dutiable goods otherwise than in prescribed containers bearing the labels	Fine upto ₹ 1000
10.	Failure to furnish proof of export within specified period	Fine upto ₹ 2000
11.	Manufacture of any dutiable goods without a valid licence	6 months/fine upto ₹ 2000 or both

OFFENCES WITH RESPECT TO WAREHOUSING

S. NO.	OFFENCES	PENALTIES
1.	Opening any locks or door of the warehouse without prior consent	Fine upto ₹ 2000 and goods liable to confiscation
2.	Making any alteration in the warehouse without prior consent	
3.	Warehousing or removing goods in contravention of the rules	
4.	Privately removing or concealing any goods either before or after being warehoused	
5.	Obstructing officers and giving false information	Fine upto ₹ 500
6.	Willfully and maliciously giving information	2 years / Fine upto ₹ 2000 or both
7.	Disclosure of information by excise officers	Fine upto ₹ 1000
8.	Breach of any rule where no penalty is provided	Fine upto ₹ 1000 and goods liable to confiscation

Drugs and Magic Remedies Act and Rules

SCAN ME

To Join FREE
Online Test

INTRODUCTION

Drugs and Magic Remedies Act Passed	1954
Drugs and Magic Remedies Act came in force	1 st April 1955
Drugs and Magic Remedies Rules came in force	1 st April 1955
Drugs and Magic Remedies Act Amendment	1963
Drugs and Magic Remedies Act was notified	30 th April, 1954

- The Act was also referred as Objectionable Advertisements Act
- Drugs and Magic Remedies Act, 1954, primarily focuses on regulating Misleading advertisements regarding drugs
- Central Government is competent under the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 to frame rules for carrying the purpose of the act

OBJECTIVES

- To control the advertisements of drugs in certain cases.
- to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities.
- To provide for matters connected therewith.

IMPORTANT SECTIONS

Section 3	Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders.
Section 4	Prohibition of misleading advertisements relating to drugs.
Section 5	Prohibition of advertisement of magic remedies for treatment of certain diseases and disorders.
Section 6	Prohibition of import into, and export from, India of certain advertisements

DEFINITIONS

Advertisement	Any notice, circular, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke.
Magic remedy	It includes a talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals



Drug Price Control Order (DPCO)

SCAN ME

To Join FREE
Online Test

INTRODUCTION

Essential Commodities Act	1955
DPCO passed	1995
Latest DPCO passed	2013
DPCO 2013 came into effect from	15 th May 2013
Amendment	DPCO-1966 DPCO - 1970: Issued under Essential Commodities Act 1955, declaring drugs as essential commodities DPCO-1978 DPCO-1979 DPCO-1987 DPCO, 1991 DPCO, 1995 DPCO, 2013

DPCO 1995	Passed on 6 th Jan 1995 by the Ministry of Chemicals and Fertilizers under Section 3 of the Essential Commodities Act
DPCO 2013	(DPCO 2013) was issued by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

- The Drug Price Control Order (DPCO) is an order issued by the Central Government under the “Essential Commodities Act” which enables it to fix the prices of some essential bulk drugs and their formulations.
- Under the Section 3 of the Essential Commodities Act, 1955 the Central Government is empowered to control the production, supply, distribution etc. of essential commodities Including drugs.
- The Essential Commodities Act is coming under Department of Consumer affairs.

OBJECTIVE

- To maintain and increase the supplies of bulk drugs and formulations.
- To ensure equitable distribution of essential bulk drug
- To fix the maximum retail prices of drug formulations in order to curb the exorbitant profiteering in drug manufacturing and distribution

IMPORTANT POINTS

- Drug Price Control Order 1995 and related orders from time to time are enforced by National Pharmaceutical Pricing Authority (NPPA).
- The power to fix the ceiling price of scheduled formulations lies with the National Pharmaceutical Pricing Authority (NPPA), which functions under the authority of the Central Government.
- The price of drugs can be launched by National Price Control Authority of India.
- In the Drug Price control Order (DPCO), 1995 imported formulation fixing of price Shall not exceed 50% of landed cost.



Insecticides Act and Rules

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The Act extends to the whole of India.
- An Act to regulate the import, manufacture, sale, transport, distribution and use of insecticides with a view to prevent risk to human beings or animals, and for matters connected therewith.



DEFINITIONS

Insecticide	Means- (i) Any substance specified in the schedule; (ii) Such other substances (including fungicides and weedicides) as the Central Government may include in the Schedule from time to time. (iii) Any preparation containing any more or more of such substances
Board	Means the Central Insecticides Board constituted under section 4
Central Insecticides Laboratory	Means the Central Insecticides Laboratory established or as the case may be, the Institution specified, under section 16
Insecticide Analyst	Means an Insecticide Analyst appointed under section 19
Insecticide Inspector	Means an Insecticide Inspector appointed under section 20
Manufacture	In relation to any insecticide, includes (i) Any process or part of a process for making, altering, finishing, packing, labelling, breaking up or otherwise treating or adopting any insecticide with a view to its sale, distribution or use but does not include the packing or breaking up of any insecticide in the ordinary course of retail business. (ii) Any process by which a preparation containing an insecticide is formulated.

CENTRAL INSECTICIDES BOARD

- Central Government shall constitute a Board called as Central Insecticides Board.

FUNCTIONS

- To advise the Central Government and State Governments on technical matters arising out of the administration of this Act



INTRODUCTION

- The Poisons Act, 1919 was passed on 3rd September, 1919
- The Act of 1919 replaced the Poisons Act of 1904 which was intentionally limited in its scope to restrict interference with legitimate industries
- Act of 1904 to control over the traffic poisons was inadequate.

OBJECTIVES

- To consolidate and amend the law regulating the importation, possession for sale and sale of poisons
- To tightening the control over traffic in poisons.

IMPORTANT POINTS

- Central Government has been empowered to regulate the import of poisons and poison can be imported only under a valid licence
- State Governments has been empowered to make rules regarding the possession for sale and sale of poison.
- Power to issue of warrant - District magistrate, Sub-divisional magistrate and Commissioner of police.
- State Government make all rules and may also make additional rules.

IMPORTANT SECTION

SECTIONS	DETAILS
Section 2	Power of the State Government to regulate possession for sale and sale of any poison.
Section 3	Power to prohibit importation into the States of any poison except under licence.
Section 4	Power to regulate possession of any poison in certain areas.
Section 5	Presumption as to specified poisons.
Section 6	Penalty for unlawful importation, etc.
Section 7	Power to issue search warrants.

POSSESSION AND SALE OF POISON

The State Government may by rule regulate the possession and sale of poison, whether wholesale or retail, within whole or specified areas of their territories. Such rules provide:

Medical Termination of Pregnancy Act and Rules



INTRODUCTION

Medical Termination of Pregnancy Act was passed	1971
Medical Termination of Pregnancy Rules was passed	1975
Medical Termination of Pregnancy Regulation was passed	2003

IMPORTANT POINTS

- Central Government has power to make rules.
- State Government has power to make regulations.
- In 2021, MTP Amendment Act 2021 was passed with certain amendments to the MTP Act 1971, an increase in gestation limit to 24 weeks and opinion of one RMP required upto 20 weeks of gestation.
- Every registered medical practitioner who terminates any pregnancy shall, within three hours from the termination of the pregnancy certify such termination in Form I.
- The proposed measure which seeks to liberalise certain existing provisions relating to termination of pregnancy has been conceived
 1. **Health measure** - When there is danger to the life or risk to physical or mental health of the women.
 2. **Humanitarian grounds** - Such as when pregnancy arises from a sex crime like rape or intercourse with a lunatic woman, etc.
 3. **Eugenic grounds** - Where there is substantial risk that the child, if born, would suffer from deformities and diseases.

OBJECTIVE

- To provide the termination of certain pregnancies by RMP and related matters.

FORMS

1. **Form A:** Application Form for Approval of a private place
2. **Form B:** Certificate of Approval
3. **Form C:** Consent Form

IMPORTANT SECTIONS

Section 3	When pregnancies may be terminated by registered medical practitioners
Section 4	Place where pregnancy may be terminated
Section 6	Power to make rules
Section 7	Power to make regulations
Section 8	Protection of action taken in good faith

Patents Act and Rules

SCAN ME

To Join FREE
Online Test

INTRODUCTION

Patents Act was passed	1970
Patents Act came into force	20 th April 1972
Patents Rules	2003
Patents Rules came into force	20 th May 2003
Patents Act Amendment	March, 1999, June 2002, 1 st January 2005
Patents (Amendment) Ordinance	2004
Intellectual Property Appellate Board (Patent Procedure) Rules came into force with effect	30 Nov 2010
Patent (Appeals and application to Intellectual Property/ Appellate Board) came into force with effect	11 March 2011

❖ Patents (Amendment) Rules, 2024 Published on 15 March 2024

- Introduction of Certificate of Inventorship (Rule 70A, Form-8A)
- Grace Period for filing an application for Patent (Rule 29A, Form 31)
- Changes in filing Request for Examination (Rule 24B)
- Ease of compliance in matters of Form-3 & Form-27
- Streamlining of Pre-Grant Opposition Process (Rule 55)
- 10% Reduction in fee if renewal fee is paid in advance for at least 4 years (Rule 80)

IMPORTANT POINTS

- **Compulsory licences-** At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent.
- Compulsory license has been granted for anti-cancer drug by Indian Patent office to Natco Vs Bayer.
- Patent act consists of 23 chapters and 162 sections.

CHAPTERS

S. NO.	CHAPTERS	DESCRIPTION
1	Chapter I	Preliminary
2	Chapter II	Inventions Not Patentable
3	Chapter III	Applications for Patents
4	Chapter IV	Publication and Examination of Applications
5	Chapter IVA	Exclusive Marketing Rights (Omitted)
6	Chapter V	Opposition Proceedings to Grant of Patents
7	Chapter VI	Anticipation
8	Chapter VII	Provisions for Secrecy of Certain Inventions

Designs Act and Rules

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The Designs Act, 2000
- Repeals the Designs Act 1911.
- Designs Rules, 2001 have repealed the Designs Rules, 1933.
- The Act is in force since 11 May 2001 and extends to the whole of India.
- Objective to consolidate and amend the law relating to the protection of designs

CHAPTERS AND SECTIONS

CHAPTERS	DESCRIPTION	SECTIONS
CHAPTER I	Preliminary	1 - 2
CHAPTER II	Registration of Design	3 - 10
CHAPTER III	Copyright in Registered Designs	11 - 20
CHAPTER IV	Industrial and International Exhibitions	21
CHAPTER V	Legal Proceedings	22 - 23
CHAPTER VI	General	24 - 31
CHAPTER VII	Powers and Duties of Controller	32 - 36
CHAPTER VIII	Evidence, etc.	37 - 42
CHAPTER IX	Agency	43
CHAPTER X	Powers, etc., of Central Government	44 - 47
CHAPTER XI	Repeal and Savings	48

DEFINITIONS

Copyright	The exclusive right to apply a design to any article in any class in which the design is registered
Design	Means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction or anything which is in substance a mere mechanical device, and does not include any trade mark or property mark or any artistic work.
Controller	Controller-General of Patents, Designs and Trade Marks referred to in section 3
Article	Means any article of manufacture and any substance, artificial, or partly artificial and partly natural; and includes any part of an article capable of being made and sold separately
Original	In relation to a design, means originating from the author of such design and includes the cases which though old in themselves yet are new in their application



Trade Marks Act

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- Trade Marks Act, 1940 was the first statute law on trade marks in India, which was replaced by the Trade & Merchandise Marks Act, 1958.
- The Trade & Merchandise Mark Act, 1958 was revised and replaced by the Trade Mark Act, 1999.
- The Trade Mark Act, 1999 was enacted to bring our law in conformity with the TRIPS Agreement 1994, to which India is a signatory.
- The Trade Marks Act, 1999 and the Trade Marks Rules, 2002 are effective from September 15, 2003 and extend to the whole of India.
- The Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) is located at Mumbai.
- The Trade Marks registry is at Mumbai and its Branches are located in Kolkata, Chennai, Ahmedabad and New Delhi.
- Central Government can appoint a Controller-General of Patents, Designs, and Trade Marks, who also serves as the Registrar of Trade Marks.

OBJECTIVES

- To amend and consolidate the law relating to trade marks.
- To provide for registration and better protection of trade marks for goods and services and for the prevention of the use of fraudulent marks.

CHAPTERS AND SECTIONS

CHAPTERS	DESCRIPTION	SECTIONS
CHAPTER I	Preliminary	1 - 2
CHAPTER II	The register and conditions for registration	3 - 17
CHAPTER III	Procedure for and duration of registration	18 - 26
CHAPTER IV	Effect of registration	27 - 36
CHAPTER IVA	Special provisions relating to protection of trade marks through international Registration under the madrid protocol	36A - 36G
CHAPTER V	Assignment and Transmission	37 - 45
CHAPTER VI	Use of trademarks and registered users	46 - 56
CHAPTER VII	Rectification and correction of the register	57 - 60
CHAPTER VIII	Collective marks	61 - 68
CHAPTER IX	Certification Trade Marks	69 - 78
CHAPTER X (Omitted)	Special provisions for textile goods	79 - 82
CHAPTER XI	Appellate Board	83 - 100



Factories Act

SCAN ME

To Join FREE
Online Test

INTRODUCTION

Factories Act passed	23 rd September, 1948
Came into force	1 st April 1949
Factories Bill	23 rd Sept. 1948
Amendment	1950, 1951, 1954, 1976

- The law relating to the regulation of labour employed in factories in India was embodied in the Factories Act, 1934.
- It was amended several times but its general framework remained unchanged. Implementation of the Act revealed several defects and weaknesses which hamper its effective administration.
- The Act extends to the whole of India

CHAPTERS AND SECTIONS

CHAPTERS	DESCRIPTION	SECTIONS
CHAPTER I	Preliminary	1 - 7
CHAPTER II	The Inspecting Staff	7A - 10
CHAPTER III	Health	11 - 20
CHAPTER IV	Safety	21 - 41
CHAPTER IVA	Provisions relating to Hazardous Processes	41A - 41H
CHAPTER V	Welfare	42 - 50
CHAPTER VI	Working hours of adults	51 - 66
CHAPTER VII	Employment of young persons	67 - 77
CHAPTER VIII	Annual leave with wages	78 - 84
CHAPTER IX	Special provisions	85 - 91A
CHAPTER X	Penalties and Procedure	92 - 106A
CHAPTER XI	Supplemental	107 - 120

OBJECTIVES

1. To afford protection to human beings from long hours of work.
2. To provide healthy and sanitary conditions in the factories.
3. To take precautions for the safety of the workers.
4. To provide for the prevention of accidents on machines and other equipment.
5. To regulate and control its working by appointment of Inspectors by the State Governments.

Industries (Development and Regulation) Act



INTRODUCTION

- On 6th April, 1948 the Central Government announced its industrial policy.
- Industries (Development and Regulation) Act passed in 1951
- It came into force on 8th May, 1952 and extends to the whole of India.
- Objective is to provides for the development and regulation of certain industries.

CHAPTERS AND SECTIONS

CHAPTERS	DECIPTION	SECTIONS
CHAPTER I	Preliminary	1 - 4
CHAPTER II	The Central Advisory Council and Development Councils	5 - 9
CHAPTER III	Regulation of Scheduled Industries	10 - 18
CHAPTER IIIA	Direct Management or Control of Industrial undertakings by Central Government in Certain cases	18A - 18F
CHAPTER IIIAA	Management or Control of Industrial undertakings owned by companies in liquidation	18FA
CHAPTER IIIAB	Power to provide relief to certain Industrial undertakings	18FB
CHAPTER IIIAC	Liquidation or Reconstruction of companies	18FC - 18FH
CHAPTER IIIB	Control of supply, distribution, price, etc., of certain articles	18G
CHAPTER IV	Miscellaneous	19 - 32

DEFINITIONS

Factory	Any premises, including the precincts thereof, in any part of which a manufacturing process is being carried on or is ordinarily so carried on— (i) With the aid of power, provided that fifty or more workers are working or were working thereon on any day of the preceding twelve months (ii) Without the aid of power, provided that one hundred or more workers are working or were working thereon on any day of the preceding twelve months and provided further that in no part of such premises any manufacturing process is being carried on with the aid of power.
Industrial undertaking	Any undertaking pertaining to a scheduled industry carried on in one or more factories by any person or authority including Government.
Scheduled Industry	Means any of the industries specified in the First Schedule

Minimum Wages Act



INTRODUCTION

- A Minimum Wages Bill was introduced in the Central Legislative Assembly on 11th April 1946 and came into force with effect from 15th March 1948.
- This Act is to provide for fixing minimum rates of wages in certain employments.

DEFINITIONS

Adolescent	Means a person who has completed his fourteenth year of age but has not completed his eighteenth year
Adult	Means a person who has completed his eighteenth year of age
child	Means a person who has not completed his fourteenth year of age
Appropriate Government	(i) In relation to any scheduled employment carried on by or under the authority of the Central Government or a railway administration, or in relation to a mine, oilfield or major port, or any corporation established by a Central Act, the Central Government. (ii) In relation to any other scheduled employment, the State Government.
Competent Authority	Means the authority appointed by the appropriate Government by notification in its Official Gazette to ascertain from time to time the cost of living index number applicable to the employees employed in the scheduled employments specified in such notification
Cost of living index number	In relation to employees in any scheduled employment in respect of which minimum rates of wages have been fixed, means the index number ascertained and declared by the competent authority by notification in the Official Gazette to be the cost of living index number applicable to employees in such employment
Scheduled employment	Means an employment specified in the Schedule, or any process or branch of work forming part of such employment
Wages	Means all remuneration, capable of being expressed in terms of money, which would, if the terms of the contract of employment, express or implied, were fulfilled, be payable to a person employed in respect of his employment or of work done in such employment, and includes house rent allowance, but does not include:- i. The value of a. any house-accommodation, supply of light, water, medical attendance. b. any other amenity or any service excluded by general or special order of the appropriate Government. ii. Any contribution paid by the employer to any Pension Fund or Provident Fund or under any scheme of social insurance iii. Any travelling allowance or the value of any travelling concession iv. Any sum paid to the person employed to defray special expenses entailed on him by the nature of his employment v. Any gratuity payable on discharge

Consumer Protection Act

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- Consumer Protection Act was passed on 1986
- Act came into force on 24th December 1986
- The Consumer Protection Rules was passed on 1987
- The Consumer Protection Regulation was passed on 2005.
- Amendment – 1991, 1993, 2002
- It is replaced by the Consumer Protection Act 2019.
- It extends to the whole of India except the State of Jammu and Kashmir.

OBJECTIVES

- To provide for better protection of the interest of consumer by establishment of consumer council
- To establish authorities for timely and effective administration and settlement of consumers disputes and for matters connected therewith or incidental thereto.

DEFINITIONS

Appropriate laboratory	Means a laboratory or an Organisation (a) Recognised by the Central Government (b) Recognised by a State Government, subject to such guidelines as may be issued by the Central Government in this behalf; (c) Established by or under any law for the time being in force, which is maintained, financed or aided by the Central Government or a State Government for carrying out analysis or test of any goods with a view to determining whether such goods suffer from any defect
Branch office	It means i. Any office or place of work described as a branch by the establishment ii. Any establishment carrying on either the same or substantially the same activity carried on by the head office of the establishment
Central Authority	Means the Central Consumer Protection Authority established under section 10
Consumer rights	i. The right to be protected against the marketing of goods, products or services which are hazardous to life and property. ii. The right to be informed about the quality, quantity, potency, purity, standard and price of goods, products or services, as the case may be, so as to protect the consumer against unfair trade practices. iii. The right to be assured , wherever possible, access to a variety of goods, products or services at competitive prices. iv. The right to be heard and to be assured that consumer's interests will receive due consideration at appropriate forums.



Prevention of Cruelty to Animals Act



INTRODUCTION

Prevention of Cruelty to Animals Act passed	1960
Act repeal	1890
Breeding of and Experiments on Animals (Control and Supervision) Rules	1998

- The Prevention of Cruelty to Animals Act passed on 1960.
- The Prevention of Cruelty to Animals Act, 1960 repeals the Act of 1890.
- The Breeding of and Experiments on Animals (Control and Supervision) Rules passed on 1998.
- The Act extends to the whole of India except the State of Jammu and Kashmir.
- State Government is the responsibility to establish Society for Prevention of Cruelty to Animals (SPCA).
- To prevent the infliction of unnecessary pain or suffering on animals.
- To amend the law relating to the prevention of cruelty to animals.

CHAPTERS AND SECTIONS

CHAPTER	DESCRIPTIONS	SECTIONS
Chapter I	Preliminary	1 - 3
Chapter II	Animal Welfare Board of India	4 - 10
Chapter III	Cruelty to animals generally	11 - 13
Chapter IV	Experimentation on animals	14 - 20
Chapter V	Performing animals	21 - 27
Chapter VI	Miscellaneous	28 - 41

IMPORTANT SECTIONS

Section 3	Duties of persons having charge of animals
Section 4	Establishment of Animal Welfare Board of India
Section 5	Constitution of the Animal Welfare Board
Section 9	Functions of the Animal Welfare Board
Section 10	Power of Animal Welfare Board to make regulations
Section 11	Treating animals cruelly
Section 14	Experiments on animals
Section 15	Committee for control and supervision of experiments on animals
Section 35	Treatment and care of animals
Section 38	Power to make rules

Right to Information Act

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The Right to Information (RTI) Act, 2005 is an act of the Parliament of India & Delhi Legislative Assembly which sets out the rules and procedures regarding citizens' right to access information.

Right to Information Act passed	15 June 2005
Right to Information Act came into force	12 October 2005
Latest Right to Information Act	2019

CHAPTER AND SECTIONS

CHAPTERS	DESCRIPTION	SECTION
Chapter I	Preliminary	1-2
Chapter II	Right to information and obligations of public authorities	3-11
Chapter III	The central information commission	12-14
Chapter IV	The state information commission	15-17
Chapter V	Powers and functions of the information commissions, appeal and penalties	18-20
Chapter VI	Miscellaneous	21-31

IMPORTANT SECTIONS

Section 3	Right to information
Section 4	Obligations of public authorities
Section 12	Constitution of Central Information Commission
Section 15	Constitution of State Information Commission
Section 18	Powers and functions of Information Commissions
Section 27	Power to make rules by appropriate Government
Section 28	Power to make rules by competent authority

OBJECTIVE

- To provide for setting out the practical regime of right to information for citizens to secure access to information under the control of public authorities.
- To promote transparency and accountability in the working of every public authority, the constitution of a Central Information Commission and State Information Commissions and for matters connected therewith or incidental thereto.

International Council For Harmonisation (ICH) Guidelines

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The full form of ICH is International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. It was formerly known as the International Conference on Harmonisation.
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines.

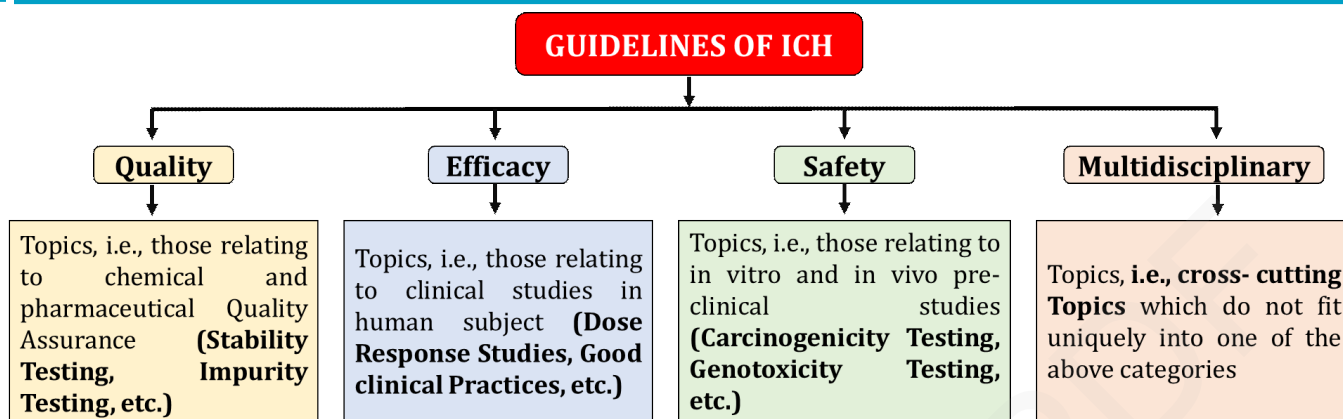
OBJECTIVES OF ICH

1. To increase international harmonization of technical requirements to ensure that safe, effective and high-quality medicines are developed.
2. To harmonize technical requirements for registration or marketing approval.
3. To develop and register pharmaceuticals in the most efficient and cost-effective manner.
4. To promote public health.
5. To prevent unnecessary duplication of clinical trials on humans.
6. To minimize the use of animal testing without compromising safety and effectiveness of drug.

PRINCIPLES OF ICH GUIDELINE FOR GCP

1. Ethical Principles of Declaration of Helsinki
2. Benefit justifies risk
3. Rights, safety, wellbeing
4. Adequate information to support trial
5. Clear, scientifically sound protocol
6. Favorable ethics approval
7. Qualified Chief Investigator
8. Researcher training, education and experience
9. Freely given informed consent
10. Accurate data handling and storage
11. Data Protection and confidentiality
12. Good Manufacturing Practice
13. Quality assurance systems

GUIDELINES OF ICH



➤ QUALITY GUIDELINES

FORM NO.	FEATURES		
Q1A to Q1F	Stability	Q1A(R2)	Stability testing of New Drug Substances and Products
		Q1A and Q1B	Stability testing: Photostability Testing of New Drug Substances and Products
		Q1C	Stability Testing for New Dosage Forms
		Q1D	Bracketing and Matrixing Designs for stability testing of New Drug Substances and Products
		Q1E	Evaluation of Stability Data
		Q1F	Q1F-Stability Data Package for registration applications in climatic Zones III and IV.
Q2	Analytical Validation		
Q3A to Q3E	Impurities		
Q4A to Q4B	Pharmacopoeias		
Q5A to Q5E	Quality of Biotechnological Products		
Q6A to Q6B	Specifications		
Q7	Good Manufacturing Practice		
Q8	Pharmaceutical Development		
Q9	Quality Risk Management		
Q10	Pharmaceutical Quality System		
Q11	Development and Manufacture of Drug Substances		
Q12	Lifecycle Management		
Q13	Continuous Manufacturing of Drug Substances and Drug Products		
Q14	Analytical Procedure Development		

➤ SAFETY GUIDELINES

FORM NO.	FEATURES
S1A – S1C	Carcinogenicity Studies
S1A	Need for carcinogenicity studies of pharmaceuticals
S1B (R1)	Testing for Carcinogenicity of Pharmaceuticals
S1C (R2)	Dose Selection for Carcinogenicity Studies of Pharmaceuticals
S2	Genotoxicity Studies
S2 (R1)	Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use

World Health Organization (WHO)

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- WHO is the directing and coordinating authority for health. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.
- The World Health Organization (WHO) is a specialized agency of the United Nations responsible for International Public Health.
- Established on 7 April 1948
- Its constitution formally came into force on the first World Health Day on 7 April 1948
- Headquartered in Geneva, Switzerland, it has six regional offices and 150 field offices worldwide.
- **Regional offices:**
 1. Africa; HQ: Brazzaville, Republic of the Congo
 2. Western Pacific; HQ: Manila, Philippines
 3. Eastern Mediterranean; HQ: Cairo, Egypt
 4. South East Asia; HQ: New Delhi, India
 5. Europe; HQ: Copenhagen, Denmark
 6. Americas; HQ: Washington, D.C., US
- The WHO is governed by the World Health Assembly (WHA), which is composed of its 194 member states.
- The head of the organization is the director-general, elected by the World Health Assembly.
- Dr Tedros Adhanom Ghebreyesus is the Director-General of WHO, elected by a vote of Member States at the World Health Assembly on 23 May 2017 and re-elected for a second 5-year term on 24 May 2022.
- The main functions of the World Health Organization include promoting the control of epidemic and endemic diseases; providing and improving the teaching and training in public health, the medical treatment of disease, and related matters; and promoting the establishment of international standards for biological products.
- The current Chairman of executive board is Dr. ASSAD Hafeez.



World Health
Organization

➤ VISION

The attainment by all people the highest level of health. (Health For All)

➤ MISSION

- ✓ To lead strategic collaborative efforts among Member States and other partners
- ✓ To promote equity in health

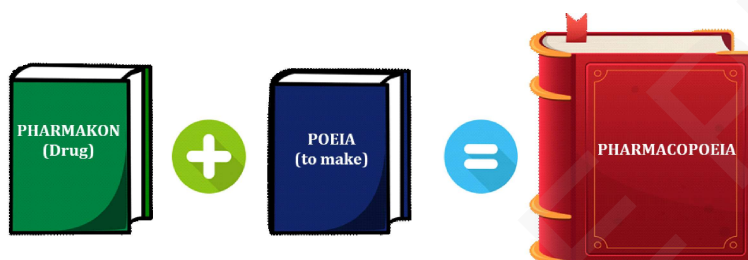


Pharmacopoeias

SCAN ME

To Join FREE
Online Test

INTRODUCTION



- It is a legal and official book issued by recognized authorities usually appointed by Government of each country.
- Pharmacopoeia is a book describing preparation of formulations, describing dispensing techniques, published by a recognized government or regulatory authority.
- Each pharmacopoeia described different strength and method of preparation for the same preparation.
- The first International Pharmacopoeia was published by the World Health Organisation in 1951 (Volume I) and in 1955 (Volume II).

➤ Pharmacopoeial Description

All Pharmacopoeias consist of the three main Section-

1. Introduction

It is useful pointer to pharmaceutical progress since last edition because it summarizes the various changes/ addition/deletions in the current edition.

2. Monographs of the official drugs

The word monograph implies the written study of a subject. The pharmacopoeial monographs gives the following information about drugs: Title, Formula Weight and Molecular Weight, Category, Dose, Description, solubility, Standard, Identification, pH, Limit of Impurities, Assay and Storage.

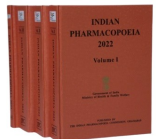
3. Appendices

It provides additional information and data to support the main sections of the regulatory submission.



List of Pharmacopeias and Some of the Standard Reference Books of Common Use in India

1. Indian Pharmacopoeia (I.P.)	9. Pharmaceutical Codex
2. British Pharmacopoeia (B.P.)	10. Merck Index
3. United States Pharmacopoeia (U.S.P.)	11. British National Formulary
4. European Pharmacopoeia	12. United States National Formulary
5. International Pharmacopoeia	13. National Formulary (N.F.)
6. Japanese Pharmacopoeia	14. United States Dispensatory
7. Martindale Extra Pharmacopoeia	15. Indian Pharmaceutical Codex (I.P.C.)
8. British Pharmaceutical Codex (B.P.C.)	16. National Formulary of India (N.F.I.)



Central Drug Standard Control Organization (CDSCO)

SCAN ME



To Join FREE Online Test

INTRODUCTION

- Central Drug Standard Control Organization (CDSCO) of India is main regulatory body for regulation of pharmaceutical, medical devices and Clinical Trials.
- Head office is located at New Delhi.
- The Central Drug Authority in India is the Central Drugs Standard Control Organization (CDSCO), which operates under the Ministry of Health and Family Welfare.
- The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India
- The Drugs Controller General (India) (DCGI) heads the CDSCO.
- Drugs Controller General of India (DCGI) is responsible for approval of New Drugs, Medical devices and Clinical Trials to be conducted in India.
- The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC)
- On June 11, 2024, Shri Jagat Prakash Nadda assumed the role of Union Minister of Health and Family Welfare and Minister of Chemicals and Fertilizers.
- In 2025, Dr. Rajeev Singh Raghuvanshi is the Drugs Controller General of India (DCGI) on a contractual, one-year reappointment starting March 1, 2025



➤ Vision:

To Protect and Promote public health in India.

➤ Mission:

To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

OBJECTIVES OF CDSCO

- To upgrade knowledge of regulators and to increase consumer awareness.
- To interact and cooperate with the State, Central Government, Union Territories and non-governmental voluntary organizations with a view to improve the quality of healthcare facilities.
- To inculcate a sense of dedication amongst regulators, assist them to improve their professional excellence, to improve their effectiveness enabling them to serve and safeguard the interest of the consumers.
- To promote and advance, in the interest of public, the art of science and pharmaceutical technology and to develop highest standards for pharmaceutical and Medical Devices industry products with the use of technology.

Investigational New Drug Application (INDA)

SCAN ME

To Join FREE
Online Test

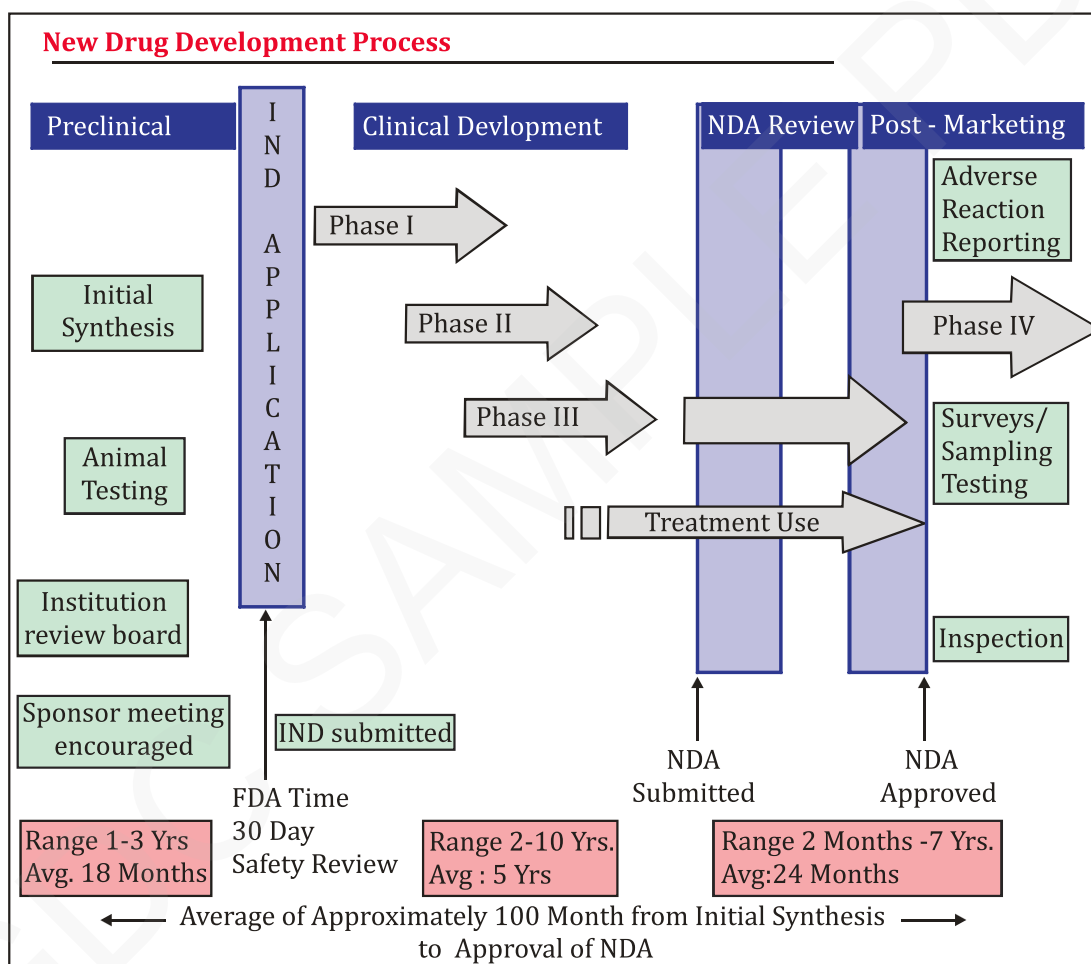
INTRODUCTION

- An Investigational New Drug (IND) Application is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.
- The IND is the means through which the sponsor technically obtains this exemption from the FDA.
- The IND is the means through which the sponsor technically obtains this exemption from the FDA.
- The Chairman of the Investigational New Drug (IND) committee in India is Drugs Controller General of India, Government of India.
- **There are two IND categories:**
 1. **Commercial-** Permits sponsor to collect data on clinical safety and effectiveness needed for application for marketing in the form of NDA
 2. **Research (non-commercial)-** Permits the sponsor to use drug in research to obtain advanced scientific knowledge of new drug, No plan to market the product
- **The IND application must contain information in three broad areas:**
 - i. **Animal Pharmacology and Toxicology Studies** - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use).
 - ii. **Manufacturing Information** - This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
 - iii. **Clinical Protocols and Investigator Information** - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators—professionals (generally physicians) who oversee the administration of the experimental compound to assess whether they are qualified to fulfil their clinical trial duties.
- **Sponsor:**
 - A sponsor is an individual, company, institution, or organization that takes responsibility for and initiate a clinical study (21 CFR 312.3(b), 21 CFR 312.50).
- **Responsibility:**
 - Selecting qualified investigators
 - Ensuring study monitoring
 - Maintaining an effective IND,
 - Ensuring AE risk information is provided to the FDA and investigators.
- **Investigator:**
 - An investigator is an individual under whose immediate direction the study drug is administered or dispensed.

IMPORTANCE OF IND

- An IND is required any time I want to conduct a clinical trial of an unapproved drug.
- An IND would be required to conduct a clinical trial if the drug is
- a new chemical entity, not approved for the indication under investigation in a new dosage form.
- Being administered at a new dosage level
- in combination with another drug and the combination is not approved.
- All clinical studies where a new drug is administered to human subjects, regardless of whether the drug will be commercially developed, require an IND.

NEW DRUG DEVELOPMENT PROCESS



EMERGENCY USE OF AN INVESTIGATIONAL DRUG OR BIOLOGIC

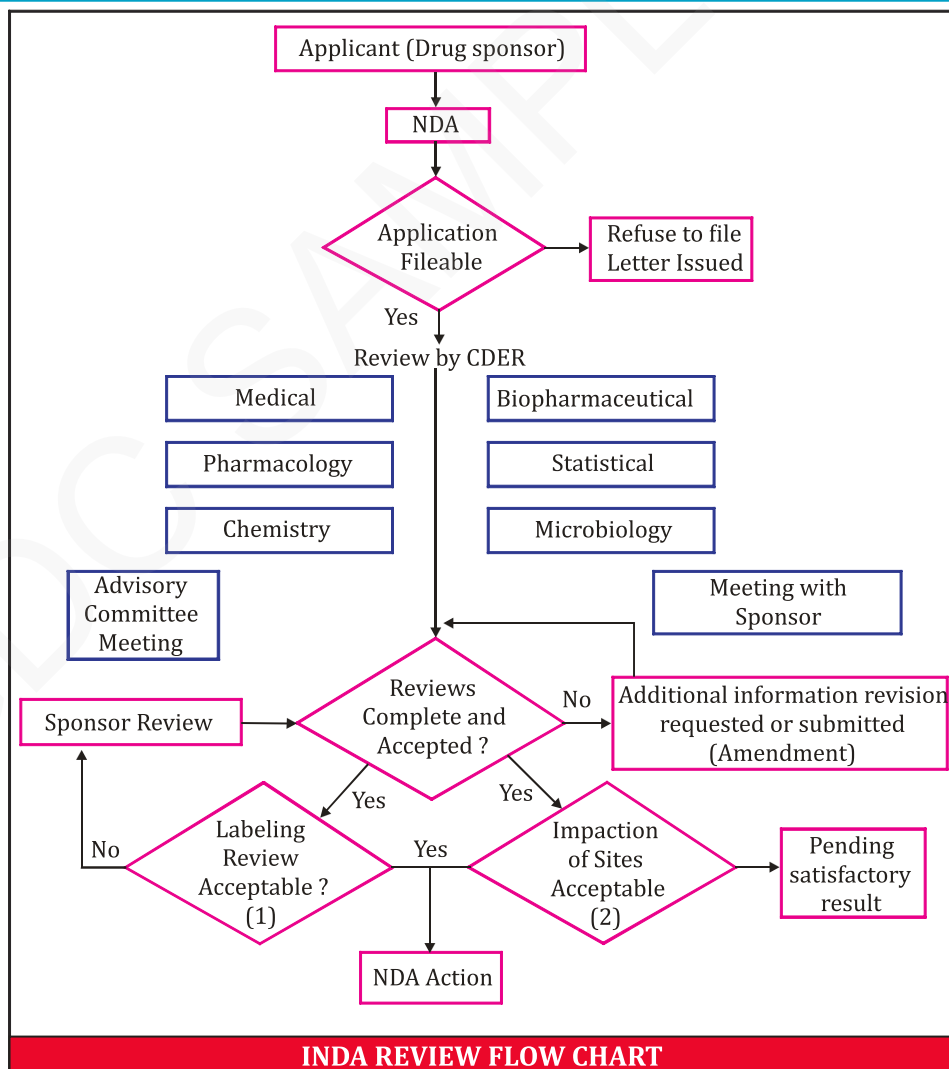
- Emergency Use of an Investigational Drug or Biologic - Information Sheet
- The Guidance for Institutional Review Boards and Clinical Investigators contains information on: Obtaining an Emergency IND, Emergency Exemption from Prospective IRB, Approval Exception from Informed Consent, and Requirement Planned Emergency Research, Informed Consent Exception.
- Physician Request for a Single Patient IND for Compassionate or Emergency Use
- Instructions for Sponsors of Emergency Investigational New Drug (EIND) Applications for Antimicrobial Products. From the Office of Antimicrobial Products, Division of Antiviral Products

CODE OF FEDERAL REGULATIONS (CFR)	
NUMBER	REGULATION
21CFR Part 201	Drug Labelling
21CFR Part 312	Investigational New Drug Application
21CFR Part 314	INDA and NDA Applications for FDA Approval to Market a New Drug (New Drug Approval)
21CFR Part 316	Orphan Drugs
21CFR Part 50	Protection of Human Subjects
21CFR Part 54	Financial Disclosure by Clinical Investigators
21CFR Part 56	Institutional Review Boards
21CFR Part 58	Good Lab Practice for Nonclinical Laboratory Animal Studies

MANUAL OF POLICIES AND PROCEDURES (MaPPs)

- CDER's Manual of Policies and Procedures are approved instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities.
- All MAPPs are available for the public to review for a better understanding of office policies, definitions, staff responsibilities and procedures.

INDA REVIEW FLOW CHART



United States Food and Drug Administration (USFDA)

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The **United States Food and Drug Administration (FDA or US FDA)** is a federal agency of the **Department of Health and Human Services**.
- **Formed:** FDA Formed in June 30, 1906.
- **FDA headquarters:** Montgomery County and Prince George's County, Maryland.
- **Preceding agencies:** Food, Drug, and Insecticide Administration (July 1927 July 1930), Bureau of Chemistry, USDA (July 1901 July 1927), Division of Chemistry, USDA (established 1862).
- **Jurisdiction:** Federal government of the United States.
- **Agency executives:** Marty Makary, Commissioner of Food and Drugs, Sara Brenner, Principal Deputy Commissioner.
- **Parent agency:** Department of Health and Human Services.
- The agency has 223 field offices and 13 laboratories located across the 50 states, the United States Virgin Islands, and Puerto Rico. In 2008, the FDA began to post employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.
- Current Good Manufacturing Practice (CGMP) regulations are established the United States FDA.
- Food and Drug Administration has developed four distinct and successful approaches to making such drugs available as rapidly as possible:
 - i. **Fast Track:** Fast track is a process designed to facilitate the Drug development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
 - ii. **Priority Review:** A Priority Review designation means FDAs goal is to take action on an application within 6 months. Two-tiered system of review times Standard Review and Priority Review. The following letter codes describe the **priority review** of the drug:
 - **Code Meaning**
 - S - Standard review** for drugs similar to currently available drugs.
 - P - Priority review** for drugs that represent significant advances over existing treatments.
 - iii. **Breakthrough Therapy:** A process designed to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy.
 - iv. **Accelerated Approval:** These regulations allowed drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint.



FDA VISION

- Patients in the U.S. have high-quality, safe, and effective medical devices of public health importance first in the world.



IND safety report.

❖ IND Application Process

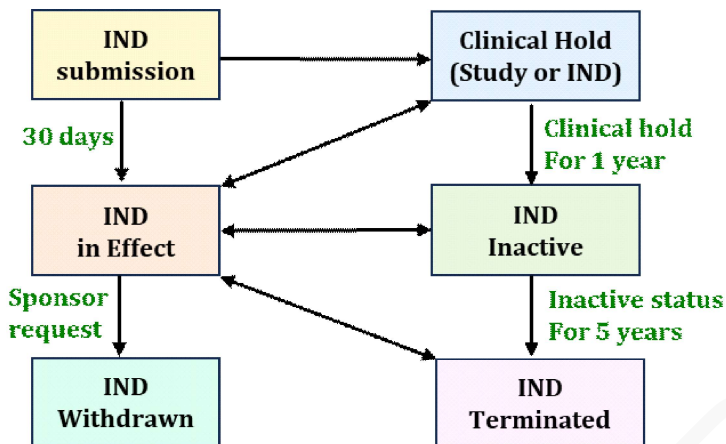


Fig: Schematic representation of the IND application process

2. New Drug Application (NDA)

- A New Drug Application (NDA) is a formal request submitted to a regulatory body like the U.S. Food and Drug Administration (FDA) by a pharmaceutical company to market a new drug in a specific country.
- The NDA serves as a comprehensive document containing all the necessary data to demonstrate the drug's safety and efficacy for its intended use.
- When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a New Drug Application (NDA).
- Application form (FDA form 356H): This form is to be submitted with each original NDA and every supplement thereof. The form can be downloaded from the FDA website.

3. Abbreviated New Drug Application (ANDA)

- An Abbreviated New Drug Application (ANDA) contains data that, when submitted to FDA's Center for Drug Evaluation and Research, and Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product.
- Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.
- Kefauver-Harris Drug Amendment (1962) and Hatch-Waxman Act (1984) are two regulations that facilitated the growth of the generic industry.
- Paper NDA (a provision under Kefauver-Harris Drug Amendment, 1962) were the early equivalents to today's ANDA, wherein the submission used to contain copies of published literature (on safety and efficacy) and bioequivalence studies comparing the generic drug to the innovator drug as the evidence of safety and efficacy.
- Applications under the "abbreviated" tag were accepted only for drugs approved prior to 1962 and which were labeled safe and effective under DESI review.
- Hatch-Waxman Act made an attempt to balance the commercial and competitive aspects of the generic and innovator drugs.
- It created provisions for Marketing Exclusivity, patent term extension for NDA holder and options of Suitability petition under Section 505(b)2 and, 180-day generic drug exclusivity to the post-innovator applicants.

Code of Federal Regulations (CFR)

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- CFR stands for Code of Federal Regulations.
- CFR a codification of general rules and regulations also known as administrative law published in the federal register by the executive department and agencies of federal government of united states
- In the law of the United States, the Code of Federal Regulations (CFR) is the codification of the general and permanent regulations
- It is promulgated by the executive departments and agencies of the federal government of the United States.
- The rules and regulations are first promulgated or published in the Federal Register.

21 CFR
21- Title Number
C- Code
 of
F- Federal
R- Regulation

➤ Structure of Code of Federal Regulations (CFR)

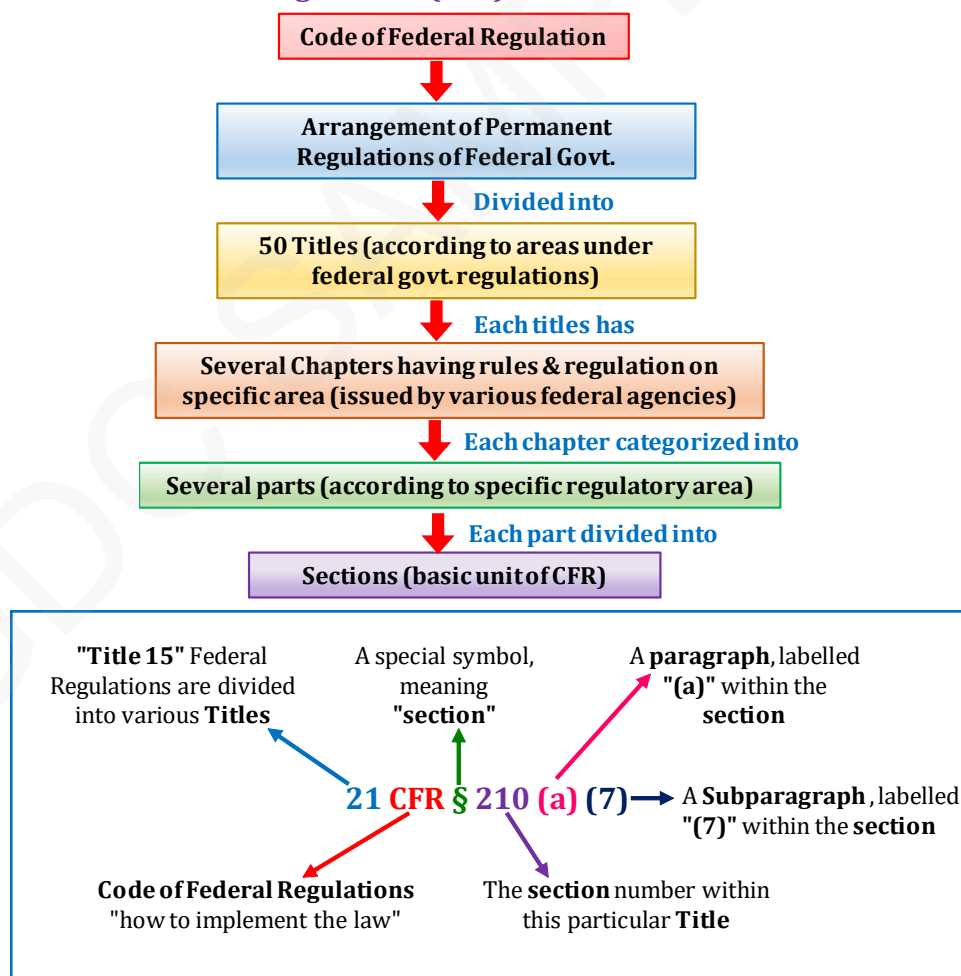


Fig: CFR citation



Organisation For Economic Co-operation and Development (OECD)

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- The Organization for Economic Co-operation and Development (OECD) is an intergovernmental organisation that works to build better policies for better lives.
- It provides a forum for governments to share experiences and seek solutions to common problems, focusing on economic progress and world trade.
- The OECD has 38 member countries, primarily democracies with market-based economies.
- **Established:** 30 September 1961 (as OECD).
- **Headquarters:** Château de la Muette Paris, France.
- **Secretary-General:** Mathias Cormann (1 June 2021).
- **The Good Laboratory Practice (GLP) principle is based on OECD guidelines.**
- The OECD Principles of Good Laboratory Practice (GLP) ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations.



➤ OECD Mission

- The mission of the OECD is to promote policies that will improve the economic and social welfare of people in developed nations.
- To encourage free and fair trade and investment among member and non-member countries.
- To ensure sound economic, social, and environmental policies for global development
- To promote evidence-based policy-making through research, data collection, and analysis.

➤ OECD Vision

- To build a better world economy and society through cooperation among nations.
- To act as a global policy forum where governments work together to promote prosperity, equality, opportunity, and well-being for all.
- To create a world where economic growth is inclusive and sustainable.

OECD HISTORY

- OECD originated in 1948, as the Organisation for European Economic Co-operation (OEEC).
- The Organisation for European Economic Co-operation (OEEC) was founded to govern the predominantly US-funded Marshall Plan for post-war reconstruction on the continent.
- The OEEC was instrumental in helping the European Economic Community (EEC). The EEC has evolved into the European Union (EU) to establish a European Free Trade Area.
- OEEC was renamed as the OECD in 1961 when the USA and Canada joined to reflect a broader membership.

OECD OBJECTIVES

The objectives of the OECD include fostering economic development and cooperation and fighting poverty through the promotion of economic stability.



International Organization for Standardization (ISO)

SCAN ME

To Join FREE
Online Test

INTRODUCTION

- ISO stands for International Organisation for Standardization.
- ISO is an **independent, non-governmental organization**, whose membership consists of different national standards bodies
- As of 2022, there are 167 members representing ISO in their country, with each country having only one member.
- **Founded** - 23 February 1947
- **Predecessor** - International Federation of the National Standardizing Associations (ISA)
- **Purpose**- International standards development
- **Headquarters**- Geneva, Switzerland
- The International Organization for Standardization is a network of 173 national standards bodies.
- The International Organization for Standardization – better known as ISO – provides organizations with guidelines to consistently achieve universally recognized standards.
- The organization develops and publishes international standards in technical and nontechnical fields, including everything from manufactured products and technology to food safety, transport, IT, agriculture, and healthcare
- ISO 9000 was first published in 1987 by the International Organization for Standardization (ISO).
- International Standards are developed by ISO technical committees (TC) and subcommittees (SC) by a process with six steps:
 - ✓ Stage 1: Proposal stage
 - ✓ Stage 2: Preparatory stage
 - ✓ Stage 3: Committee stage
 - ✓ Stage 4: Enquiry stage
 - ✓ Stage 5: Approval stage
 - ✓ Stage 6: Publication stage
- **ISO Mission**
 - To develop and publish international standards that ensure quality, safety, efficiency, and interoperability of products, services, and systems.
 - To facilitate global trade by providing common standards.
 - To support innovation and knowledge sharing across industries.
 - To address societal challenges like sustainability, health, and safety.
 - To build confidence among consumers, businesses, and governments through trustworthy standards.
- **ISO Vision**
 - To be the leading international body for global standardization.
 - To create a world where standards improve lives everywhere.
 - To promote sustainable development goals (SDGs) through international standards.



ISO 9000 SERIES QUALITY MANAGEMENT PRINCIPLES

The ISO 9000 series are based on seven quality management principles (QMPs), namely:

QMP	PRINCIPLE	ABOUT
QMP 1	Customer focus	Organizations depend on their customers, both direct and indirect, and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.
QMP 2	Leadership	Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
QMP 3	Engagement of people	People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
QMP 4	Process approach	A desired result is achieved more efficiently when activities and related resources are managed as a process.
QMP 5	Improvement	Improvement of the organization's overall performance should be a permanent objective of the organization.
QMP 6	Evidence-based decision making	Effective decisions are based on the analysis of data and information.
QMP 7	Relationship management	An organization and its external providers (suppliers, contractors, service providers) are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

POPULAR STANDARD OF ISO

ISO 9001	Quality management
ISO 9002	Model for quality assurance in production, installation and servicing
ISO 9003	Quality assurance in final inspection and test
ISO 9004	Guidance on achieving sustained organizational success
ISO 13485	Medical devices
ISO 14001	Environmental Management
ISO 14644	Cleanrooms and associated controlled environments
ISO 26000	Social responsibility
ISO 27001	Information Security Management System
ISO 50001	Energy management
ISO 31000	Risk management
ISO 22000	Food safety management
ISO 27001	Information security management
ISO 20121	Sustainable events
ISO 37001	Anti-bribery management systems
ISO 45001	Occupational health and safety

ISO 9000-QUALITY MANAGEMENT

- A series of Quality Management System (QMS) standards
- This family of standards make sure that products and services meet customer's needs.
- The current version of the ISO 9001 standard is 9001:2015.

PRACTICE MCQs

1. **Who was the Chairman of the Drugs Enquiry Committee which was established in the year 1927**
(a) B. Mukherje (b) Joseph Bhore
(c) S.S. Bhatia (d) R.N. Chopra
2. **Who among the following is referred to the Father of Indian Pharmacy**
(a) M. L. Schroff (b) Ashima Chatterjee
(c) R. N. Chopra (d) H. G. Khorana
3. **The first National Institute for Pharmacy Education and Research (NIPER) was started at**
(a) Banaras (b) Chennai
(c) Mohali (d) Chhattisgarh
4. **The committee appointed by Government of India to look into the drug industry and various aspects of drugs like licensing price control, imports, role of foreign sector quality control was headed by**
(a) Mudaliar Committee (c) Hathi Committee
(b) Bhatia Committee (d) Bhore Committee
5. **All India Pharmaceutical Congress Association was established in**
(a) 1940 (b) 1941
(c) 1939 (d) 1942
6. **Who was appointed as the chairman of the Hathi Committee**
(a) Laxman Hathi (b) Jaisukhlal Hathi
(c) C. Rangarajan (d) Raghuram Rajan
7. **Which committee recommended the establishment of the Central Drugs Laboratory in India, based on the findings of the Drug Enquiry Committee**
(a) Chopra Committee (b) Mudaliar Committee
(c) Bhatia Committee (d) Kelkar Committee
8. **The main function of the Pharmacy Council of India is to regulate**
(a) Drug manufacturing
(b) Medical education
(c) Pharmacy education and profession
(d) Hospital management
9. **When was the Indian Pharmacopoeia Commission established**
(a) 1946 (b) 1947
(c) 1948 (d) 1950
10. **Who was the chairman of the Health Survey and Development Committee**
(a) Dr. B.C. Roy (b) Sir Joseph Bhore
(c) Dr. Rajendra Prasad (d) Dr. S. Radhakrishnan
11. **When did BHU start the 3-years B.Pharm course**
(a) 1934 (b) 1936
(c) 1937 (d) 1938
12. **What was the primary objective of the Bhore Committee**
(a) To address issues related to sanitation and hygiene
(b) To recommend measures for improving public health in India
(c) To regulate the pharmaceutical industry
(d) To establish medical colleges across the country
13. **Where was the Indian Hospital Pharmacists Association (IHPA) launched**
(a) Delhi (b) Mumbai
(c) Pilani, Rajasthan (d) Chennai
14. **Which committee was appointed to review the drug legislation in India and ultimately led to the enactment of the Drugs and Cosmetics Act 1940**
(a) Bhore Committee (b) Chopra Committee
(c) Mudaliar Committee (d) Bhatia Committee

491. What is the term length for the Secretary-General of the OECD

- (a) 3 years (b) 4 years
(c) 5 years (d) 6 years

492. OECD stand for

- (a) Organisation for Economic Coordination and Development
(b) Organisation for Economic Co-operation and Development
(c) Organisation for Environmental Control and Development
(d) Organisation for Economic and Cultural Development

493. Which section of the OECD Guidelines for the Testing of Chemicals deals with physical chemical properties

- (a) Section 1 (b) Section 2
(c) Section 3 (d) Section 4

494. ISO stands for

- (a) International Standard Organisation
(b) International Standardization Organisation
(c) International Organisation for Standardization
(d) International Statistical Organization

495. ISO 14000 is primarily concerned with one or more than one of events mentioned below

- (a) Chemical safety (b) Automotive belts
(c) Quality management (d) Environmental Safety

496. Which of the following statements about ISO is INCORRECT

- (a) ISO certifies organizations which apply for ISO 9001 compliance
(b) ISO 9000 is not a prescriptive standard for quality
(c) ISO 9000 is a process oriented rather than result oriented standard

(d) ISO 9000 does not provide industry specific performance requirements

497. Which one of the following is NOT correctly matched as per the classification of clean rooms ISO-14644

- (a) Part 1 : Classification of air cleanliness
(b) Part 3 : Test methods
(c) Part 4 : Design, construction and start-up
(d) Part 5 : Terms and definitions

498. According to ISO 9001 inspection and testing comes under which management responsibility

- (a) Document control management
(b) Data control management
(c) Process control management
(d) Maintenance control management

499. Which of the following is true about ISO 14000 certification

- (a) ISO 14000 mainly deals with environmental management
(b) ISO 14000 is all about quality of the micro environment of the organization
(c) ISO 14000 is far superior than other ISO systems and standards
(d) ISO 14000 is completely outdated and non-essential standard

500. In International organization for standardization (ISO), standard pertaining to quality system model for quality assurance in production, installation and servicing is given under

- (a) ISO 9002 (b) ISO 9000
(c) ISO 9001 (d) ISO 9004

ANSWER KEY

1-d	2-a	3-c	4-a	5-a	6-b	7-a	8-c	9-c	10-b
11-c	12-b	13-c	14-b	15-b	16-b	17-c	18-b	19-d	20-b
21-b	22-d	23-b	24-a	25-d	26-d	27-a	28-d	29-c	30-c
31-c	32-c	33-b	34-b	35-b	36-c	37-c	38-c	39-a	40-a
41-b	42-c	43-b	44-b	45-a	46-b	47-c	48-a	49-c	50-d
51-c	52-c	53-c	54-c	55-a	56-a	57-b	58-c	59-d	60-a
61-b	62-c	63-b	64-c	65-a	66-b	67-a	68-c	69-c	70-c