	Contents
	ntributors v face vii
1.	General Principles of Law, History and Various Acts related to Drugs and Pharmacy Profession 1
2.	Pharmacy Act 1948 and Rules 5
	Objectives, Definitions, Pharmacy Council of India; its Constitution and Functions, Education Regulations, State and Joint State Pharmacy Councils, Registration of Pharmacists, Offences and Penalties, Pharmacy Practice Regulations 2015
3.	Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments 17
	Objectives, Definitions, Legal Definitions of Schedules to the Act and Rules  Import of Drugs—Classes of Drugs and Cosmetics Prohibited from Import, Import Under License or Permit  Manufacture of Drugs—Prohibition of Manufacture and Sale of Certain Drugs, Conditions for Grant of License and Conditions of License for Manufacture of Drugs, Manufacture of Drugs for Test, Examination and Analysis, Manufacture of New Drug, Loan License and Repacking License, Study of schedule C and C1, G, H, H1, K, P, M, N, and X.
	<b>Sale of Drugs</b> —Wholesale, Retail Sale and Restricted License, Records to be kept in a Pharmacy, Drugs Prohibited for Manufacture and Sale in India
	Administration of the Act and Rules—Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government Analysts, Licensing Authorities, Controlling Authorities, Drug Inspectors

4. Narcotic Drugs and Psychotropic Substances Act 1985 and Rules 43

Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties

5.	Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954	46
	Objectives, Definitions, Prohibition of Certain Advertisements, Classes of Exempted Advertisements, Offences and Penalties	
6.	Prevention of Cruelty to Animals Act, 1960	50
	Objectives, Definitions, CPCSEA-Brief Overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of Animals for Experiment, Records, Power to Suspend or Revoke Registration, Offences and Penaltic	es
7.	Poisons Act 1919	53
	Introduction, Objective, Definition, Possession, Possession for Sales and Sale of any Poison, Import of Poisons	
8.	FSSAI (Food Safety and Standards Authority of India) Act and Rules	59
	Brief Overview and Aspects Related to Manufacture, Storage, Sale, and Labelling of Food Supplements	
9.	National Pharmaceutical Pricing Authority	62
	Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale Prices of Bulk Drugs, Retail Price of Formulations, Retail Price and Ceiling Price of Scheduled Formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)	
10.	Code of Pharmaceutical Ethics	70
	Definition, Ethical Principles, Ethical Problem Solving, Registration, Code of Ethics for Pharmacist in Relation to his Job, Trade, Medical Profession and his Profession, Pharmacist's Oath	
11.	Medical Termination of Pregnancy Act and Rules	74
	Basic Understanding, Salient Features, and Amendments	
12.	Role of all the Government Pharma Regulator Bodies	77
	Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	
13.	Good Regulatory Practices	81
	Documentation, Licenses, Renewals, E-governance in Community Pharmacy, Hospital Pharmacy, Pharma Manufacturing, Wholesale Business, Inspections, Import, Export of Drugs and Medical Devices	

	Contents	хi
14.	Introduction to BCS System of Classification	85
	Basic Concepts of Clinical Trials, ANDA, NDA, New Drug Development, New Drugs and Clinical Trials Rules, 2019, Brand v/s Generic, Trade Name Concept, Introduction to Patent Law and Intellectual Property Rights, Emergency	
15.	Blood Bank	90
	Basic Requirements and Functions	
16.	Clinical Establishment Act and Rules	93
	Aspects Related to Pharmacy	
17.	Biomedical Waste Management Rules, 2016	96
	Basic Aspects, and Aspects Related to Pharma Manufacture to Disposal of Pharma/Medical Waste at Homes, Pharmacies, and Hospitals	
18.	Bioethics	99
	Basic Concepts, History and Principles, Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants	
19.	Introduction to the Consumer Protection Act	103
20.	Introduction to the Disaster Management Act	106
21.	Medical Devices	110
	Categorization, Basic Aspects Related to Manufacture and Sale	