

Contents

Preface	(v)
---------------	-----

Chapter 1

General Principles of Law, History, and Various Acts Related to Drugs and the Pharmacy Profession	1
--	----------

Chapter 2

Pharmacy Act 1948 and Rules

Introduction	4
Objectives.....	4
Definitions.....	4
Registration of Pharmacist	6
Pharmacy Practise Regulation, 2015.....	8

Chapter 3

Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments

Definition	11
Import of Drugs and Cosmetics	12
Manufacture of Drugs	14
Schedule C	20
Schedule G	22
Schedule H	24
Schedule K	24
Schedule M.....	25
Schedule N	34
Schedule P.....	35
Schedule X	36
Sale of Drugs.....	40
Administration of the Act and Rules.....	42
Licensing Authorities	45
Government Analyst	45

Chapter 4

Narcotic Drugs and Psychotropic Substances Act 1985 and Rules

Introduction	48
Objectives.....	48
Definition	49
Prohibition, Control and Regulation	51

Chapter 5

Drug and Magic Remedies (Objectionable Advertisement) Act 1954

Definition	53
Objectives.....	53
Commencement.....	54
Prohibition of Certain Advertisement	54
Classes of Prohibited Advertisement	54
Classes of Prohibited Advertisement Includes	55
Offences and Penalties	58

Chapter 6

Prevention of Cruelty to Animals Act-1960

Introduction	60
Objectives.....	60
CPCSEA.....	61
Institutional Animal Ethics Committee.....	62
Breeding and Stocking of Animals	63
Performance of Experiments.....	64
Transfer and Acquisition of Animals for Experiment.....	65

Chapter 7

Poison Act-1919

Introduction	69
Scope.....	70
Objectives.....	70
Possession and Sale of Poisons	70
Import of Poisons	72

Chapter 8

Food Safety and Standards Authority of India (FSSAI)

Introduction	74
The Food Safety and Standards Act 2006	75

Chapter 9

DPCO

Introduction	79
Objectives	79
DPCO 2013	79
Pricing of Scheduled Formulation	81
Conclusion	82

Chapter 10

Code of Ethics

Law	83
Ethics	83
Pharmaceutical Code of Ethics	83
Pharmacist in Relation to His Job	84
Pharmacist in Relation to His Trade	85
Pharmacist in Relation to Medical Profession	86
Pharmacist in Relation to His Profession	86
Pharmacist's OTH	87

Chapter 11

Medical Termination of Pregnancy Act and Rules

Induction of Abortion	88
MTP Act: Addressing a Public Health Priority	88

Chapter 12

Government Pharma Regulatory Bodies

Role of Regulatory Bodies	91
Central Drug Standard Control Organization (CDSCO)	91
Indian Pharmacopoeia Commission (IPC)	93

Chapter 13

Good Regulatory Practices

Introduction	96
Principles of GRP	96
Licenses Required under (GRP).....	98
E-governance.....	101

Chapter 14

Introduction to BCS System

Introduction	103
Abbreviated New Drug Application (ANDA)	104
NDA (New Drug Application).....	105
Brand v/s Generic Drugs	106
Trade Name Concept.....	106
Emergency Use Authorization (EUA)	107

Chapter 15

Blood Bank

Introduction	109
Objective	110
Various Services Provided in a Blood Bank	110
Legal Framework Scenario	112

Chapter 16

Clinical Establishment Act and Rules

Introduction	117
National Accreditation Board for Hospitals and Healthcare Providers (NABH) Standards.....	118
Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002	119
Consumer Protection Act, 2019	119
Drugs and Cosmetics Act, 1940	119
Indian Nursing Council Act, 1947	120

Chapter 17

Biomedical Waste Management Rules 2016

Introduction	122
--------------------	-----

Chapter 18

Bioethics

Introduction	127
History of Bioethics	127
Principle of Bioethics	128
Indian Council of Medical Research (ICMR)	129

Chapter 19

Introduction to Consumer Protection Act

Introduction	133
How to File a Complaint?	135

Chapter 20

Introduction to Disaster Management Act

Introduction	137
Role of Pharmacist in Disaster Management	139

Chapter 21

Medical Devices

Introduction	141
Classification of Medical Devices.....	142
Basic Aspects Related to Manufacture and Sale	142