

Pharmacy Law and Ethics

Course Code: **ER20-26T**

for **Second Year Diploma in Pharmacy**

is strictly written according to the new syllabus framed by Pharmacy Council of India (PCI) as per ER-2020. This book is presented and published to meet the requirements of students of second year Diploma in Pharmacy (DPharm). The book, written in a simple and lucid language, attempts to demystify and simplify the basic concepts for the students of pharmacy for proper understanding of the subject and to get a sure success in the State Board Examinations.

Salient features of the book :

- All topics are described in an easy to understand language.
- Gives to-the-point answers.
- Covers all the requisite contents as per new syllabus.
- Shows success key in Board Examination.

This book, as well as **CBS Confident Pharmacy Series**, will be useful not only for the students and teachers but also for candidates desiring to attempt competitive examinations for job opportunities in pharmacy profession such as hospital pharmacists in PHCs, civil hospitals, etc.

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He is recipient of 'Best Participation Award' at national level IAPST conference held in 2011. Since 2008, he has been writing books in the field of pharmacy: So far he has published 11 popular titles, each title going to the third edition.

Now, as per PCI's new syllabus (ER-2020), he is in the process of completing fourth edition of 6 titles and bringing out fresh edition of 5 new titles according to the recent subjects introduced in the syllabus.

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As per new syllabus prescribed by Pharmacy Council of India



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As per new syllabus prescribed by Pharmacy Council of India

Salient Features

- Lucid and easy language
- To the point answers
- Remembering the concepts in the simplest way
- Infusing confidence in the reader to appear in the board examinations

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Preface

The book builds self-confidence in students which helps to get success in the examinations. The book has been written to meet the requirements of students of Diploma in Pharmacy (D Pharm) in accordance with the new revised syllabus ER-2020 prescribed by Pharmacy Council of India.

This book is small and humble effort has been put in for compiling necessary information on the subject. An attempt has been made to demystify and simplify the basic concepts for the students of pharmacy and to enable them get an evergreen success in MSBTE examinations.

The salient features of the present book are:

- Lucid and easy language
- To the point answers
- Remembering facts in the simplest way
- Infusing confidence in the reader to appear in the board examinations.

Hence, the series is named

CBS Confident Pharmacy Series

I am confident that this book will be useful to both the students and the teachers of Diploma in Pharmacy as well as the candidates desiring to succeed in competitive examinations for better job opportunities in pharmacy profession such as hospital pharmacists in PHCs, civil hospitals, etc.

Raje Vijay N

to
my beloved family

Acknowledgements

I express my heartfelt thanks to Prof Madan Jagtap, Chairman, Gourishankar Education Society, Satara, Maharashtra, for consistent encouragement and inspiration for writing this book.

I wish to acknowledge the prompt and efficient help given by Prof Milind Jagtap, Mr Jaywant Salunkhe, Mr Appa Rajage, Mr Nitin Mudalgikar, and Mr Shirang Katekar of Gourishankar Education Society, Satara.

I am also thankful to Shri Satish Kumar Jain, Chairman & Managing Director, and Shri Shantanu Sarkar, General Manager, Mumbai Branch, CBS Publishers & Distributors Pvt Ltd, for their sustained efforts and keen interest in the publication of this book.

I wish all my beloved students to have a great success in the board examinations.

Raje Vijay N

Syllabus

(As per PCI New ER 2020)

Pharmacy Law and Ethics

Course Code: ER20-26T

75 Hours (3 Hours/week)

1. General Principles of Law, History and various Acts related to Drugs and Pharmacy profession.
2. **Pharmacy Act, 1948 and Rules:** 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:** 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.
Sale of Drugs: 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:** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.

5. **Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.
6. **Prevention of Cruelty to Animals Act, 1960:** 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 Penalties.
7. **Poisons Act, 1919:** Introduction, objective, definition, possession, possession for sales and sale of any poisons, import of poisons.
8. **FSSAI (Food Safety and Standards Authority of India) Act and Rules:** Brief overview and aspects related to manufacture, storage, sale and labelling of Food Supplements.
9. **National Pharmaceutical Pricing Authority:** 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:** 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:** Basic understanding, salient features and Amendments.
12. **Role of all the government pharma regulator bodies:** Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)
13. **Good regulatory practices** (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital Pharmacy, Pharma Manufacturing, Wholesale business, Inspections, import, export of drugs and medical devices.
14. **Introduction of BCS system of classification,** 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 Use Authorization.

15. **Blood bank:** Basic requirements and functions.
16. **Clinical Establishment Act and Rules:** Aspects related to Pharmacy.
17. **Biomedical Waste Management Rules, 2016:** Basic aspects and aspects related to pharma manufacture to disposal of pharma/medical waste at homes, pharmacies and hospitals.
18. **Bioethics:** 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.**
20. **Introduction to the Disaster Management Act.**
21. **Medical Devices:** Categorization, basic aspects related to manufacture and sale.

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