

TEXTBOOK OF PHARMACEUTICS

For Diploma in Pharmacy First Year

Education Regulation 2020 (New PCI Syllabus)

Dr. Sandip Prasad Tiwari

Principal, Faculty of Pharmacy, Kalinga University, Raipur (C.G.)

Rajni Yadav

Assistant Professor, Faculty of Pharmacy, Kalinga University,
Raipur

Pranjul Shrivastava

Assistant Professor, Faculty of Pharmacy, Kalinga University,
Raipur



ISBN No. 978-81-953544-0-5-0

First Edition 2021

© 2021 All rights reserved. No part and style of this book be reproduced or transmitted in any form, or by any means— electronic, mechanical, photocopying, recording, or otherwise, without prior permission of the publisher.

Published by

Probecell Press

Block H1, Chauhan Town, Bhilai

Chhattisgarh-490020, India

Website - www.probecell.com

Email - info@probecell.com

Printed by

Sagar Printers

Near Purani Basti, Police Station

Amin Para, Raipur, Chhattisgarh, India

Authors info

Dr. Sandip Prasad Tiwari completed his B.Pharm from Roland Institute of Pharmaceutical Sciences, Berhampur, Odisha (Berhampur University), M.Pharm (Pharmaceutical Technology) from Jeypore College of Pharmacy, Jeypore, Odisha (Biju Patnaik University of Technology, Rourkela, Odisha) and Ph.D from Bhagwant University, Ajmer, India. He has many more years of U.G, P.G teaching and research experience. Presently he is working as a Principal at Faculty of Pharmacy, Kalinga University, Raipur, Chhattisgarh. Guided many B.Pharm and M. Pharm Students for dissertation works. He has many Research papers and Review articles published in National and International Journals with very good citations and h-Index to his credit. Dr. Sandip is a life member of Indian Pharmaceutical Association and Society of Pharmacognosy.

Ms. Rajni Yadav: Joined as Assistant Professor in Faculty of Pharmacy, at Kalinga University. She completed her M.Pharm (Pharmacology) in the year 2014 from Chhattisgarh Swami Vivekananda Technical University, Bhilai, Chhattisgarh, MBA (Hospital Management) in the year 2015 from Shobhit Deemed University, Meerut, India, and her B.Pharm in the year 2012 from Chhattisgarh Swami Vivekananda Technical University, Bhilai, Chhattisgarh, She is a GPAT qualified and has 07 years of teaching and research experience. She is the recipient of the DST INSPIRE fellowship for pursuing her Ph.D. In addition, she was a university topper and received a gold medal for her academic excellence in her post-graduation. She is a lifetime member of multiple professional bodies such as the British Pharmacological Society, Indian Pharmaceutical Association, Association of Pharmaceutical Teachers of India, Society of Pharmacognosy, and Registered Pharmacist of Chhattisgarh Pharmacy Council of India. She has several awards in her credits. She is also an approved editor in a reputed Indian journal. She has published various research and review papers in reputed journals and published 02 book chapters to her credits. Her area of interest is in the field of cancer chemotherapeutics and pharmacological drug interactions.

Mr. Pranjul Shrivastava has completed his post-graduate degree (M Pharmacy, specialization- Pharmaceutics) from Smriti College of pharmaceutical education, Indore (M.P) India in 2013 and undergraduate (B. Pharmacy) from IPS College of Pharmacy, Gwalior (M.P) India in 2011. He is presently working as an Assistant Professor, at Kalinga University, Faculty of Pharmacy, New Raipur (Chhattisgarh) India. He has around 06 years of Industrial experience in the Quality Assurance department at different MNCs like Torrent Pharmaceutical Ltd., Macleods pharmaceutical Ltd., Rusoma Laboratories, and 02 years of teaching experience. He has undergone various regulatory audits like USFDA, MHRA, TGA, WHO, ANVISA. He has qualified in GPAT-2011. Mr. Pranjul Shrivastava has various research and review papers published in reputed national and international journals. He has participated in various national and international conferences, workshops,

Acknowledgment

We are thankful to Dr. Akanksha Jain, Assistant Professor at Shri Shankaracharya Mahavidyalaya, Juwani road, Bhilai for the Hindi translation of this book. She completed her B.Sc. Biotechnology in the year 2009 from Govt. Digvijay autonomous P.G. College Rajnandgaon, Chhattisgarh. Her M.Sc. (Biotechnology) in the year 2011 from Pandit Ravishankar Shukla University, Raipur (C.G.) and Ph.D. Biotechnology in the year 2020 from Guru Ghasidas Vishwavidyalaya, Bilaspur India. She is a GATE and CGSET qualified and has 06 years of teaching and research experience. She is recipient of Start-up India (Abhinav RABI-RAFTAAR IGKV Raipur, IARI Government of India) In addition, she was a university merit (forth rank) holder and received gold medal for her academic excellence in her under graduation. She has several awards in her credits. She is also an approved reviewer in Elsevier Biocatalysis and Agricultural Biotechnology journal. She has published various research papers in reputed journals and published 01 Indian Patent to her credits. Her area of interest is in the field of Plant Biotechnology, Microbiology, Molecular DNA Fingerprinting, Pharmacognosy and Biochemistry.

Preface

The textbook of Pharmaceutics has been written for students of diploma in pharmacy first-year students keeping in mind specific requirements of the Pharmacy Council of India (PCI), Education Regulation - 2020. This is a bilingual book in both English and Hindi for easy understanding to students. This book is covering the entire syllabus as per new PCI norms including practicals and previous year question papers.

This book containing thirteen chapters with an introduction to the pharmacy profession and career. In preceding chapters, packaging materials and pharmaceutical aids have been discussed. In chapter 4 the unit operations required in the preparation of formulations have been discussed like mixing, drying, extraction, size reduction, and separation. In chapters, 5-10 different pharmaceutical formulations have been discussed including tablets, capsules, liquid, semisolid, and parenteral dosage forms. The remaining chapters are about immunological products, manufacturing plants, and novel drug delivery systems.

I would like to acknowledge the invaluable contributions provided by the Probecell editorial team. I give great thanks to the graphic designers who were instrumental in preparing much of the artwork for this text. I would also like to acknowledge my colleagues and students for their willingness to serve as test subjects for many of the useful contents in this book. Finally, I would like to thank my teachers and parents for their guidance, support, and encouragement throughout the process of completing this book.

“You must be the change you wish to see in the world” — Mahatma Gandhi

We expect to bring out new editions in the coming years. Suggestions to improve the content are welcome from the teachers and students.

Raipur
10 September 2021

Sandip Prasad Tiwari
Rajni Yadav
Pranjul Shrivastava

Contents

Chapter	Topics
1	Pharmacy profession <ul style="list-style-type: none">• History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations.• Pharmacy as a career• Pharmacopoeia: Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia
2	Pharmaceutical packaging: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials
3	<ul style="list-style-type: none">• Pharmaceutical aids: Organoleptic (Colouring, flavouring, and sweetening) agents• Preservatives: Definition, types with examples and uses
4	Unit operations: Definition, objectives/ applications, principles, construction and workings of: <ul style="list-style-type: none">• Size reduction: hammer mill and ball mill• Size separation: Classification powder according to IP, Cyclone separator, Sieves and standards of sieves• Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer• Filtration: Theory of filtration, membrane filter and sintered glass filter• Drying: working of fluidized bed dryer and process of freeze drying• Extraction: Definition, classification, method and applications
5	Tablets: Coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, double layered)
6	Capsules: Hard and soft gelatin capsules
7	Liquid oral preparations: Solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution
8	Topical preparations: Ointments, creams, pastes, gels, liniments and lotions, suppositories and pessaries, Nasal preparations, Ear preparations

9	Pharmaceutical powders: Insufflations, dusting powders, effervescent powders and effervescent granules
10	Sterile formulations: Injectables, eye drops and eye ointments
11	Immunological products: Sera, vaccines, toxoids and their manufacturing methods
12	<ul style="list-style-type: none"> • Pharmaceutical manufacturing plants: Basic structure, layout, sections and their activities • Quality control and quality assurance: Definition and concepts of quality control & quality assurance, current good manufacturing practice (cGMP), Introduction to concept of calibration
13	Novel drug delivery systems: Introduction, Classification with examples, advantages and challenges

Experiments

Experiment no.	Title
1	To prepare and submit Simple Syrup IP (20 ml)
2	To prepare and submit Piperazine citrate elixir BP (20 ml)
3	To prepare and submit aqueous Iodine solution BP (Lugol's iodine solution)
4	To prepare and submit a strong Iodine solution USP
5	To prepare and dispense Castor oil emulsion (30 ml)
6	To prepare and dispense Cod liver oil emulsion (30 ml)
7	To prepare and dispense Calamine lotion (10 ml)
8	To prepare and dispense Magnesium hydroxide mixture (10 ml)
9	To prepare and dispense Simple ointment BP (10 g)
10	To prepare and dispense Sulphur ointment IP (20 g)
11	To prepare and dispense Cetrimide cream IP (10 g)
12	To prepare and dispense Turpentine liniment
13	To prepare and dispense Sodium Phosphate effervescent granules (20 g)
14	To prepare and dispense Dusting powder
15	To prepare and dispense Normal saline (20 ml)
16	To prepare and dispense Calcium gluconate injection IP (10 ml)
17	To prepare and dispense Indomethacin Extended-release capsules
18	To prepare and dispense 20 Tablets of Paracetamol IP

CHAPTER 1 PHARMACY PROFESSION

History of Pharmacy profession in India

India has been a country with a glorious past in various disciplines of knowledge which includes Pharmaceutical Sciences. The concept of Pharmacy evolved and was practised in ancient India. Ayurveda (Science of Life) and Siddha originated in India. The sources of drugs at that time were herbs and animals.

- The opening of a chemist shop in 1811 by Scotch in Bathgate, Kolkata was the start of the pharmacy profession or practice in India.
- In 1870, a training programme for the chemists was started by the Madras Medical College which was later converted to a Diploma programme.

भारत में फार्मसी पेशे का इतिहास

- भारत ज्ञान के विभिन्न विषयों में एक गौरवशाली अतीत वाला देश रहा है जिसमें फार्मास्युटिकल साइंस भी शामिल है। फार्मसी की अवधारणा विकसित हुई और प्राचीन भारत में इसका अभ्यास किया गया। आयुर्वेद (जीवन का विज्ञान) और सिद्ध की उत्पत्ति भारत में हुई। उस समय दवाओं के स्रोत जड़ी-बूटियाँ और जानवर थे।
- कोलकाता के बाथगेट में स्कॉच द्वारा 1811 में एक केमिस्ट की दुकान खोलना भारत में फार्मसी पेशे या अभ्यास की शुरुआत थी।
- 1870 में, मद्रास मेडिकल कॉलेज द्वारा रसायनज्ञों के लिए एक प्रशिक्षण कार्यक्रम शुरू किया गया था जिसे बाद में डिप्लोमा कार्यक्रम में बदल दिया गया था।

Pharmacy education

- The systematic and well-defined University education was initiated in 1932 when the Banaras Hindu University pioneered pharmaceutical education under the guidance of Professor M. L. Shroff, the father of pharmaceutical education in India.
- In India, formal pharmacy education leading to a degree began with the introduction of a 3-year Bachelor of Pharmacy (B. Pharm) at Banaras Hindu University in 1937.
- Before India gained independence in 1947, there were 3 institutions offering pharmacy degree programs.
- In 1944, the Punjab University started a pharmacy department; in 1947 L.M. College was established in Ahmedabad.
- In 1940, a Master of Pharmacy (M. Pharm.) research Degree was also introduced at BHU.
- Subhadra Kumar Patni and Gorakh Prasad Shrivastava became the first Pharmacy graduates in 1940 and post-graduates in pharmacy in 1943, respectively.
- Similarly, Shevohari Lal became the first PhD holder in 1953 from the University of Patna.
- After independence: Recognition of pharmacy as a profession.
- The foremost task of the Indian govt is to raise the economy by developing sectors like Agriculture, Economics, and industries.

- To establish and develop pharmaceutical industries pharmacy education must be developed.
- Regulations for practising pharmacy was passed by the central government.

फार्मसी शिक्षा

- व्यवस्थित और अच्छी तरह से परिभाषित विश्वविद्यालय शिक्षा 1932 में शुरू की गई थी जब बनारस हिंदू विश्वविद्यालय ने भारत में फार्मास्युटिकल शिक्षा के जनक प्रोफेसर एम एल श्राफ के मार्गदर्शन में फार्मास्युटिकल शिक्षा का बीड़ा उठाया था।
- भारत में, औपचारिक फार्मसी शिक्षा की शुरुआत 1937 में बनारस हिंदू विश्वविद्यालय में 3 वर्षीय बैचलर ऑफ फार्मसी (बी. फार्म) की शुरुआत के साथ हुई।
- 1947 में भारत को स्वतंत्रता मिलने से पहले, फार्मसी डिग्री प्रोग्राम की पेशकश करने वाले 3 संस्थान थे।
- 1944 में, पंजाब विश्वविद्यालय ने एक फार्मसी विभाग शुरू किया; 1947 में अहमदाबाद में एलएम कॉलेज की स्थापना हुई।
- 1940 में, बीएचयू में मास्टर ऑफ फार्मसी (एम.फार्म) शोध डिग्री भी शुरू की गई थी।
- सुमद्रा कुमार पाटनी और गोरख प्रसाद श्रीवास्तव 1940 में पहले फार्मसी स्नातक और 1943 में फार्मसी में स्नातकोत्तर बने।
- इसी तरह, शिवोहारी लाल 1953 में पटना विश्वविद्यालय से पहले पीएचडी धारक बने।
- आजादी के बाद: फार्मसी को पेशे के रूप में मान्यता।
- भारतीय सरकार का सबसे महत्वपूर्ण कार्य कृषि-संस्कृति, अर्थशास्त्र और उद्योगों जैसे क्षेत्रों को विकसित करके अर्थव्यवस्था को ऊपर उठाना है।
- दवा उद्योग स्थापित करने और विकसित करने के लिए फार्मसी शिक्षा का विकास किया जाना चाहिए।
- फार्मसी का अभ्यास करने के लिए विनियम केंद्र सरकार द्वारा पारित किया गया था।

Pharmacy education in India

- In 1948, the Pharmacy Act was enacted as the nation's first minimum standard of educational qualification for pharmacy practice to regulate the practice, education, and profession of pharmacy.
- Provisions of the Act are implemented through the Pharmacy Council of India (PCI).
- The Act requires individual states to establish state pharmacy councils that are responsible for controlling and registering pharmacists in their respective states.

भारत में फार्मसी शिक्षा

- 1948 में, फार्मसी अधिनियम को फार्मसी अभ्यास के लिए देश के पहले न्यूनतम शैक्षिक योग्यता मानक के रूप में अधिनियमित किया गया था ताकि फार्मसी के अभ्यास, शिक्षा और पेशे को विनियमित किया जा सके।
- अधिनियम के प्रावधानों को भारतीय फार्मसी परिषद (पीसीआई) के माध्यम से लागू किया जाता है।
- अधिनियम में अलग-अलग राज्यों को राज्य फार्मसी परिषदों की स्थापना करने की आवश्यकता है जो अपने संबंधित राज्यों में फार्मासिस्टों को नियंत्रित करने और पंजीकृत करने के लिए जिम्मेदार हैं।

Present scenario of the profession

- More than 1500 institutions are existing in the country.
- The annual enrollment in the colleges is around 1,00,000 students.
- Due to the incremental growth of the Pharmaceutical Industry in India, there has been a rapid expansion in the pharmaceutical education sector as well.