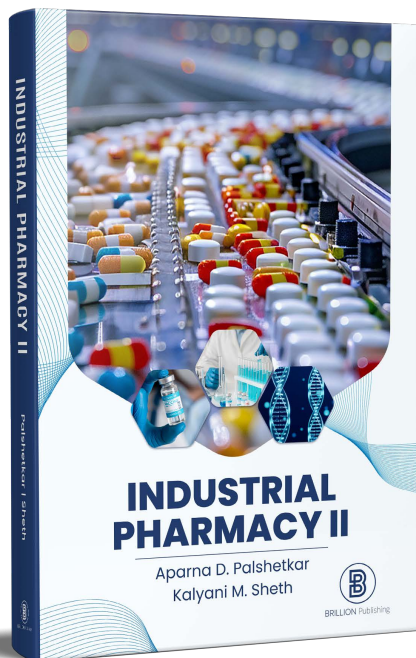




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INDUSTRIAL PHARMACY II

Industrial Pharmacy is a branch in Pharmacy which deals with scientific, industrial and technological aspects related to design and development of pharmaceutical dosage forms. Pharmaceutical industries deals with several aspects such as research and discoveries, formulation development, processing and production, sales and marketing of drug products which needs to meet regulatory requirements.

The current curriculum implemented by Pharmacy Council of India (PCI), New Delhi as Regulations 2014 has "Industrial Pharmacy-II" subject at Semester - VII of final year B.Pharm course. This book covers whole of the topics as specified in the PCI syllabus.

The book has been divided into five main units of total six chapters covering all the concepts related to pharmaceutical industry including topics such as Pilot Plant Scale-Up Techniques, Technology Transfer, WHO guidelines, ICH guidelines, ISO standards, Quality by Design (QbD), Six sigma, NABL accreditation, regulatory requirements and drug approval procedures. The book is designed as teaching resource for graduate, post graduate students as well as experienced and novice industrial pharmaceutical scientists. Each chapter begins with a premise to familiarize the reader with the topic. A few salient features of this book are enriched artworks, flow charts, tables, mind maps and point-by-point summary. The mind maps help to communicate numerous complicated ideas in a clear and easy-to-grasp way. The presentation of content is given in a very systematic order using different headings and sub-headings in hierarchical manner.

This book will be useful not only to the pharmaceutical scientists for developing the pharmaceutical dosage form but also to the formulation scientists and regulatory affairs department in finding the most efficient way of drug product registration around the globe.

After completion of this core syllabus students will be industrial ready and will be able to understand manufacturing techniques and all the related and practical aspects of dosage forms development.

At the end of each unit Review Questions which includes MCQs, Short answer type questions and Long answer type questions are provided along with Answer Keys for the students to assess their knowledge gained after learning all the units.

Our sincere thanks to Brillion Publishing for helping us publish this nicely printed book.

Aparna D. Palshetkar | Kalyani M. Sheth

(Contents)

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- Technology Development And Transfer
- Regulatory Affairs
- Regulatory Requirements for Drug Approval
- Quality Management Systems
- Indian Regulatory Requirements

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