



A Text Book of

A Text Book of

PHARMACEUTICAL REGULATORY SCIENCES

(Exclusively Designed for B.Pharmacy Semester-VIII Students)

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JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY
ETHIRAMEDU, KOMARAPURAM, TAMIL NADU



A Text Book of
**PHARMACEUTICAL
REGULATORY SCIENCE**

*Strictly As Per Syllabus Prescribed for B. Pharmacy
Semester-VIII by Pharmacy Council of India, New Delhi*

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Preface

It gives us great pleasure and privilege to present book of Pharmaceutical Regulatory Science which is based on new PCI syllabus.

In last few decades Indian Pharma sector has significantly increased its contribution in management of the health. We have not only satisfied the need of Indian market but also tried to fulfil the requirements of foreign countries. However; for export purpose knowledge of regulation in different countries is essential. All countries try to deliver drug and food product of good standard in order to achieve highest level of health. Moreover; developed countries now making regulation more stringent and hence, awareness of nature of regulation in different countries is essential task.

This book has covered all points of syllabus as given by PCI which will help to understand worldwide regulation. We tried to maintain language as simple as possible. We have also tried to cover information in much more depth in order to ensure that reader will be benefited for competitive exams preparation. This book will be helpful for pharmacy students, academicians as well as to industrial person.

We hope that this book will be appreciated and accepted by all Institutes, students and by all those peoples which are directly or indirectly associated with Pharmacy profession. There may be few mistakes and deficiencies, we will be grateful if readers point out them and revert to us. Also we will welcome any suggestions from your side.

We hope this book will leave the desired impression and look forward to receive the comments from the readers.

Above all, we would to thank our energetic and dynamic Publishers Shri. P.K. Jain and Mr. Vikas Jain for bringing out this quality based book.

January, 2023



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