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Pharmaceutical Jurisprudence

AS PER PCI SYLLABUS
D.Pharm
Part-II

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Dr. Lokesh Kumar Bhardwaj
Gaurav Nanda

PHARMACEUTICAL JURISPRUDENCE

D. Pharm., Part II

According to the syllabus based on **'Pharmacy Council of India'**

Dr. Lokesh Kumar Bhardwaj
D. Pharm.,B. Pharm., M. Pharm,
Ph.D (Pharmaceutical Sciences)
Principal,
Prem Raghu Institute of Pharmacy, Hathras

Mr. Gaurav Nanda
M. Pharm,
Principal,
Maa Pitambara College of Pharmacy, Agra

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E-mail: thakurpublication@gmail.com

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"Dedicated

to

*my **Family Members**"*

***-** Dr. Lokesh Kumar Bhardwaj*

"Dedicated

to

*my **Teacher** & **Students**"*

- Mr. Gaurav Nanda

Preface

It is with great pleasure that we introduce the book "**Pharmaceutical Jurisprudence**". The book allows for the lucid understanding of different dosage forms and processing methods. This book is a genuine effort to clarify the basics of Pharmaceutics in an effortless and interesting manner and as per the syllabus prescribed for the **D.Pharm** (Part II) students by **Pharmacy Council of India**.

All efforts have been made to keep the text error-free and to present the subject in a student friendly and easy to understand. However, any suggestions and constructive comments would be highly appreciated and incorporated in the future edition.

Learning Outcomes Related to Knowledge and Cognitive Skills:

At the end of the course student will be able to:

1) Understand the pharmaceutical legislation and code of ethics.

2) Know about the pharmacy act and Pharmacy Council of India.

3) Know about the Drug and Cosmetics Act, Poisons Act, etc.

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Acknowledgement

I would like to express my gratitude to many **People,** who saw me going through this book, to all those who provided support, talked things over, read, wrote, offered comments, and assisted in the editing and proofreading.

I express thanks to my **Parents** and all **Family Members**, for extending their support, guiding me at every step and for allowing me to follow my ambition throughout my childhood.

This book would not have been completed without the philanthropic support of my **Mentors** and **Teachers**, who provided me support that were important in my ability to create or clarify many of the examples included in this edition of the book.

I would like to express my heartfelt thanks to my **Friends** and **Colleagues**, for their support and cooperation.

Last but not the least, I would like to thank **Thakur Publication Pvt. Ltd.** especially to **Ms. Tuhina Banerjee** (Copy Editor) and **Ms. Deepa Thapa** (Marketing Coordinator), for going through this manuscript and helping in the neat execution of the text.

- Dr. Lokesh Kumar Bhardwaj

I want to express my grateful thanks and sincere gratitude to all those **People**, who gave me valuable advice and inputs for this endeavour.

First and foremost I am thankful to my **Mother** and **Father**, for their guidance throughout my life.

Mere words can never encompass my profound inward emotions of ineffable and gratitude towards all my **Family Members**, who inspired, guided, and supported me in every aspect of my life.

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I am very grateful to **Thakur Publication Pvt. Ltd.** and its Editorial Panel especially**, Ms. Tuhina Banerjee** (Copy Editor) and **Ms. Deepa Thapa** (Marketing Coordinator), for their efforts in bringing out this book in an excellent manner.

- Mr. Gaurav Nanda

Syllabus

PHARMACEUTICAL JURISPRUDENCE

Theory (50 Hours)

Origin and nature of pharmaceutical legislation in India, its scope and objectives. Evolution of the "Concept of pharmacy" as an integral part of the Healthcare system.

Principles and Significance of Professional Ethics: Critical study of the code of pharmaceutical Ethics drafted by pharmacy council of India.

Pharmacy Act, 1948: The General study of the pharmacy Act with special reference to Education Regulations, Working of state and central councils, constitution of these councils and functions, Registration procedures under the Act.

Drugs and Cosmetics Act, 1940: General study of the Drugs and cosmetics Act and the Rules there under. Definitions and salient features related to retail and whole sale distribution of drugs. The powers of Inspectors, the sampling procedures and the procedure and formalities in obtaining licenses under the rule. Facilities to be provided for running a pharmacy effectively. General study of the schedules with special reference to schedules C,C1,F,G,J,H,P and X and salient features of labelling and storage conditions of drugs.

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954: General study of the Act, objectives , special reference to be laid on Advertisements, magic remedies and objections1 and permitted advertisements – diseases which cannot be claimed to be cured.

Narcotic Drugs and Psychotropic Substances Act, 1985: A brief study of the act with special reference to its objectives, offences and punishment.

Brief introduction to the study of the following acts:
Latest Drugs (price control) order in force.

Poisons Act 1919(as amended to date).

Medicinal and Toilet preparations (excise Duties) Act, 1955 (as amended to date).

Medical Termination of Pregnancy Act, 1971(as amended to date).

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Chapter-6: Narcotic Drugs and Psychotropic Substances Act, 1985

Chapter-7: Miscellaneous Acts

CHAPTER 1

Pharmaceutical Legislation

1.1. PHARMACEUTICAL JURISPRUDENCE

1.1.1. Introduction

The Latin word ***jurisprudentia*** denotes **knowledge of law** (***juris*** signifies **law**, and ***prudentia*** denotes **skill** or **knowledge**). Thus, the word **jurisprudence** is derived from ***jurisprudentia***. Jurisprudence means knowledge of law and its application. It governs all the legal principles in the world. History states that as per this concept of law, jurisprudence at different times had various meanings; hence a single definition is not enough to define it completely. From the initiation of the classical Greek period to the 21st century of modern period, jurisprudence has evolved to a greater extent. It has gone through various alterations at different evolution stages.

In a constricted way, jurisprudence can be defined as the principles on which actual rules of law are based. It holds the rules of external conduct that a person must obey. Therefore, jurisprudence etymologically is the science giving knowledge about law. **Law** itself has many meanings, **e.g.,** different branches of law are present in a modern state, like contracts, torts, crimes, property, etc. So jurisprudence is basically the study of principles of each branch, but it does not convey the detailed rules of these laws.

Jurisprudence also refers to the philosophy of law concerned with its nature and function. This jurisprudence approach in modern times is gaining more attention due to rapid social changes occurring around the world in recent years. This approach is named as **functional jurisprudence**, and depicts the inter-relationship between law and justice.

1.1.2. Pharmaceutical Legislation in India

A society's social and economic aspect can be secured through Pharmaceutical Legislations, denoting a mixed type legislation.

Pharmaceutical legislation ensures the drug quality, its testing and evaluation criteria, and efficacy for its intended use by the patient. Overall these legislations function as a backbone of our healthcare system.

1.1.2.1. Origin

Towards the closing of 19th century, manufacturing of modern drug began in India. Bengal Chemical and Pharmaceutical Works (Calcutta) was established by **Acharya P.C. Ray** in **1901**. A small factory at Parel (Bombay) was initiated by

Prof. T.K. Gajjar in **1903**. Later, Alembic Chemical Works (Baroda) was laid down by **Prof. T. K. Gajjar Rajmitra**, and **B.D. Amin** in **1907**. All these became the foundation stone.

India imported crude drugs costing around ₹73 lacs in 1908-09. In the same period, India also exported finished drugs of about ₹15.5 lacs. This era had no legislation available in India for governing the import or export of drugs. At that time anything could be manufactured as drug. During the First World War due to 'Swadeshi' movement, the Indian Pharmaceutical Industry advanced and restarted the import of drugs. Back then the manufacturing plants of sera, vaccines, and surgical dressings were established. Still, the legislation required for controlling or ensuring the quality of imported drugs was absent. Foreign fraudulent manufacturers took this as an advantage and saturated Indian markets with adulterated and spurious drugs. An **example** of such a condition is the **Great quinine fraud** which occurred under the British rule in India.

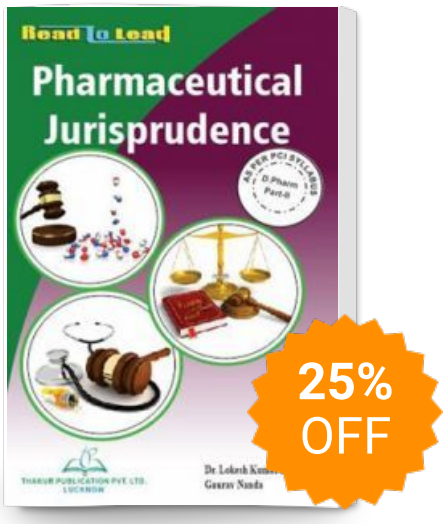
Then the need for an organisation to control such misconducts arose. The press media, along with Pharmaceutical Journal of England was in favour of it. In **1926**, The Medical Research Workers' Conference passed a resolution to ask the Central Government for an organisation and a laboratory that would check for the standardisation of drugs issued through the medical stores.

From **1920-1930**, many reports were published in Indian press regarding the marketing of harmful substitutes and adulterants instead of genuine drugs and also the toxic effects of drugs. A report submitted by the Indian Medical Gazette stated that there was no control over the manufacturing, sale, and distribution of drugs in India. Many lost their lives on consuming the spurious drugs. Eye drops were replaced with croton oil. Chalk powder was used to adulterate drug formulations. Many cases of toxicity were reported due to overdose of mercury compounds. Since there were no effective Acts and Rules related to drugs and pharmaceuticals in the country, all the fraudulent manufacturers were in a competition to manufacture sub-standard, spurious, and adulterated formulations.

When a large number of people started dying due to spurious and adulterated drugs, the public started protests in the country and even outside as the British rulers in India provided poor medical facilities. As a result, the British Government was forced to take action for drug legislations.

During the Presidential address at Indian Science Congress in **1927**, Lahore appealed for necessary steps to eradicate spurious drugs. The Council of States on **March 9**, **1927** put forward a resolution to the Governor General to make quick control over the craze for medicinal drugs by Legislation including standardisation and sale of drugs. **Sir Haroon Zaffer** stated that the drugs of defective strength and impure quality have taken over the market. The deceitful traders are making sale of potent drugs including sera and vaccines, without evaluating their quality and efficacy. Therefore, the **Council of State in British India**, headed by the **Viceroy** passed a resolution to put a check on the malpractices in drug dispensation and medication.

Pharmaceutical Jurisprudence



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