



**Birla Institute of Technology & Science, Pilani**  
Hyderabad Campus

## SECOND SEMESTER 2023-2024

Course Handout

Date: 09/01/2024

*Course No* : PHA F343  
*Course Title* : Forensic Pharmacy  
*Instructor-in-charge* : Prof. Balaram Ghosh

### 1. Scope and Objective of the Course:

This course is designed to impart a working knowledge of the various legislations that have a direct bearing on the medical and pharmaceutical professions. These laws embrace various fields such as manufacturing pharmacy, professional pharmacy, pharmaceutical education, drug administration and patenting etc. A professional pharmaceutical scientist, whatever be his field of activity in later life, is bound to work within the framework of these laws. Therefore, it is essential for every graduate in pharmacy to be familiar with the outlines of these laws and that is what this course aims to achieve. The course also includes a brief discussion on the ethics of the pharmaceutical profession.

**Objectives of the course:** Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian Pharmaceutical Acts and Laws.
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
4. The code of ethics during the pharmaceutical practice.

### 2a. Text Book (TB):

Mithal B. M., Text Book of Forensic Pharmacy Vallabh , 10<sup>th</sup> Ed., 1999.

### 2b. Reference Books:

- R1: Sidney H. Willig, Murray M. Tuckerman and William S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control. Marcel Dekker, New York, 4<sup>th</sup> Edn., Vol. 78, 1997.
- R2: Richard A. Guarino, New Drug Approval Process. Marcel Dekker, New York, 2<sup>nd</sup> Edn., Vol. 56, 1993.
- R3: Jain N.K., Pharmaceutical Jurisprudence. Vallabh Prakashan, Delhi, 3<sup>rd</sup> Edn., 1995.

### 3. Course Plan:



L.No	Learning Objectives	Topics to be Covered	Reference
1	Introduction to importance of Forensic Pharmacy	Introduction; Importance of Forensic Pharmacy; Growth of modern pharmacy & pharmaceutical industry	TB-Chap 1; Class notes
2	Regulatory interventions in Pharmacy Profession	Overview of Regulatory interventions in various aspects of Pharmacy Profession	Lecture Notes
3-4	Committee for the purpose of control and supervision of experiments on animals (CPCSEA)-Guidelines, Constitution of IAEC. Guidelines for breeding, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.	To explain the purpose and provisions prevention of cruelty to animals act	Lecture Notes and CPCSEA website
6-7	Introduction; The need for pharmaceutical legislation. Importance of Forensic Pharmacy; Growth of modern pharmacy & pharmaceutical industry. Code of Pharmaceutical Ethics and Pharmacists Oath.	To make students aware of the need and importance of different laws, their provisions.	TB- Chap 1; Lecture notes
8-11	Provisions of Drugs and Cosmetics Act (1940)	Laws under Drugs and Cosmetics Act (DCA 1940) and Rules related to import, manufacture, labelling and sale of Allopathic, Ayurvedic and Homeopathic drugs; Administration of Act and Rules	TB-Chap 6
12-15	Various provisions of Schedule M (Concepts and tools in the implementation and control of current Good Manufacturing Practices in the Pharmaceutical industry)	Overview of Good Manufacturing Practices w.r.t. Organization & Personnel, Buildings & Facilities, Equipment, Production & Process control, Packaging & Labeling control, Laboratory controls- Documentation, Reports & Records (cGMP, QC and QA)	TB-Chap 6; Various chapters of R1
16	Costing of Pharmaceutical Products	Provisions of Drug Price Control Order	TB- Chap13; Lect. notes
17	Provisions of Narcotic and Psychotropic Substances Act	Narcotic and Psychotropic Substances Act; Prohibited and Controlled Operations; Miscellaneous Matters	TB-Chap 4 R3
18	Provisions of Medicinal and Toilet Preparations Act	Medicinal and Toilet Preparations Act; Bonded and non-bonded laboratories; Excise Duty calculation	TB-Chap 5
19	Provisions of Drugs and Magic Remedies Act	Drugs and Magic Remedies Act; Objectionable advertisements	TB-Chap 7
20-23	Understanding the regulations, requirements, procedures and applications of new drug approval process (NDA)	New Drug Approval Process <ul style="list-style-type: none"> <li>• Pre-clinical studies</li> <li>• Brochure preparation for IND &amp; ANDA</li> <li>• Brochure preparation for DMF</li> <li>• Clinical research protocols</li> </ul>	R2 Ch.1-3, 5, 10, 11



		<ul style="list-style-type: none"> <li>Design of product labels/ inserts and monographs</li> </ul>	
24-26	Over view of WTO. Understanding the requirements of patents, copyrights, designs and trademarks under TRIP's in relation to pharmaceutical industry and provisions of Indian Patent Act	Introduction to IPR; Types of IPR; Procedure for obtaining IPRs like patents, copyrights and trademarks with emphasis on pharmaceutical industry and products; Examples of patent applications; Implication of product patent regime on Indian pharmaceutical Industry	Lecture notes; R2 and R3
27-28	Provisions of Consumer protection Act pertaining to Pharmacy & Medical profession; Ethics in Pharmacy & Medical profession	Consumer Protection Act; Code of Pharmaceutical Ethics in dispensing, clinical and hospital pharmacy	Class notes R2

#### 4. Evaluation Scheme:

Component	Duration	Weightage	Date	Time	Remarks
Pre Mid-term surprise Quiz	2x10 min	15 %		TBA	OB
Mid-term Test	90 min	35 %	14/03 - 9.30 - 11.00AM		CB
Post Mid-term surprise Quiz	2x10 min	15%		TBA	OB
Compre. Exam.	180 min	35 %		13/05 FN	CB

OB: open book; There will be no make up for surprise quiz

**5. Mid-Semester Grading:** Will be announced after Mid-term test.

**6. Make-up:** Prior approval or intimation to take a make-up is mandatory. It is solely at the discretion of the instructor-in-charge, depending upon the genuineness of the circumstances, to allow or disallow a student to appear for a make-up evaluation component. No makeup will be granted for Assignments/Quizzes under any circumstances.

#### 7. Grading Procedure:

- Grading will be done by “bunching” procedure. Total marks obtained by the students will be arranged in descending order, ‘bunches’ will be identified and grades awarded accordingly. Fine grading system (A, A-, B, B-....) will be followed.
- It is not mandatory for the instructor-in-charge to award all the grades (A to E); subjective judgment will be used for awarding the grades.
- As specified in Handout – Part I, appended to the timetable, the instructor in-charge reserves the right to award a NC report in case the student does not make himself/ herself available for any of the evaluation component mentioned above.
- Borderline cases during grading will be judged on the basis of regularity to classes and consistency or progress in the performance in evaluation components.

**8. Common Hours:** To be announced in class.

**9. Notices:** All the notices pertaining to this course will be displayed in google classroom.

**10 Academic Honesty and Integrity Policy:** Academic honesty and integrity are to be maintained by all the students throughout the semester and no academic dishonesty is acceptable.

**Instructor-in-Charge**  
**PHA F242**

