

SECOND SEMESTER 2022-2023

Course Handout

Date: 16/01/2023

*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 , 10th 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, 4th Edn., Vol. 78, 1997.
  + R2: Richard A. Guarino, New Drug Approval Process. Marcel Dekker, New York, 2nd Edn., Vol. 56, 1993.
  + R3: Jain N.K., Pharmaceutical Jurisprudence. Vallabh Prakashan, Delhi, 3rd Edn., 1995.

# Course Plan:

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| **L.No**  **.** | **Learning Objectives** | | **Topics to be Covered** | **Reference** |
| 1 | Introduction to importance Forensic Pharmacy | of | Introduction; Importance of Forensic Pharmacy; Growth of modern pharmacy & pharmaceutical industry | TB-Chap 1; Class notes |
| 2 | Regulatory interventions  Pharmacy Profession | in | 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 breading, 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 Psychotropic Substances Act | and | 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   * Pre-clinical studies * Brochure preparation for IND & ANDA * Brochure preparation for DMF | R2 Ch.1-3, 5, 10, 11 |

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|  |  | * Clinical research protocols * Design of product labels/ inserts and monographs |  |
| 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 |

1. **Evaluation Scheme:**

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| **Component** | **Duration** | **Weightage** | **Date** | **Time** | **Remarks** |
| Pre Mid-term **surprise**  Quiz | 2x10 min | 15 % | TBA | | OB |
| Mid-term Test | 90 min | 35 % | 14/03 | 4.00 - 5.30PM | CB |
| Post Mid-term **surprise**  Quiz | 2x10 min | 15% | TBA | | OB |
| Compre. Exam. | 180 min | 35 % | 11/05 | AN | CB |

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

1. **Mid-Semester Grading:** Will be announced after Mid-term test.
2. **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.

# 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.

1. **Common Hours:** To be announced in class.
2. **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