Birla Institute of Technology & Science, Pilani
Hyderabad Campus

SECOND SEMESTER 2018-2019

Course Handout

Date: 07/01/ 2019

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

1a. Course Description:

A study of the professional pharmacist's relation to the public and to other professions; a critical survey

of statutory regulations governing the practice of pharmacy and drug industry in all its aspects; history and ethics of the profession of pharmacy.

1b. Learning Outcomes (course benefits): Students who have undergone the course are expected to:

- have a working knowledge of the various legislations that have a direct bearing on the medical and pharmaceutical professions.
- understand how the laws embrace various fields such as manufacturing pharmacy, professional pharmacy, pharmaceutical education and drug administration.
- understand the regulations, requirements, procedures and applications of new drug approval process (NDA)
- Know the procedures for obtaining IPRs like patents, copyrights and trademarks with emphasis on Indian patent filing details.
- Remember the Ethics in Pharmacy & Medical profession in their profession.

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.

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	Regulatory control of teaching and practice of pharmacy	Various provisions of Pharmacy Act; Structure and Functions of Pharmacy Council of India and State Pharmacy Councils; Provisions of Shops and Establishment Act w.r.t. retailing of drugs	TB-Chap 3
5-10	Provisions of Drugs and Cosmetics Act	Laws under Drugs and Cosmetics Act and Rules related to import, manufacture, labelling and sale of Allopathic, Ayurvedic and Homeopathic drugs; Administration of Act and Rules	TB-Chap 6
11-14	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	TB-Chap 6; Various chapters of R1
15-16	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-	Understanding the	New Drug Approval Process	R2 Ch.1-3,

25	regulations, requirements, procedures and applications of new drug approval process (NDA)	• Pre-clinical studies • Brochure preparation for IND & ANDA • Brochure preparation for DMF • Clinical research protocols • Design of product labels/ inserts and monographs	5, 10, 11
26-29*	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
30	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	3x5 min	15 %	Will be announce in class		CB
Mid-term Test	90 min	35 %	13/3	9.00 - 10.30AM	CB
Post Mid-term surprise Quiz	3x5 min	10%	Will be announce in class		CB
Compre. Exam.	3 h	40 %	06/05 FN		CB (20%) OB (20%)

OB: open book; CB: closed book

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. Chamber Consultation Hours: To be announced in class.

9. Notices: All the notices pertaining to this course will be displayed only on Dept. of Pharmacy Notice Board.

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

Instructor-in-Charge
PHA F242