In addition to Part- I (General Handout for all courses appended to the time table) this portion gives further details regarding the course.

Course No : PHA F343

Course Title : Forensic Pharmacy

Instructor-in-charge : Dr. Gautam Singhvi

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.

2. Text Book (TB):

Mithal B. M., Text Book of Forensic Pharmacy. National Book Centre, Calcutta, 10th Ed., 1999, rpt 2014.

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: Ganguli, P., Gearing up for patents; the Indian scenario. Univ. Press, 1998.

R4: Jain N.K., Pharmaceutical Jurisprudence. Vallabh Prakashan, Delhi, 3rd Edn., 1995.

3. Course Plan:

Lecture 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
3-6	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
7-15	Provisions of Drugs and Cosmetics Act	Laws under Drugs and Cosmetics Act and Rules related to import, manufacture, labelling and sale	TB-Chap 6

		of Allopathic, Ayurvedic and Homeopathic drugs; Administration of Act and Rules	
16-22	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
23	Costing of Pharmaceutical Products	Provisions of Drug Price Control Order	TB-Chap 13; Lecture notes
24	Provisions of Narcotic and Psychotropic Substances Act	Narcotic and Psychotropic Substances Act; Prohibited and Controlled Operations; Miscellaneous Matters	TB-Chap 4
25-26	Provisions of Medicinal and Toilet Preparations Act	Medicinal and Toilet Preparations Act; Bonded and non bonded laboratories; Excise Duty calculation	TB-Chap 5
27-28	Provisions of Drugs and Magic Remedies Act	Drugs and Magic Remedies Act; Objectionable advertisements	TB-Chap 7
29-30	Provisions of Medical Termination of Pregnancy Act	The Medical Termination of Pregnancy Act	TB
31-32	The prevention of cruelty to animals act	Committee for the purpose of control and supervision of experiments on animals (CPCSEA)-Guidelines, Constitution of IAEC	Class Note
33	Provision of Insecticide Act	Provision of Insecticide Act	Class Note/ TB
34-37	Understanding the regulations, requirements, procedures and applications of new drug approval process	New Drug Approval Process • Pre-clinical studies • Brochure preparation for IND ,NDA & ANDA ,Clinical research protocols • Design of product labels/ inserts and monographs	R1Ch.1-3, 5, 10, 11
38-41	Over view of WTO. Understanding the requirements of patents, TRIP's in relation to pharma industry and provisions of Indian Patent Act	Introduction to IPR; Types of IPR; Patents, copyrights and trade marks with emphasis on pharmaceutical industry and products; patent applications; Implication of product patent regime on Indian pharmaceutical Industry	Lecture notes;

4. Evaluation Scheme:

Sr. No.	Evaluation Component	Weightage	Date and Time	Duration	Remarks
1	Mid-Term examination	30%	15/3 9:00 - 10:30 AM	90 Min	Closed Book
2	Continues assessment (Quizzes /application/ assignments)*	30%	During regular class hours		
3	Comprehensive examination	40%	5/5 FN	180 Min	Closed Book & Open Book

* Will be in the form of quizzes and will be conducted during tutorial and regular class hours.

5. Mid-semester evaluation: Will be announced after mid test

6. Attendance: Regularity in attendance will be one of the criteria in deciding the borderline cases at the time of final grading.

7. Grading Procedure:

1. It is not necessary that all the five grades (i.e. A to E) would be awarded.
2. In borderline cases subjective judgment will be exercised for pull-up's (max. 3%). Basic guiding factors will be regularity, consistency in performance (above average) or/and steady improvement throughout the semester.

8. Make-up: Make-up will be given only for genuine reasons.

9. Chamber consultation hours: To be announced in the class.

10. Notices: Notices pertaining to this course will be displayed only on Department of Pharmacy Notice board.

Instructor-in-Charge

PHA F343