SECOND SEMESTER 2020-21

COURSE HANDOUT

Date: 16.01.2021

In addition to part I (General Handout for all courses appended to the Time table) this portion gives further specific details regarding the course.

Course No : **PHA F343**

Course Title : **Forensic Pharmacy**

Instructor-in-Charge : **Dr. Vaibhav A. Dixit**

Tutorial Instructor : **Dr. Vaibhav A. Dixit**

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.

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

3. Course Plan:

Lecture No.	Topics to be Covered	Learning Objectives	Reference
1	Course overview, operational details and grading scheme.	To understand the course structure, objective and teacher/student expectations.	This handout.
2	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; Class notes
3-4	Overview of Regulatory interventions in various aspects of Pharmacy Profession. Health surveys and development committee, Hathi committee and Mudaliar committee.	To introduce the topic to the students.	Lecture Notes
5-8	Various provisions of Pharmacy Act; Definitions, objectives, registration of pharmacists, offences and penalties. Structure and Functions of Pharmacy Council of India and State Pharmacy Councils; Provisions of Shops and Establishment Act w.r.t. retailing of drugs	To inform and explain about the regulatory control of teaching and practice of pharmacy.	TB-Chap 3; Official website of PCI
9-16	Laws under Drugs and Cosmetics Act and definitions, sale, wholesale, retail, rules related to import, manufacture, labelling and sale of Allopathic, Ayurvedic and Homeopathic drugs; Administration of Act and Rules	Introduce the student to the provisions of Drugs and Cosmetics Act.	TB-Chap 6; Official website of CDSCO
17-18	Overview of Good Manufacturing Practices w.r.t. Organization & Personnel, Buildings & Facilities, Equipment, Production & Process control, Packaging & Labeling control, Laboratory controls- Documentation, Reports & Records. Conditions for grant of license, repacking, manufacture of new drugs.	Give an overview of various provisions of Schedule M (Concepts and tools in the implementation and control of current Good Manufacturing Practices in the Pharmaceutical industry).	TB-Chap 6; Various chapters of R1

19-21	Provisions of Drug Price Control Order	To explain how the prices of the drugs and drug products are regulated.	TB-Chap 13; Lecture notes; Official website of NPPA
22-23	Narcotic and Psychotropic Substances Act; Prohibited and Controlled Operations; Miscellaneous Matters	To explain the purpose and provisions of Narcotic and Psychotropic Substances Act.	TB-Chap 4; Lecture notes
24-25	Medicinal and Toilet Preparations Act; definitions, objectives, offences and penalties. Bonded and non bonded laboratories; Excise Duty calculation	To explain the purpose and provisions of Medicinal and Toilet Preparations Act	TB-Chap 5
26-28	Drugs and Magic Remedies Act; Objectionable advertisements. Exempted advertisements, offences and penalties.	To explain the purpose and provisions of Drugs and Magic Remedies Act	TB-Chap 7; Lecture notes
29-30	The Medical Termination of Pregnancy Act	To explain the purpose and provisions of Medical Termination of Pregnancy Act.	TB-Chap 12; Lecture notes
31-32	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	Class Note
33	Provision of Insecticide Act	Provision of Insecticide Act	Class Note/ TB chap 11
34	Consumer protection Act Right to information act.	To explain the purpose and provisions consumer protection Act	R2- Chap 27
35-37	New Drug Approval Process	To give an overview of the various stages for drug approval process for USFDA.	R1Ch.1-3, 5, 10, 11
38-40	Branded and Generic medicines	To introduce students to the benefits and limitations of generic medicines, schemes for generic promotions.	Lecture notes; Official website of The Department of Pharmaceuticals, Govt of India.
41-44	Various case studies reported in journals, newspapers, and related official website related to pharmaceuticals and health.	To discuss case studies and create awareness on current pharmaceutical regulations and topics.	Lecture notes

45	Introduction to IPR; Types of IPR; Patents, copyrights and trademarks with emphasis on pharmaceutical industry and products.	To develop an understanding of the requirements of IPR laws and provisions related to pharma industry.	R2- Chap 15-18 Lecture notes; Self-reading

4. Evaluation Scheme:

Sr. No.	Evaluation Component		Weightage	Date and Time	Duration	Remarks
1	Mid-Term examination		30%	Will be announced by AUGSD-AGSRD	90 Min	Closed Book
2	Continues assessment (Quizzes /case studies /application/ assignments / presentation)	Quizzes	20 %	During regular class hours	20-40 min	Open book + closed book
		Assignments	10 %		Will be allotted as per the nature of the assignment.	
3	Comprehensive examination		40%	Will be announced by AUGSD-AGSRD	180 Min	Closed Book Open book

Note: Continuous assessment will be based on theory covered in class. Topics and number will be announced in the class. It will be based on home assignments, tutorials, quiz, seminar, laboratory Day to Day work, viva-voce and class participation.

Students should note the following important points.

a) Students are strongly advised to prepare their own class notes using relevant information from lectures, text, reference books, and research/review articles given above. These notes are to be prepared/written in separate, dedicated notebook for this course and notebooks containing notes from other courses will not be allowed during closed book exam/quizzes. These handwritten notes and prescribed text would only be allowed for consultation during exams and should only be used for answering the open book components. Photocopies of any material (including research/review articles), written or printed will not be permitted. Stapled sheets, loose sheets of information written or printed, photocopies of slides used for discussion in class will not be allowed.

b) Slides, web-resources, educational/informative videos, multimedia resources and/or software/databases displayed during lectures provide key information for which additional supportive information is expected to be collected from these and aforementioned sources. The slides and selected material/information may (or may not) be shared and hence students are requested/advised to make their own notes during lecture

hour. Recent developments in the area/topic will be discussed in class based on their significance to pharma sciences or regulations, and may differ from the information in text, reference material and hence students are expected to take note of such key discussions during lectures. Such discussions held in class will be considered as primary source of information in the assessments.

c) Quiz(zes) may/will be conducted as a part of evaluation component, at random, during contact hours including lectures, tutorial hours, as convenient, with/without prior intimation and hence it is expected that the students come prepared to every class on topics covered in earlier lectures. Students are also requested to refresh their knowledge in basic organic reactions, chemical and biochemical concepts, and in topics and concepts covered in the prerequisite courses.

d) Mid-Sem. Grading would be done once at least 30-40 % evaluation components are completed.

e) For all evaluation components, information given during online lectures, aforementioned text books and reference books in the same order, will be considered as correct. Students are advised to follow the text, reference material as given in hand-out. All evaluation components are equally important, irrespective of weightage. Hence, students failing to attend scheduled online classes/lab sessions, or absenting themselves in one or many of the evaluation components, may become ineligible for obtaining a valid grade at the end of the semester. Attendance in online lectures, timely submission of assignments, and quizzes are all equally important as they are all integral components of learning, irrespective of weightage and will be taken into consideration, during grading.
Hence, students are strongly advised to keep away from absenting themselves from all aforementioned contact sessions. Clearing the course would require adequate performance in written quizzes, tests, assignments, and examinations, separately (i.e. earning low marks in evaluation components, aforementioned, would not suffice, to clear the course).
Any other adaptive changes in the handout, will be announced in class, if any.
Reading Assignments: Students are advised to read, collect additional information on the above mentioned topics as per given schedule.

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. **Make-up:**

   Generally make-up will be considered only for regular students (~90% attendance) under very rare circumstances based on the genuineness of the case assessed on a case-to-case basis. No makeup will be granted for assignments, quizzes and all would be considered for evaluation.
8. **Online/Chamber consultation hours:**

   Students are advised to attend the majority of the classes (>95 %), read study material, given literature, textbooks and reference books on all topics within a week of the topic being covered in the lectures. They are also encouraged to ask clarification on major queries on the subject matter within the lecture hours and minor (non-urgent) queries can be reserved for consultation hours. The consultation hour has been set for every Wednesday 4-5 pm and may be adjusted based on alterations in the time table and availability of the

instructor(s). Students should join the google meet sessions at this day/time using this link and their BITS email id.

Commented [VD1]: Give the link here

9. Any other adaptive changes in the handout, will be announced in class, if any.
10. **Notices:** Notices and information pertaining to this course will be shared on the google classroom and displayed only on Department of Pharmacy Notice board.

Instructor-in-Charge
PHA F343