SILVER OAK UNIVERSITY

Silver college of Pharmacy (067)
Programme Name: D.Pharm (18)
Subject Name: Pharmacy Law & Ethics
Subject Code: 1180672206
Year: II

Prerequisite:
This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India

Course Objectives: This course will discuss the following

1. General perspectives, history, evolution of pharmacy law in India
2. Act and Rules regulating the profession and practice of pharmacy in India
3. Important code of ethical guidelines pertaining to various practice standards
4. Brief introduction to the patent laws and their applications in pharmacy

Teaching and Examination Scheme:

Teaching Scheme				
L	T	P	Contact Hours	Credit
4	2*	0	6	6

Content:

Unit No.	Contents	Teaching Hours	Weightage %
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	02 Hrs	03%
2	**Pharmacy Act-1948 and Rules:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties**.** **Pharmacy Practice Regulations 2015**	05 Hrs	07%
3	**Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments** Objectives, Definitions, Legal definitions of	23 Hrs	31%

	schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. **Manufacture of drugs**: Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Study of schedule C and C1, G, H, H1, K, P, M, N, X and Y. **Sale of Drugs**: Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India **Administration of the Act and Rules**: Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.		
4	**Medicinal and Toilet Preparations Act 1955:** Objectives, Definitions, Licensing, Offences and Penalties	02 Hrs	03%
5	**Narcotic Drugs and psychotropic substances Act 1985 and Rules** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	02 Hrs	03%
6	**Drugs and Magic Remedies (Objectionable Advertisements) Act 1954** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties	02 Hrs	03%
7	**Prevention of cruelty to Animals Act-1960: Objectives, Definitions, CPCSEA -** brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties	02 Hrs	03%
8	**Poisons Act-1919:** Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	02 Hrs	03%
9	**FSSAI (Food Safety and Standards Authority of India) Act and Rules:** Brief overview and aspects related to manufacture, storage, sale and labelling of Food Supplements	02 Hrs	03%
10	**National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, pharmaceutical policy 2002, National List of Essential Medicines (NLEM)	05 Hrs	07%
11	**Code of Pharmaceutical Ethics:** Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession	05 Hrs	07%

	and his profession, Pharmacist's oath**.**		
12	**Medical Termination of Pregnancy Act and Rules:** Basic understanding/salient features	02 Hrs	03%
13	**Role of all the government pharma regulator bodies**: Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC	01 Hrs	01%
14	Good Regulatory practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices	03 Hrs	04%
15	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, Schedule Y. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	05 Hrs	07%
16	**Blood bank:** Basic requirements and functions	02 Hrs	03%
17	Clinical Establishment Act and Rules – Aspects related to Pharmacy	02 Hrs	03%
18	**Biomedical Waste Management Rules 2016:** Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, **pharmacies, and hospitals**	02 Hrs	03%
19	**Bioethics:** Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	02 Hrs	03%
20	Introduction to the Consumer Protection Act	02 Hrs	03%
21	**Medical Devices:** Categorization, basic aspects related to manufacture and sale	02 Hrs	03%
	Total	75 Hrs	100%

Course Outcome: Upon successful completion of this course, the students will be able to

Sr. No.	CO statement
CO-1	Describe the history and evolution of pharmacy law in India
CO-2	Interpret the act and rules regulating the profession and practice of pharmacy in India
CO-3	Discuss the various codes of ethics related to practice standards in pharmacy
CO-4	Interpret the fundamentals of patent laws from the perspectives of pharmacy

Teaching & Learning Methodology: -

The various methods or tools follows by the faculties to teach the above subject are:

1. Student centered learning
2. Experimental learning

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale and licensing requirement
2. Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
3. Licenses required, application processes (online/offline), drug regulatory office website of the respective state
4. Case studies – actions taken on violation of any act / rule related to pharmacy from the literature / media
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Generic Medicines
9. Before or after food/Medicines and Meals

Books Recommended: -

1. Handbook of forensic medicine and toxicology (medical jurisprudence): chadha
2. Pharmaceutical Jurisprudence: Gandhi
3. Pharmaceutical Jurisprudence: Nanjwade B.K.
4. Bare Acts of the said laws published by Government.
5. Pharmaceutical Jurisprudence by N.K. Jain.
6. A text book of Forensic Pharmacy by B.M. Mittal.

List of Open Source Software/learning website:

- http://silveroakuni.ac.in/video-lecture
- https://nptel.ac.in/
- https://nptel.ac.in/courses/112/105/112105124/