



Shree H. N. Shukla Institute of Pharmaceutical Education & Research

(Affiliated to Gujarat Technological University, Approved by PCI)

Shree H. N. Shukla College Campus, Nr. Lalpari Lake, B/H. Marketing Yard,
Amargadh – Bhichari, Raikot. Mo. 9099063150, 9727753360

Bachelor of Pharmacy
Subject Code: BP405TT

SEMESTER: IV

Subject Name: PHARMACEUTICAL JURISPRUDENCE

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

Objectives: Upon completion of the course the student shall be able to

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

Teaching scheme and examination scheme:

| Teaching Scheme | | | | Evaluation Scheme | | | |
|-----------------|----------|-----------|-------|-------------------|----------|-----------|----------|
| Theory | Tutorial | Practical | Total | Theory | | Practical | |
| | | | | External | Internal | External | Internal |
| 3 | 1 | 0 | 4 | 80 | 20 | 0 | 0 |

Course Content:

| Sr No | Topics | % weightage |
|-------|--|-------------|
| 1. | Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. 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. | 10 |
| 2. | Drugs and Cosmetics Act, 1940 and its rules 1945. Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors | 10 |
| 3. | • Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties | 10 |



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| | <ul style="list-style-type: none"> • Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties. • Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties | |
| 4. | <ul style="list-style-type: none"> • Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties • Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for 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 • 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, National List of Essential Medicines (NLEM) | 8 |
| 5. | <ul style="list-style-type: none"> • Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee • Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath • Medical Termination of Pregnancy Act • Right to Information Act • Introduction to Intellectual Property Rights (IPR) | 7 |

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh 123
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

LEARNING OUTCOMES:

| UNIT | LEARNING OUTCOME |
|------|---|
| 1 | Knowledge about pharmaceutical legislations and their implications in drug development and marketing. |
| 2 | Understanding and implementation of code of ethics in pharmacy practice. |



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| | |
|---|---|
| 3 | Knowing about regulatory authorities and agencies governing the manufacturing and sale of pharmaceuticals. |
| 4 | Knowledge about various indian pharmaceutical act and laws including schedules of drugs and its implications in pharmacy practice |

BOOK LIST:

| Sr. no | Book name | Price (Rs.) |
|--------|--|-------------|
| 1 | Forensic Pharmacy by B. Suresh 123. | 150/- |
| 2 | Text book of Forensic Pharmacy by B.M. Mithal. | 129/- |
| 3 | Hand book of drug law-by M.L. Mehra. | 1,250/- |
| 4 | A text book of Forensic Pharmacy by N.K. Jain. | 299/- |
| 5 | Drugs and Cosmetics Act/Rules by Govt. of India publications. | 956/- |
| 6 | Medicinal and Toilet preparations act 1955 by Govt. of India publications. | 45/- |
| 7 | Narcotic drugs and psychotropic substances act by Govt. of India publications. | 550/- |
| 8 | Drugs and Magic Remedies act by Govt. of India publication. | 100/- |
| 9 | Bare Acts of the said laws published by Government. Reference books (Theory). | 276/- |