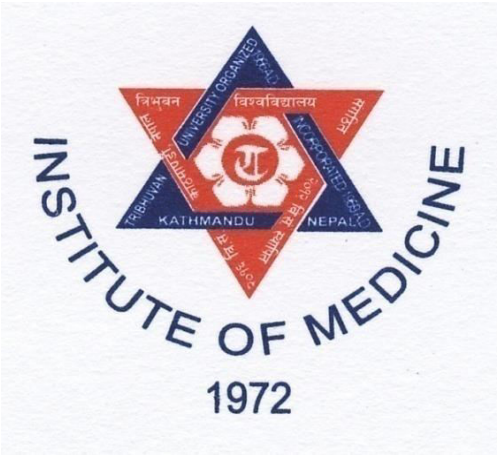
Curriculum

on

Bachelor in Pharmacy

(B. Pharm)



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Maharajgunj, Kathmandu, Nepal

2020 (2076

PHARMACEUTICAL JURISPRUDENCE

Subject: Theory	Year: Third	Code: BP 606 A
Full Marks: 100	Total Teaching hours: 90	Credit hour: 6

Course Description: This course gives a brief knowledge of legal and ethical aspects of pharmacy practice including national and international rules and regulations and their enforcingbodies.This also includes pharmaceutical ethics and the codes of conduct for pharmacists and skills for regulatory affairs.

General objectives:

At the end of the course, the students will be able

a. Describe the legal system related to different areas of pharmacy practice (Manufacturing, sale distribution, use and control)

b. Gain the skills for applying the drug-related legislation, regulation pertaining to pharmaceutical products & practices.

Specific objectives:

Unit 1: Introduction to Jurisprudence: [**5 hrs**]

After the completion of the course, students will be able to

a Discuss definition, objectives and principle of Jurispridence

b Discuss the types of Law

c Explain how laws are made and ammended

d Describe the relationship of Jurisprudence with other social sciences.

e Provision of Health Related provisions in Constitution.

Unit 2: Regulatory affairs: [3 Hrs]

After the completion of the course, students will be able to

a Discuss regulatory affairs and regulatory authorities

b Explain good regulatory practices

c Discuss regulatory affairs pharmacist and role of regulatory affairs pharmacists.

Unit 3: Acts, Regulation and Codes [25 Hrs]

After the completion of the course, students will be able to

a Give a brief account of recent Drug Act in Nepal and the rules Regulations, Codes and institutions

- Drug Act
- Drug Consultative and Advisory rule
- Drug Registration rule
- Drug Inspection and Investigation rule
- Drug Standard Rule
- Drug manufacturing code
- Drug sale and distribution code

- Nepal Pharmacy Council Act and Regulations

Unit 4: Pharmacopoeia [2 Hrs]

After the completion of the course, students will be able to

a Define Pharmacopoiea
b List the Pharmacopoiea recognized by Government of Nepal
c Explain the components and importance of monograph

Unit 5: International Harmonization on Pharmaceutical regulations [10 hrs]

After the completion of the course, students will be able to

a. Discuss ICH: Organization, Mission, Quality Guidelines, Safety Guidelines, Efficacy Guidelines, Multidisciplinary Guidelines, Common Technical Dossier and its components.
b. Discuss WHO Prequalification: History, Mission and Benefits of WHO prequalification.
c. Discuss PIC/S: Mission, Vision and Benefits
d. Discuss INCB: Mission, Vision, Conventions, International convention on control of Narcotics, Psychotropic substances

Unit 6: Pharmaceutical Waste management [5 Hrs]

After the completion of the course, students will be able to

a Discuss definition and objectives of Pharmaceutical Waste management
b List types of Pharmaceutical waste
c Discuss steps to be taken when disposing of unwanted pharmaceuticals
d Explain waste disposal methods
e Discuss integrated waste waste management techniques as per national and international guidelines.

Unit 7: WHO certification Scheme for pharmaceutical product (COPP) moving into international market. [3 hrs]

After the completion of the course, students will be able to

a Discuss the objectives of COPP
b Discuss Explain the eligibility for participation in scheme
c Discuss information provided by the COPP to regulatory authority
d List pharmaceutical products covered under the Scheme
e Discuss problems encountered in the use of the Scheme
f Explain requirements for member States and regional organizations to issue a CPP

Unit 8: Common Acts in relation to pharmacy practice

After the completion of the course, students will be able to

a Give a brief account of drug related section from following Acts in relation to pharmacy practice. **[15 Hrs]**
- Narcotic control Act
- Industrial Enterprises Act.
- Consumer Act

- Public Health Act
- Muliki Aparad Samhita Ain 2074
- Patent, Design and Trademark Registration
- Black Market Act
- Insurance Act

Unit 9: Professional ethics and norms pertaining to standard pharmacy practice [8 Hrs]

After the completion of the course, students will be able to

a Discuss Codes of ethics/conduct for pharmacists

b Discuss Professional code of conduct of Nepal Pharmacy Council

c Discuss WHO Ethical criteria on drug promotion.

d Discuss Guidelines on Ethical criteria for medicinal Drug Promotion (National and International): Introduction, Objectives, Ethical criteria.

Unit 10: Occupational health and medication safety.[1 Hrs]

After the completion of the course, students will be able to

a Discuss aim Occupational health and medication safety

b List key principle of Occupational health and medication safety

c List major causes of occupational hazards

d List factors that may influence medication errors

e List objectives of medication safety

f List ways to make medication use safer/Reduce medication error

Unit 11: International Treaties / Conventions.[5 Hrs]

After the completion of the course, students will be able to

a Discuss the Salient Features and Impact of

- Paris Convention
- Berne convention
- Doha Declaration (Compulsory Licensing and Parrallel import)
- World Intellectual Property Organization (WIPO)
- Trade Related Aspects of Intellectual Property Rights (TRIPS)
- Patent Co-operation Treaty (PCT), Madrid Protocol

Unit 12: Federal Food, Drugs and Cosmetics Act [8 Hrs]

After the completion of the course, students will be able to

a Discuss Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on the following.

- General drug approval process
- Investigational New Drug application (INDA)
- New Drug Application (NDA) and BLA
- ANDA
- SNDA, SUPAC and BACPAC
- Post marketing surveillance

Reference books [Latest Editions]

1. Different Act, Regulations, Codes and Guidelines of Nepal and other countries National Drug Policy
2. Practical Exercise in Pharmacy, Laws and Ethics. Appelbe GE and Wingfield J, The Pharmaceutical Press.
3. Essential Drugs WHO Publications:
4. Guidelines for Safe Disposal of Pharmaceutical Wastes.
5. Dumetriu H. Good Drug Regulatory Practices-A Regulatory Affairs Quality Manual. CRC Press
6. Websites: fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org