

3.2 PHARMACEUTICAL JURISPRUDENCE AND ETHICS (THEORY)

50 hours ; 2 hours/week

1. Introduction

a) Pharmaceutical legislations - brief review. **1 hour;2-3 marks**

2. An elaborate (practical oriented) study of the following

a) Code of pharmaceutical ethics. **1 hour;2-3 marks**

b) Pharmacy act 1948. **2 hours;3-5 marks**

c) Drugs and cosmetic act 1940 and rules 1945 (with special reference to schedules M,P,U,V, and Y). **20 hours;25-30 marks**

d) Medicinal and toilet preparations (Excise Duties) Act 1955. **3 hours;5-7 marks**

e) Medical Termination of pregnancy act **2 hours;3-5 marks**

f) Narcotic drugs and psychotropic substances act 1985 and rules. **3 hours;5-7 marks**

g) DPCO 2013. **2 hours;3-5 marks**

h) Pharmaceutical policy 2002. **2 hours;3-5 marks**

i) Right to information act. **2 hours;3-5 marks**

j) Hatch Waxman act 1984. **2 hours;3-5 marks**

3. A brief study of the following with special reference to be main provisions

a) Drugs and magic remedies (Objectionable advertisements) act 1954 **2 hours;3-5 marks**

b) Prevention of cruelty to animals act 1960 including study of CPSCEA guidelines **2 hours;3-5 marks**

c) Indian Patents Act with special reference to pharmaceuticals along with amendment bills, process patent and product patent. a. General procedure for obtaining pharmaceutical patents, introduction to intellectual properties. Trademark, copyright, trade secrets. **4 hours;6-10 marks**

4. New Drug Application, Abbreviated new drug application (ANDA) 2 hours;3-5 marks

Note: The teaching of all the above acts should cover the latest amendments.

PHARMACEUTICAL JURISPRUDENCE AND ETHICS REFERENCE BOOKS

1. CPSCEA Guidelines.
2. Gennaro AL. Remington: The science and practice of pharmacy Vol I and II. 20th ed. Philadelphia:Lippincott Williams and Wilkins;2000.
3. Helsinki Guidelines.
4. ICMR Guidelines.
5. Jain NK. A textbook of forensic pharmacy. 6th ed. New Delhi:Vallabh Prakashan,2003.
6. Jani GK. Pharmaceutical jurisprudence vol I and II. Ahmedabad:Atul Prakashan.
7. Kuchekar BS. A textbook of pharmaceutical jurisprudence. Pune:Nirali Prakashan;1994.
8. Latest issues of CIMS, MIMS, PDR, DDR.
9. Latest issues of IDMA Bulletin.
10. Mithal BM. A textbook of forensic pharmacy. Delhi:Vallabh Prakashan. Year
11. Parikshit B. IPR handbook for pharma students & researchers.
12. Saikishore. Drug regulatory affairs.
13. Subramanyam CVS, Thimmasetty J. Pharmaceutical regulatory affairs. Delhi: Vallabh Prakashan;2012.
14. Sudhakar Y. Novel drug delivery systems & regulatory affairs.
15. Suresh B. A text book of forensic pharmacy.