

PHARMACY LAW AND ETHICS

(ER20-26T)

Time : Three Hours

Maximum Marks : 80

Note : i) Attempt any five questions.

ii) Each question carry equal marks.

1. a) Explain the role of Pharmacist in Health Care System. 5
b) Why should pharmacist study law? 5
c) Describe the functions of Pharmacy Council of India. 6
2. a) Give qualifications for appointment as Drug Inspector? Explain their powers and procedures. 8
b) State the offences and penalties relating to sale of drugs. 4
c) Define the following terms: 4
i) New Drug
ii) Spurious drugs
iii) Ethics
iv) Clinical trial
3. a) Explain the objectives of Narcotic Drugs and Psychotropic Substance Act. 6
b) Compare the advertisements which are 6
i) Prohibits
ii) Exempted
c) Describe the layout and construction of bonded laboratory. 4
4. a) Describe constitution and functions of Institutional Animal Ethics Committee. 6
b) What is meant by specified poisons? How are the import, possession and sale of poisons regulated under the Act? 6

c) Explain the procedure for FSSAI registration. 4

5. a) How are the prices of formulations to the whole sales and retailers calculate? 6
b) Who can terminate a pregnancy and what experience or training etc should be passes? 6
c) Define Registered Pharmacist and give the qualification for registration. 4

6. a) Explain the vision, mission and functions of Indian Pharmacopoeia Commission. 6
b) Discuss the key components of Good Regulatory Practices. 6
c) Explain the terms: 4
i) Genetic drugs ii) NDA
iii) Patent iv) PPE

7. a) Discuss the functions of hospital blood bank. 6
b) Discuss the functions of Clinical Establishment Act. 6
c) Explain the General Guidelines for Clinical trial. 4

8. Write notes on the following (any four): 16
a) Consumer rights
b) National Disaster Management Authority
c) Medical and Non-medical Devices
d) Importance of Pharmacist and Oath
e) Drug Enquiry Committee