

Second Year Pharmacy  
**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

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- 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