

PY-802

B.Pharm. VIII Semester

Examination, June 2014

Pharmaceutical Jurisprudence

Time : Three Hours

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Maximum Marks : 70

Note: Attempt any five questions. All questions carry equal marks.

1. a) Describe the general requirements of GMP for premises and Materials under schedule M-part I of Drugs and Cosmetics Act and rules.
b) How are the prices of formulations to the retailers calculated under DPCO?
2. a) What classes of drugs and cosmetics cannot be manufactured and imported in India?
b) What are Education Regulations and how are they implemented by the PCI?
3. a) Give the qualifications and duties of a Drugs Inspector.
b) Define "magic remedies". How should misleading advertisements be scrutinized?
4. a) Compare the functions of PCI and State Pharmacy Councils.
b) What are the objects of Patent Act?

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5. a) Discuss the provisions of MTP Act relating to approval of a place for medical termination of pregnancy.
b) Explain the functions of Institutional animals Ethics Committee.
6. a) Who can not be appointed as Drugs Inspector?
b) Discuss the provisions of Insecticides Act regarding import, manufacture, sale, distribution and use of insecticides.
7. a) Explain the provisions of Shops and Establishments Act relating to shops dealing in drugs, medicines and surgical supplies.
b) Discuss the provision of Factories Act relating to "health and safety".
8. Write notes on any three of the following.
 - i) Schedule N
 - ii) Unfair trade practice
 - iii) Clinical trials
 - iv) Drugs Enquiry committee

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