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2022

B.Pharm. 5th Semester End-Term Examination

Pharmacy

PHARMACEUTICAL JURISPRUDENCE

(New Regulation)

Full Marks – 75

Time – Three hours

The figures in the margin indicate full marks
for the questions.

1. Answer the following (20 × 1 = 20)
- (i) The application to import drug as a part of bonafide luggage is made to the licensing authority in
- (a) Form 12A (b) Form 12B
(c) Form 12 (d) Form 26
- (ii) Which of the following is a magic remedy
- (a) Talisma (b) Mantra
(c) Kavacha (d) All the above
- (iii) The list of drugs which are exempted from the provisions of import is dealt in
- (a) Schedule K (b) Schedule D
(c) Schedule P (d) Schedule Y
- (iv) Who among the following is not a Pharmacy Council of India
- (a) The Director General of Health Service, India
(b) The Drug Controller of India
(c) The Director, Central Drug Laboratory
(d) The Director, Central Research Institute

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- (v) The prevention of cruelty to animals act was enacted in the year
- (a) 1948 (b) 1970
(c) 1960 (d) 1955
- (vi) The hospital or place for the termination of pregnancy is approved by
- (a) Medical Council of India
(b) Drug Inspector of the District
(c) Chief Medical Officer of the District
(d) None of the above
- (vii) As per Drugs and Cosmetics Act, Schedule FF deals with
- (a) Parenteral Preparation (b) Ointment formulation
(c) Skin Cosmetic preparation (d) Ophthalmic preparation
- (viii) Which of the following class of drugs is prohibited to be imported
- (a) Drugs containing alcohols (b) Schedule X drugs
(c) Spurious drugs (d) Misbranded Drugs
- (ix) Patent Act was enacted in the year
- (a) 1960 (b) 1955
(c) 1970 (d) 1980
- (x) DTAB has how many ex-officio members
- (a) Five (b) Six
(c) Four (d) Eight
- (xi) Schedule _____ of the Drugs and cosmetics Act includes requirements and guidelines on clinical trials for import and manufacture of new drugs
- (a) Schedule X (b) Schedule Y
(c) Schedule C (d) Schedule M
- (xii) Drug and Magic remedies act was enacted in the year
- (a) 1954 (b) 1964
(c) 1948 (d) 1978
- (xiii) NDPS Act provides Licencing system to regulate _____ of Narcotic and psychotropic substances:
- (a) Manufacturing (b) Transportation
(c) Cultivation (d) All the above
- (xiv) What does ED stands for in Retail price calculation
- (a) Extra Duty (b) Extreme demand
(c) Excise Duty (d) Exempted duty

(xv) Exempted advertisement includes those:

- (a) Advertisements that directly or indirectly give false impression regarding the true nature of drugs
- (b) Advertisement relating to a drug which is sent confidentially in a prescribed manner to registered medical practitioner
- (c) Advertisements using misleading images
- (d) All the above

(xvi) The Narcotics Drugs and Psychotropic substances Consultative Committee has a maximum of _____ members

- (a) 10
- (b) 12
- (c) 15
- (d) 20

(xvii) For bonded and non-bonded laboratories, License is issued by

- (a) Office of the Central Research Laboratory
- (b) Office of the Excise Commissioner of the state
- (c) Office of the Drug Controller of India
- (d) Office of the Drug Controller of the state

(xviii) Head office of CPCSEA is situated in

- (a) Kolkata
- (b) Mumbai
- (c) New Delhi
- (d) Vizag

(xix) Select the correct statement from the following about Bonded Laboratories:

- (a) There should be only one entrance to the laboratory and only one door for each of its compartments.
- (b) License for manufacturing of preparations containing alcohol or other narcotic substance should be obtained from the excise commissioner of the concerned state
- (c) The consignment of the spirit upon arrival has to be verified in volume and strength by the Excise officer
- (d) All the above

(xx) Right to information Act was passed on:

- (a) 12th June 2004
- (b) 14th Sep 2004
- (c) 12th July 2005
- (d) 15th June 2005

2. Answer the following question (Any Seven):

(5 × 7 = 35)

- (a) Explain the term "Manufacture in Bond". Outline the procedures for manufacturing in a bonded laboratory.
- (b) Write the objectives of NDPS Act, 1985, Discuss briefly the offences and penalties of the NDPS Act.
- (c) When was the Pharmacy Act enacted? Detailed? Detail out about the constitution of the PCI.
- (d) What are the objectives of Pharmaceutical Legislation? Write a note on the Hathi committee.
- (e) State the important features of the Right to Information Act. Detail out the role of the public information officers according to this act.
- (f) Define Prohibited advertisement and exempted advertisement. Give suitable examples of those advertisements that come under these two classes respectively.
- (g) Write a short note on intellectual property rights.
- (h) Enlist the main objectives of the Medical termination of pregnancy act. What are the conditions under which the medical termination of pregnancy is permitted?
- (i) Detail out the procedure for obtaining licence for the manufacture of Schedule C drugs.

3. Answer the following question (Any two):

(2 × 10 = 20)

- (a) Write short note on:
 - (i) DTAB
 - (ii) Mudaliar Committee
 - (iii) National List of Essential Medicines
 - (iv) Chopra Committee
- (b) Give an account of the code of Pharmaceutical Ethics to be practiced in the profession of Pharmacy.
- (c) Differentiate between a Branded drug and a generic drug. What are the salient features of the National Pharmaceutical Pricing Authority? What is the purpose of controlling prices of Drug.