

Question Paper

Exam Date & Time: 29-Nov-2023 (10:00 AM - 01:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Regulations and Legislation for Drugs and Cosmetics Medical Devices Biologicals and Herbals and Food [PRM-MRA104T]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) "A" was instituted on the basis of a written complaint by Rajesh Kumar Sinha, Drug Inspector, Nalanda alleging that on secret information, a raid was conducted in Sanjivani Hospital, Biharsharif, Nalanda. During the raid, it was found that the accused persons tried and made attempts to destroy the medicines. The raiding team could lay its hands upon Hologram of Bihar Government supply, which is not meant for sale generally. A Medical Hall also was found to be existing near the Doctors' Chambers without any valid licence. It was, therefore, alleged that without any valid licence, the accused persons were engaged in manufacturing medicines, thereby violating the various provisions of the I.P.C. and the Drugs and Cosmetics Act, 1940. (10)

Answer the following with appropriate justification:

A. Was the FIR legally valid?

B. Were police correct in registering the complaint and investigating?

- 2) **A.** Nestle is planning to launch a new instant spaghetti in India, who is the regulatory authority and mention the documents to be submitted, process to be adopted for attaining license to market. (5M) (10)
B. Enlist the contents of Quality profiling of a drug to be submitted for attaining marketing authorization. (5M)
- 3) Mention the requirements to establish the stability of new drug substance as per ICH guidance. (10)
- 4) Enlist the study requirement parameters for a company to establish under CDSCO, to ensure the bioequivalence of the drug and attain marketing authorization. (10)
- 5) **a.** Enlist the advantages and disadvantages of pharmaceutical patents in Indian scenario.(5M) (10)
b. Explain trademark infringement and remedies as per Trademark Act 1999.(5M)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

- 6) I give a lecture on "Prevention of Cruelty to Animal Act" at an engineering college in Bangalore. Can it be sponsored by 'Animal Welfare Board' of India. Justify your answer. (5)
- 7) A cruise ship was passing at a distance of 100 nautical miles from Mumbai. Indian coast guards while inspecting the ship found two stewards selling codeine syrup 250mg/mL to the inmates of the ship. The ship had Indian flag. Can these two stewards be sued under "Narcotic Drugs and Psychotropic Substances Act 1985"? If 'yes', how can they save themselves? (5)
- 8) Discuss the procedure to be adopted by a pharmaceutical manufacturer in India to attain license for marketing the recently developed drug under CDSCO. (5)
- 9) An adverse event has occurred in KMC due to a pharmaceutical product, explain the process of (5)

collecting the data related to the event.

- 10) X has been granted patent, after 3yrs, Y has applied for revocation of the patent granted to X, (5)
mention the grounds for revoking the patent as per Indian patent act 1970.

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