Exam Date & Time: 19-Dec-2022 (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 [PQA-MRA104T - S3]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

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

1) Write and explain the category of drugs which are "not of standard quality" as per section 17 of drugs and cosmetic act 1940 for the following cases.
A. Mr. Raj is a B. Pharm graduate starts a drug manufacturing unit. His first project is of manufacturing diclofenac sodium tablets. However, being the first time he forgot to include the Schedule H warning on the tablet label.
B. Ranbaxy lost its FDA licensing for manufacturing of drugs in its Indian factories. Traces of human hair were found in the final tablets supplied by Ranbaxy.
C. Mr. Sharma has recently shifted his factory from Hyderabad to Baddi. However he has not made necessary changes in the labelling of drugs.
D. Ms. Priya takes in charge of her father's pharmaceutical industry producing Paracetamol tablets. She starts manufacturing tablets in violet colour to improve the overall elegance of the product. (10)

2) An adverse event has occurred in KMC due to medical devices, explain the process of collecting the metrovigilance data related to the event. (5M)

Britannia is planning to launch a new oats brand in India, enlist the regulatory authority to be contacted and explain the process to attain license to market the same. (5M) (10)

3) A. Sun pharmaceuticals is planning to launch and new drug product in two formulations with multiple strength as shown below:
Tablets : 50mg, 150mg, 250mg
Suspension : 50ml, 150ml, 250ml
Mention the studies to be performed and submitted to the regulatory authorities to establish the stability of the drug product. (5M) (10)

B. Enlist the requirements for an animal study as mentioned in CPSCEA guidelines. (5M)

4) Enlist the salient features of the latest Clinical Trials rules 2019 and write a note on clinical trial management systems. (5M)

Explain in detail the regulations for establishing an animal house. (5M) (10)

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

B. Define copyrights and explain the subject matters that CANNOT BE protected under copyrights. (5M)

SECTION - B

Answer all the questions.

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

6) Mention the global classification of herbals on basis of origin, quality and safety. (5M) (5)

7) Enlist the responsibilities and enforcement of drug inspector as per D&C act 1940. (5M) (5)

8) Mention the competent authorities and guidelines involved in registration of biologics under CDSCO and draw a flow chart on biologics approval process in India. (5)

9) Mention the organizational structure of central and state regulatory governance for pharmaceuticals in India (5)

10) Enlist the circumstances where the government allows third party to produce the patented product or process without the consent of the patent owner with example. (5)

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