Exam Date & Time: 31-Mar-2021 (01:30 PM - 04:30 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 - S2]

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) Mention the competent authorities and guidelines involved in registration of biologics under CDSCO and draw a flow chart on biologics approval process in India. (10)

3) Mention the requirements to establish the stability of new drug substance as per ICH guidance. (10)

4) Enlist the salient features of the latest Clinical Trials rules 2019 and write a note on clinical trial management systems. (10)

5) An inventor from Nagar Haveli wants to file a patent, mention the patent office he must approach and explain the process with timelines of attaining patent. (10)

SECTION - B

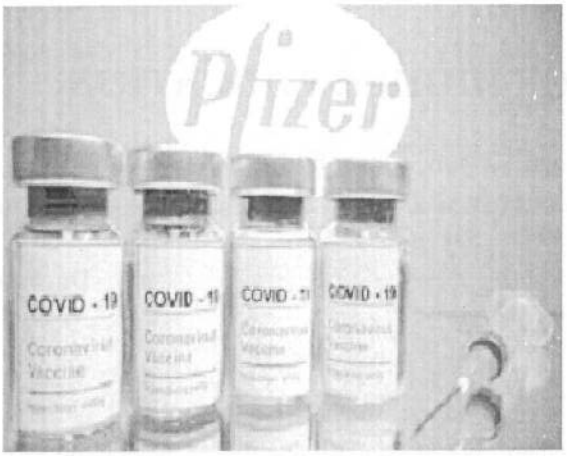
Answer all the questions.

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

6)

(5)

If the following advertisement is published in leading newspapers of India, will it be a violation of "Drugs and Magic Remedies (Objectional Advertisement) Act 1954, as amended on 2013? Justify your answer.



7) Discuss the major lacunae in Drug Price Control Order 2013. (5)

8) Define Medical Device and classify as per Indian regulations. Enlist the regulatory documents to be submitted for registering heart valves in India. (5)

9) Enlist the contents of Quality profiling of a drug to be submitted for attaining marketing authorization. (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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