Exam Date & Time: 14-Mar-2022 (10:00 AM - 01:00 PM)

# MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences, Manipal
MPharm Theory End-Semester Examinations. March 2022
Subject: REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS
Subject Code: PQA -MRA 104T

**Regulations and Legislation for Drugs and Cosmetics - Medical Devices - Biologicals and Herbals and [PQA-MRA104T]**

**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) a. 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)
b. Discuss the procedure to be adapted by a pharmaceutical manufacturer in India to attain license for marketing the recently developed drug under CDSCO. (5M) (10)

3) Explain the steps involved by Pharmacopeial Working Group in harmonizing a drug monograph. (10)

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| 4) | Design a protocol to be submitted to animal ethical committee to attain license to perform non- clinical trial for an anti-cancer drug. | (10) |
| 5) | An America company wants to attain patent for a product, enlist the subject matter to be considered by the inventor that the Indian Patent office might not grant patent. | (10) |

## SECTION - B

**Answer all the questions.**

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

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| 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) | Can "white petroleum jelly" be taxed as per Medicinal and Toilet Preparations (Excise Duties) Act, 1955? Justify your answer. | (5) |
| 8) | Mention the organizational structure of central and state regulatory governance for pharmaceuticals in India. | (5) |
| 9) | Enlist the contents of Quality profiling of a drug to be submitted for attaining marketing authorization. | (5) |
| 10) | Define copyrights and explain the subject matters that CANNOT BE protected under copyrights. | (5) |

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