Question Paper

Exam Date & Time: 11-May-2023 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

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

Regulatory Aspects of Drugs and Cosmetics [PRM-MRA201T -S2]

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

SECTION - A

Answer all the questions.

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

1)	What is Drug Master Files? Discuss different types of Drug Master Files as per USFDA. Add note on orange book and purple book. (2+3+5=10marks)	(10)
2)	Discuss in brief about Investigational New Drug (IND) and Supplement New Drug Application (SNDA) as per USFDA. Add note on different modules of ACTD.	(10)
3)	Discuss drug approval in EU. Write a note on orphan drug regulatory status in USA, Japan and India.	(10)
4)	Explain drug and cosmetic approval process as per the Pharmaceuticals and Medical Devices Agency.	(10)
5)	Discuss regulatory pre-requisites related to marketing authorization requirements for drugs and cosmetics in Saudi Arabia and UAE.	(10)

SECTION - B

Answer all the questions.

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

6)	Discuss regulatory requirements for drug approval process in China.	(5)
7)	Write a note on variations & extensions.	(5)
8)	Discuss regulatory requirements for registration of drugs in Association of Southeast Asian Nations (ASEAN)	(5)
9)	Write a note on CFR (code of federal regulation). Add note on Eudralex.	(5)
10)	Write brief note on Investigation of Medicinal Products Dossier (IMPD).	(5)

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