

Exam Date & Time: 29-Mar-2021 (01:30 PM - 04:30 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

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

**Regulatory Affairs [PMA-MPD103T]**

**Marks: 75**

**Duration: 180 mins.**

### SECTION - A

**Answer all the questions.**

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

- 1) Explain role of WHO, WTO, WIPO and ICH. Add a note on drug regulations pertaining to US, EU, UK, Japan and India. (10)
- 2) Write in brief about GCP, GMP and GLP. Add brief note on category of cosmeceuticals and nutraceuticals in different parts of the world market. (10)
- 3) Write the composition and responsibilities of Institutional Review Board. Add note on informed consent. (10)
- 4) Define medical devices. Classify medical devices as per Indian regulatory system and add a note on CTD and benefits of eCTD. (10)
- 5) What is non-clinical study? Explain the types of non-clinical studies. (10)

### SECTION - B

**Answer all the questions.**

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

- 6) Explain concept of complex generics. (5)
- 7) Describe steps involved in Drug Discovery and Development process. (5)
- 8) Define Pharmacovigilance. Explain the two scales used for classification of ADR's. (5)
- 9) Explain objectives of Hatch-Waxman Act. (5)
- 10) Discuss some unfortunate events that catalysed the development of medicines regulation. (5)

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