

Time: 05-Dec-2018 (02:00 PM - 05:00 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
Specialization: Pharmaceutics and Pharmaceutical Administration (PMA-MPD103T / PMA-MPH104T)

Date: 05-12-2018

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) Explain in brief drug approval process followed in US, EU and India. (10)
- 3) Explain in brief outsourcing of BA and BE to CRO. Add a note on objectives of Hatch-Waxman Act. (10)
- 4) Write in brief about modules of CTD and benefits of eCTD. Add a note on classification of medical devices as per Indian regulatory system. (10)
- 5) Write the composition of Institutional review board. Add short notes on required elements of informed consent. (10)

SECTION - B

Answer all the questions.

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

- 6) Explain principal medicines regulatory functions. (5)
- 7) Write in brief about GCP, GMP and GLP. (5)
- 8) Write a note on Investigator brochure. (5)
- 9) Add a note on categorization of cosmeceuticals in few major markets. (5)
- 10) Write a note on post marketing surveillance (5)

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