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Seat Number

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DADU-73

MPH 104T : Regulatory Affairs

(181104)

Total Page : 1]

Time: 3 Hours

Max. Marks : 75

Instructions to Candidates:

1. Do not write anything on question paper except Seat No.
2. Graph or diagram should be drawn with the black ink pen being used for writing paper or black HB pencil.
3. Students should note, no supplement will be provided.
4. Each question carries equal marks.
5. Attempt any five questions from the following.

1. What is Hatch-Waxman act and amendments & explain in detail documentation of Pharmaceutical Industry. 15
2. Write in detail the developing of clinical trials protocols & other working procedures for conducting the clinical trials. 15
3. Discuss the following: 15
 - a) NDA regulatory Approval Process.
 - b) Active Pharmaceutical ingredients & its specifications.
4. Describe the outsourcing protocol for the bioavailability and bioequivalence studies to contract research organization. 15
5. Explain about the Institutional Review Board, Independent Ethics Committee & Pharmacovigilance Monitoring in Clinical Trials. 15
6. Elaborate on: 15
 - a) What are the regulatory requirements of EU and MHRA.
 - b) Pharmacovigilance safety monitoring in clinical trials.
7. What are the Regulation for Combination Products and Medical devices & describe it in detail? 15
8. What is ICH Guidelines & explain details guidelines of ICH-Q, S, E, and M. 15