Code. No: 13306/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (Suppl.) Examination, August 2019

Subject : Regulatory Affairs

Time: 3 Hrs **Max. Marks: 75**

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. (a) Write a note on importance and types of Drug Master file 7
   (b) Explain the contents of Hatch-Waxman Act 5
   (c) Write abt the importance of Post marking surveillance 3

2. Explain the regulatory requirements for ANDA approval process in US 15

3. (a) Describe the importance, preparation and organization of CTD 10
   (b) Describe the objectives and structure of Harmonization guidelines (ICH) 5

4. Explain in brief
   a. The regulations for medical devices 8
   b. Regulatory requirements of MHRA 7

5. Give a brief note on each part of the contents of Investigational New Drug Application (IND) 15

6. (a) What is Investigational Medicinal Product dossier (IMPD)? Explain the requirements and contents of IMPD. 7
   (b) Write a note on Scale up process 8

7. Explain briefly varis phases of clinic al trials and design of clinical trials for the submission of data to FDA for getting NDA approval. 15

8. Give a brief note on the following:
   a. Institutional Review Board (IRB) 8
   b. Informed Consent 7

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