# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutics) I-Semester (Main & Backlog) Examination,**

**February 2019**

**Subject : Regulatory Affairs**

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

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

1. (a) Describe varis parts of master formula record and write its importance. 7
   (b) Explain salient features of Hatch Waxman Act and its amendments. 8

2. Enlist different sections of NDA and Write a note on NDA approval process. 15

3. (a) Explain regulatory requirements of US registration for foreign durgs. 8
   (b) Explain SUPAC guidelines specific to manufacturing changes 7

4. (a) Describe the objectives of harmonization guidelines. Enlist ICH quality guidelines. 10
   (b) Explain the objectives of CMC considerations during drug development. 5

5. (a) Explain the regulatory requirement for biologics product approval. 8
   (b) What is the purpose of Investigator's Brochure? Give a brief note on the Information to be filled in each part of the IB. 7

6. (a) Write a note on eCTD. 7
   (b) Write different designs of BE studies for Generic drugs assessment. 8

7. (a) Give an tline of factors that must be addressed in the clinical trial protocols as per USFDA check list. 8
   (b) Give a brief note on Pharmacovigilance and safety monitoring in clinical trials. 7

8. Write brief notes on:
   a. Regulatory requirements of EU 7
   b. Health Insurance Portability and Accntability Act. 8

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