Code No. 1292/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Supple.) Examination, August 2018

Subject: Regulatory Affairs

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

Note: Answer any five questions. All questions carry equal marks.

1 (a) Explain the importance of documentation in pharmaceutical industry and add a note on master formula record, distribution records. (10)
(b) Write a note on Code Of Federal Regulation. (5)

2 Explain ANDA regulatory approval process. (15)

3 What are the regulatory requirements for approval of an API? (15)

4 Write a note on
(a) CTD and eCTD (9)
(b) ICH Quality guidelines (6)

5 Explain the regulatory requirements of EU (15)

6 Discuss abt regulations for Combination products a nd Medical devices. (15)

7 Write a note on
(a) informed consent process and procedures (6)
(b) Pharmacovigilance safety monitoring (9)

8 Write a note on
(a) Investigator brochure (7)
(b) investigation of medicinal products dossier (8)

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