Code No: 6105/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, January 2020

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 CFR (code of federal regulation). (8)
(b) Write a note on distribution records and master formula record. (7)

2 Explain NDA regulatory approval process. (15)

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

4 (a) Explain the objectives of CMC considerations during drug development. (9)
(b) Enlist ICH Quality guidelines. (6)

5 Explain the regulatory requirements of TGA (15)

6 Discuss abt :
a) global submission of ANDA (9)
b) Bio-equivalence studies for generic drugs assessment. (6)

7 Write a note on:
(a) HIPAA (6)
(b) Pharmacovigilance safety monitoring (9)

8 Write a note on:
(a) Investigator brochure (8)
(b) Clinical trial protocol (7)

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