

Code No. 1156/PCI

FACULTY OF PHARMACY**M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main) Examination, February 2018****Subject: Regulatory Affairs****Time: 3 Hrs****Max. Marks: 75****Note: Answer any five questions. All questions carry equal marks.**

- 1 (a) Explain Hatch-Waxmann Act, its benefits in generic approval. (10)
(b) Write a note on Bolar Amendment. (5)
- 2 Explain NDA regulatory approval process. (15)
- 3 What are the regulatory requirements for approval of biologics? (15)
- 4 Write a note on
(a) CTD and eCTD (9)
(b) ICH Quality guidelines (6)
- 5 Explain the regulatory requirements of TGA (15)
- 6 Discuss abt global submission of ANDA (15)
- 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)
