

Code: 17S03103

M.Pharm I Semester Regular Examinations February 2018

REGULATORY AFFAIR

(Pharmaceutics)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

- 1 Explain Hatch-Waxman act and amendments in detail.
OR
- 2 Explain about:
 - (a) Post marketing surveillance.
 - (b) Master formula record.
- 3 Write the major regulatory considerations to be for US registration for foreign drugs.
OR
- 4 Explain the regulatory requirements for product approval of API.
- 5 Explain the regulations for combination products and medical devices.
OR
- 6 Write in detail about the pharmaceutical regulatory requirements for launching a drug product in EU.
- 7 Explain the global submission of NDA and ANDA.
OR
- 8 Write in detail about investigator brochure.
- 9 Define pharmacovigilance. Explain its role in safety monitoring of clinical trials.
OR
- 10 Explain the requirements for clinical trial process.
