

Code: 17S11102

M.Pharm I Semester Regular Examinations February 2018

DOCUMENTATION & REGULATORY WRITING

(Pharmaceutical Regulatory Affairs)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

- 1 Describe about Master Formula and Manufacturing Record documentation.
OR
- 2 How to carry out Batch Reconciliation and Certificate of analysis process?
- 3 Describe the electronic common technical document submission and the validation process.
OR
- 4 Explain the dossier submission procedure involved in sugam system.
- 5 Explain the regulatory auditing process for manufacturing facilities.
OR
- 6 Discuss the guidance document specified in ISO 13485.
- 7 Explain different approaches used in root cause analysis and preventive action strategies.
OR
- 8 What are the requirements for pre approval inspection and the inspection protocol in a pharmaceutical manufacturing unit?
- 9 Outline the FDA inspection process and implementation requirements.
OR
- 10 Elaborate in detail ISO risk management standards.

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