

Code: 17S04103

M.Pharm I Semester Regular Examinations February 2018

AUDIT & REGULATORY COMPLIANCE

(Common to PA&QA and PA&QC)

(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

- 1 Describe the basic steps involved in the management planning process.
OR
- 2 Explain about audit of the management, scope, objective, advantages and disadvantages.
- 3 Explain in detail about quality assurance functions and quality system approach in pharmaceutical industry.
OR
- 4 Discuss about cGMP regulations in detail.
- 5 Explain in detail about vendor audit in pharmaceuticals.
OR
- 6 Describe about auditing of sterile production and packaging.
- 7 Elaborate auditing of manufacturing process in microbiology laboratory.
OR
- 8 Discuss the product and process information audit in microbiological quality control.
- 9 Explain about audit of quality assurance procedures in pharmaceutical industry.
OR
- 10 Discuss the quality assurance audit of HVAC, water and water for injections.

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