

Code: 17S04102

M.Pharm I Semester Regular Examinations February 2018
QUALITY CONTROL & QUALITY ASSURANCE
(Pharmaceutical Analysis & Quality Assurance)
(For students admitted in 2017 only)

Time: 3 hours

Max. Marks: 60

Answer all the questions

- 1 (a) Write briefly on Q series of ICH guidelines.
(b) Give scope of GLP.

OR

- 2 (a) Write about quality control unit as per GLP.
(b) What is a protocol for non-clinical testing?

- 3 Give the concepts of sanitation and environmental control. What is EMEA?

OR

- 4 (a) What is good warehouse practice?
(b) Give an account on organization and functioning of USFDA and WHO.

- 5 Explain guidelines on purchase and specifications of raw materials.

OR

- 6 (a) Give IPQC of parenterals.
(b) Write the Qc test for glass containers.

- 7 (a) Write the need for SOPs.
(b) Write on specifications and test procedure.

OR

- 8 Write on quality audit plan, reports and distribution records.

- 9 Brief on premises for manufacture, contamination, process of individual and bulk products.

OR

- 10 What is drug product inspection, expiry date calculations and aseptic process control?
