J-MQA-103-T

Seat No. _____

M. Pharm. (Sem. I) (External) Examination

January - 2020

Quality Assurance : MQA - 103T

(Quality Control & Quality Assurance) (Theory)

Time : **3** Hours] [Total Marks : **75**

Instructions : (1) Figure to the right indicates marks.
(2) Draw neat and clean diagrams as required.

1 Answer the following questions : **10×2=20**

(a) Define Trade mark and Copyright.
(b) Write importance of intellectual property rights in Pharma. Industry.
(c) Enlist Q series ICH guidelines.
(d) Write down scopes of Quality control.
(e) Define in process quality control and patent.
(f) State the importance of Quality audit plan.
(g) What are process deviations?
(h) Write significance of Master Batch Records.
(i) Give full name of CDER and CBER.
(j) Write Scope of GLP.

2 Answer any **two** out of following : **2×10=20**

(a) Write in detail about Organization, personnel, responsibilities, training, and hygiene as per USFDA.
(b) Write a note on finished products quality control for Tablet and parenterals.
(c) Discuss in detail about Electronic Common Technical Documentation.

3 Answer any **seven** out of following : **7×5=35**

(a) Discuss briefly about CPCSEA guidelines.
(b) Discuss in detail about Batch Manufacturing Record.
(c) Write a short on protocol for conduct of non clinical testing.
(d) Discuss as per EMEA about Drug industry location, design, construction and plant lay out.
(e) Describe In process quality control test for capsules.
(f) Write in detail about DMF.
(g) Write a short note on maintenance of sterile areas and control of contamination according to USFDA.
(h) Briefly describe Change control and process deviations.
(i) Write a short note on Pharmaceutical Inspection Convention (PIC).