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PAT-MQA-203-T Seat No. _____

M. Pharm. (Quality assurance) (Sem. II) Examination

August / September - 2020

MQA-203-T : Audits And Regulatory Compliance

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

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

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

(a) Give the role of management for balance quality and manage audit in pharmaceutical industries.
(b) Mention any two audits question regarding reference standards in microbiological laboratory.
(c) Define audit. Give the importance of it.
(d) Briefly explain about resources for audit in pharmaceutical industry.
(e) Enlist the critical concepts of Quality system approach as per FDA.
(f) Enumerate the steps for auditing of packaging material in microbiological laboratory.
(g) Briefly explains about deficiencies observed during the audit in pharmaceutical industry.
(h) What are the responsibilities of auditor?
(i) Enumerate the various steps for planning process of audit.
(j) What is the aim and objectives of management audit?

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

(a) Describe process for auditing of vendors of bulk pharmaceutical chemicals. Prepare a checklist for vendor audit of packaging material.
(b) Describe audit checklist for drug industries. Explain auditing of Tablet manufacturing department
(c) Discuss about role of quality system approach in pharmaceutical industries. Write a brief note on Internal audit

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

(a) Discuss general standards of building raw materials for Microbiology laboratory.

(b) Explain standards and evaluation parameters for water for injection.

(c) Briefly explain about audit of Effluent treatment plant.

(d) Discuss role of quality assurance in Pharmaceutical manufacutring.

(e) Explain general cGMP regulation for pharmaceutical industries.

(f) Explain in brief about auditing of HVAC system.

(g) Write an informative note on audit of warehouse in pharmaceutical company.

(h) Write a note on auditing of capsule department.

(i) Write a brief note on Quality assurance maintenance.
