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DBY-MQA-203-T Seat No. _____

M. Pharm. (Sem. II) Examination

July - 2022

MQA-203T : Quality Assurance

(Audits and Regulatory Compliance)

Time : $2\frac{1}{2}$ 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 classification of deficiency observed during audit.

(b) Mention different types of resources which are helpful for audit to maintain quality in pharmaceutical industry.

(c) Enumerate the different section in CFR cGMP regulation related to evaluation activities.

(d) Define the term Aide Memoir and compliance audit.

(e) What are the functions of quality assurance in pharmaceutical industry?

(f) What are the management responsibilities for balance quality and manage audit in pharmaceutical industry?

(g) What is the importance of ETP?

(h) Mention two important points to be considered while packaging auditing the HVAC system.

(i) What is the purpose of Audit in pharma company?

(j) Enumerate the various stages for planning an audit.

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

(a) Enumerate the important aspects of auditing microbiology laboratory and discuss briefly.

(b) Describe the steps and processes of vendor Audit. Explain in brief about auditing of capsule department.

(c) What is cGMP? Describe general components of cGMP. Explain the element requirements of QMS.

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

(a) Give an audit checklist for pharmaceutical drug industry.

(b) Enlist the critical and non-critical parameters of HVAC system. Explain any two.

(c) Discuss the auditing process of packaging department in pharmaceutical industry.

(d) Give a Checklist to verify the sterile manufacturing area before the audit.

(e) Discuss the auditing process of tablet manufacturing department.

(f) Write a note on auditing of pharmaceutical Effluent treatment plant.

(g) Describe audit checklist for water and water for injection system in pharma unit.

(h) Briefly describe the Checklist for an audit in warehouse of pharmaceutical industry.

(i) Write a note on auditing of quality assurance department.