P-MQA203-T Seat No. _____

M. Pharm. (Sem. II) (CBCS)
(Quality Assurance External) Examination

July - 2018

MQA 203-T : Audit & Regulatory Compliance (Theory)

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

Instructions :

(1) Figures to the **right** indicate full marks.

(2) Draw neat and clean diagrams as required.

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

(a) Define vendor and HVAC.

(b) What are the objectives of pharmaceutical audit ?

(c) Define audit and quality system approach.

(d) Enumerate importances of being audited.

(e) Enlist five checklist questions for auditing of weighing.

(f) Write classification of deficiencies.

(g) What importance of vendor audit ?

(h) What is ETP ?

(i) Enlist five checklist questions for auditing of packaging material.

(j) Enlist five Quality Assurance functions.

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

(a) Discuss Auditing of Granulation and Tableting.

(b) Discuss in detail about Responsibilities, management of audit and Planning process of an audit.

(c) Explain auditing warehouse and bulk Pharmaceuticals Chemicals.

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

(a) Explain Auditing of packaging.

(b) Discuss in detail about audit checklist for capsules.

(c) What is a compliance audit ? What are the activities of compliance department ?

(d) How do internal auditors gather and analyse information ?

(e) Explain cGMP Regulations in brief.

(f) Discuss in detail about audit checklist for drug industries.

(g) Discuss auditing of microbiological laboratory.

(h) Write a note on auditing of sterile production.

(i) Explain in detail auditing of HVAC system.
