Roll No. | | | | | | | | | | | |

Total No. of Pages : 01

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M.Pharmacy (Pharmaceutical Quality Assurance) (2017 & Onwards)
(Sem.–2)

AUDITS & REGULATORY COMPLIANCE

Subject Code : MQA-203T

M.Code : 76352

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carry FIFTEEN marks.**

1. A) Enumerate the objectives of an audit and responsibilities of an auditor. Enlist the types of audit and their purpose.

   B) Discuss the information gathered during audit process.

2. A) Write a note on quality systems approach.

   B) Give an overview of the cGMP requirements with respect to auditing of pharmaceutical manufacturing units.

3. A) Describe the key features involved during auditing of a sterile powder manufacturing section.

   B) Outline the process adopted for auditing packaging material vendors.

4. A) Discuss the importance of product information for microbiological processes with regards to auditing.

   B) Give an overview of auditing of manufacturing process involving microbiological laboratory.

5. Highlight the importance of HVAC auditing in a sterile manufacturing plant. Give a detailed account of auditing these systems.

6. What is effluent treatment plant and what is its purpose? Give a detailed account of its auditing process.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.