Seat No: _____ Enrollment No:_____

PARUL UNIVERSITY
FACULTY OF PHARMACY
M.Pharm., Summer 2017-18 Examination

Semester: 2 **Date: 18/05/2018**
Subject Code: MQA203T **Time: 10:00 am to 1:00 pm**
Subject Name: Audits and Regulatory Compliance **Total Marks: 75**

Instructions:
1. Figures to the right indicate full marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay type Questions. (Any 2 out of 3) (15 marks each) **(30)**

1. Write in detail about bulk pharmaceutical chemicals vendor facility audit.
2. Describes the Role of quality systems and audits in Evaluation activities.
3. Explain the basic requirements for HVAC audit with flow chart and a brief checklist.

Q.2 Short Essay type Questions. (Any 5 out of 6) (5 marks each) **(25)**

1. What are the important points of checklist of a Warehouse auditing?
2. Write functions of Engineering department and give overview of an audit of Engineering department.
3. What is ETP? What are the parameters to be checked during audit of an ETP Plant?
4. Why audit of a water system is important? Give specific points to be emphasize more during audit.
5. Explain different classes of deficiencies found during audit.
6. Write in detail about responsibilities of an Auditor.

Q.3 Answer in short. (2 marks each) **(20)**

1. Define: (i) Assessment (ii) Audit
2. Differentiate General laboratory and microbiology laboratory.
3. What do you mean by vendor validation? Explain.
4. Enumerate management responsibilities in auditing in pharmaceutical manufacturing environment.
5. Define: (i) Compliance (ii) Findings
6. Comment: Microbiology laboratory audits emphasize more on safety issues.
7. Enlist QA functions during audit.
8. Define: (i) Observation (ii) Mitigation
9. Comment: Before conducting an audit it is necessary to set an objective of an audit.
10. Enlist important parameters to be observed specially in sterile manufacturing area.