Code No: B134204 **R13** SET - 1

IV B. Pharmacy II Semester Regular Examinations, April/May - 2017
QUALITY ASSURANCE, GMP & GLP

Time: 3 hours Max. Marks: 70

Note: 1. Question Paper consists of two parts (**Part-A** and **Part-B**)
2. Answering the question in **Part-A** is Compulsory
3. Answer any **THREE** Questions from **Part-B**

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PART –A

1. a) Discuss the relevance and importance of practicing GLP in pharmaceutical industries. (4M)
   b) Write short notes on contamination controlling measures in industry. (3M)
   c) Write the guidelines followed for selection of equipment for purchase. (3M)
   d) Discuss the quality control procedures for non-sterile products. (4M)
   e) Write short notes on maintenance of data in a quality control lab. (4M)
   f) Write in brief on handling of recovered materials. (4M)

PART –B

2. a) What is the role of QA in pharmaceutical industry? Explain the significance of documentation. (10M)
   b) Write in brief on layout of an analytical lab for regulatory compliance. (5M)

3. a) Write in detail on the GMP issues pertaining to technical personnel. (8M)
   b) What is change control? Write in detail on its role in production division of a pharmaceutical industry. (7M)

4. Write short notes on
   a) Purchase specification for raw material (8M)
   b) Store management. (7M)

5. Elaborate on
   a) SOPs (8M)
   b) Master Formula Record. (7M)

6. a) Write in detail on GLP protocols for animal house maintenance. (6M)
   b) Elaborate the audit issues involved in finished product approval. (9M)

7. Write short notes on
   a) Product recall procedures (8M)
   b) Complain evaluation. (7M)
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