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

IV B. Pharmacy II Semester Regular/Supplementary Examinations, April - 2018
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) What is the importance of CGMP in pharmaceutical industry? (4M)
   b) Write about the hierarchy of QA team in a pharmaceutical industry and mention their responsibilities. (4M)
   c) Write in brief on selection of vendors. (4M)
   d) Write in brief on in process quality control on labeling. (3M)
   e) What in brief on batch release document. (3M)
   f) Write in brief on data storage methods used in pharmaceutical industry. (4M)

PART -B

2. a) What is GLP? Why it is relevant to pharmaceutical industry? (8M)
   b) Write regulatory requirements for plant location and design. (8M)

3. a) Write in detail on GMP with respect to sanitation and hygiene. (8M)
   b) Write in detail on GLP regulations for maintenance of sterile area. (8M)

4. a) Write in detail on structure, contents and maintenance of Master Formula Records. (8M)
   b) Write in brief on responsibilities of quality audit personal. (8M)

5. a) Write in detail on in-process quality control measures for cleaning. (8M)
   b) Discuss the in process audit controls for biological products. (8M)

6. a) Write in brief on significance of equipment validation. (7M)
   b) Write in detail on quality control measures used in animal house. (9M)

7. a) Write in detail on product recall procedures. (8M)
   b) Write in brief on procedures and documentation involved in handling recovered products. (8M)
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