

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)

