

Code No: B134204

R13**SET - 1****IV B. Pharmacy II Semester Regular/Supplementary Examinations, April/May - 2019**
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) Write the role of quality assurance unit in a pharmaceutical industry. (4M)
- b) Write in brief on selection of location for pharmaceutical industry. (4M)
- c) Write guidelines for selection of seller for procuring equipment. (4M)
- d) What is a quality audit? Write its significance. (4M)
- e) Write short note on methods of data storage. (3M)
- f) Enumerate records pertaining to recall of a product. (3M)

**PART -B**

2. a) Discuss the philosophy of cGMP and its relevance to globalized pharmaceutical industry. (8M)
- b) With a note of training personnel in pharmaceutical manufacturing section. (8M)
3. a) With a neat block diagram explain plant layout for solid oral formulation unit. (8M)
- b) What is sanitation? How it is maintained in pharmaceutical industry? (8M)
4. a) Write the purchase specification for obtaining raw material. (8M)
- b) Explain the process and significance of store maintenance. (8M)
5. a) Write in detail on in-process control of biological products. (10M)
- b) Write SOP for drying powders. (6M)
6. a) Write in detail on quality maintenance in animal house. (10M)
- b) Write the role and responsibility of quality control laboratory. (6M)
7. Write in detail on (16M)  
(a) Product recall procedure (b) handling of returned goods