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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

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