UKA TARSADIA UNIVERSITY

M.Pharm. Sem. 1 (Quality Assurance)

040030103 Good Manufacturing and Good Laboratory Practice

Duration: 3 Hours **Max. Marks: 70**

Instructions: Attempt all questions.
Figures to the right indicate full marks.

SECTION 1

Q.1. Answer briefly.

a Explain the concept of Quality Assurance. **3**

OR

a What are GMP guidelines? Explain the objectives of these guidelines. **3**

b Discuss the responsibilities of personnel as per GMP. **4**

c Describe the different utilities required in a pharmaceutical company. **4**

Q.2. Answer the following.

a Discuss the guidelines for receipt, storage and issue of raw materials. **6**

OR

a Explain the GMP guidelines followed during manufacturing steps. **6**

b Write the importance of a good documentation system. Write the content of a batch record. **6**

OR

b Discuss the advantages of SOPs. Write the SOP for operation of a tray dryer. **6**

Q.3. Answer any two of the following.

a What points should be considered during selection and purchase of equipments? **6**

b What is a master formula? Write its content. **6**

c Describe the in-process tests required during manufacture of tablets. **6**

SECTION 2

Q.4. Answer briefly.

a What are specifications? Write about the different types of specifications. **3**

OR

a What are recalls? Write about the different levels of recalls. **3**

b Write the guidelines given for handling of complaints. **4**

c Explain the terms 'line clearance' and 'reconciliation of labels'. **4**

Q.5. Answer the following.

a Discuss the duties of a quality control laboratory. **6**

OR

a What are quality audits? Discuss their different types and the importance of each. **6**

b Explain the benefits of WHO certification. What are the different types of certifications? **6**

OR

b Describe the tests performed on glass containers. **6**

Q.6. Answer any two of the following.

a Describe the different methods of pharmaceutical waste disposal. What records are maintained at the time of disposal? **6**

b Write a note on GLP. **6**

c Describe the good warehousing practices. **6**

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