UKA TARSADIA UNIVERSITY

M.Pharm. (QA) (1st Semester)

Subject :040030103 **-** Good manufacturing and Good Laboratory Practice

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

Instructions:

1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks allocated to that question.
5. Draw diagrams/figures whenever necessary.

Section-1

Q-1 (A) Answer the following. **[07]**

I) What is full form of cGMP?
II) What is Schedule M?
III) What is meant by layout of a plant?
IV) Write the importance of in-process quality control.
V) What are control charts?
VI) Who are vendors?
VII) Name the different utilities required in pharma manufacturing.

Q-1 (B) Answer the following in brief. (Any 4) **[08]**

I) Discuss the benefits of vendor certification.
II) What are purchase specifications?
III) Discuss the benefits of making SOPs.
IV) What is the difference between master formula and batch records?
V) What are CIP and SIP type of equipments?
VI) Enumerate the IPQC tests performed on liquid oral dosage forms.

Q-2 Answer the following. **[10]**

A) Discuss the responsibilities of personnel as per GMP.

OR

A) What points are considered for selection of location and premises for a pharma plant?
B) Write the content of batch production record.

OR

B) Write a detailed SOP for drying of granules in a tray dryer.

Q-3 Answer the following in detail. (Any 2) **[10]**

A) How are GMP, QA and QC inter-related? Explain role of each.
B) Describe the GMP guidelines to be followed during manufacturing operations.
C) Discuss Sch M guidelines for selection, location, use and maintenance of equipments.

Section-2

Q-4 (A) Answer the following. **[07]**

I) What is Sch L1?
II) What are retention samples?
III) What is quality review?
IV) Write the importance of proper sampling.
V) How are returned goods handled?
VI) What is product recall?
VII) What is line clearance?

Q-4 (B) Answer the following in brief. (Any 4) **[08]**

I) What is meant by reconciliation of labels?
II) What is the role of QA unit of a testing laboratory as per GLP?
III) Describe the information to be included in distribution records.
IV) What are the different methods of disposal of pharmaceutical waste?
V) Name the tests performed on rubber closures as packaging material.

VI) What are the different types of specifications?

Q-5 Answer the following. **[10]**

A) What activities does the quality control department perform?

OR

A) Define 'complaint'. Explain the procedure for complaint handling.

B) Who is a study director? What are the duties of the study director as per GLP?

OR

B) Explain the GMP guidelines for packaging operation.

Q-6 Answer the following in detail. (Any 2) **[10]**

A) Discuss the good warehousing practices.

B) Write a note on WHO certification scheme.

C) Discuss the importance of quality audits. Describe briefly internal audits.