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) Define following terms. **[07]**

I) Quality Control
II) Quality Assurance
III) Good Manufacturing Practices
IV) Good Laboratory Practices
V) Reference substance
VI) Clean in Place
VII) Complaint

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

I) Explain philosophy of GMP.
II) What are the requirements for personnel under GMP?
III) What are the objectives and importance of IPQC with reference to pharmaceutical products?
IV) Explain purchase specifications for equipment giving an example.
V) Write the requirements about sanitation and hygiene with reference to GMP.
VI) Enlist IPQC tests for solid oral dosage forms.

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

A) Write about the buildings and facilities in context to good manufacturing practices for pharmaceutical products.

OR

A) What are the individual & joint responsibilities of Head (production) and Head (quality control) in an organization?
B) Discuss sterile area layout with emphasis on personnel movement.

OR

B) "Equipments cleaning & maintenance is the important parameter in ensuring the quality, safety, purity & identity of the drug product" Justify the statement by explaining the role of cleaning & maintenance of equipments.

Q-3 Write note on the following. (Any 2) **[10]**

A) Quality Control Charts
B) Batch Formula Record
C) SOP for SOP

Section-2

Q-4 (A) Do as directed. **[07]**

I) What is OECD?
II) Define Counterfeit products.
III) Define salvaged drug products.
IV) Explain retention samples.
V) Define Audit.
VI) Define Good Distribution Practices.
VII) What is the purpose for reconciliation of labels?

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

I) Write essential properties of QC documents.
II) What are the objectives behind preparation of SOP?
III) Mention different types of Product Recalls.
IV) Differentiate Extractable and Leachable.
V) Enlist the tests to be performed on Plastic containers for Non-parenteral preparations and parenteral preparations.
VI) Write about distribution records.

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

A) Describe waste material disposal methods.

OR

A) Describe GMP requirements with reference to Batch release of a pharmaceutical product.
B) What do you mean by Representative sample? Discuss different sampling plans.

OR

B) Explain the term Tamper resistant packaging. What are the requirements for Tamper-resistant packaging as per GMP subpart G?

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

A) Discuss benefits of Quality Audit.
B) Write a note on WHO certification scheme.
C) Write about Good Warehousing Practices.