UKA TARSADIA UNIVERSITY

M.Pharm. (QA) (3rd Semester)

Subject :040030302 – Validation and Product Development

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) Define the term validation.

II) Name the different types of process validation.

III) What is meant by FAT of equipments?

IV) What is change control?

V) When is revalidation required?

VI) What do URS and DQ stand for?

VII) What is a measured response in process validation?

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

I) Give the scope of validation.

II) Define process characterization and process ranging.

III) Write the difference between calibration and validation.

IV) How is the tablet coating operation validated?

V) Write the difference between a validation master plan and a protocol.

VI) How are batches selected for retrospective validation?

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

A) What is validation protocol? Describe the content of a validation protocol.

OR

A) Describe the validation of non-sterile manufacturing facilities.

B) Describe retrospective validation and discuss its limitations.

OR

B) Describe the qualification of a double cone blender.

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

A) What are D, Z and F values? How are autoclaves validated?

B) Describe the validation of HVAC system.

C) Discuss the prospective validation of liquid oral dosage forms.

Section-2

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

I) Differentiate accuracy from precision.

II) Differentiate linearity from range.

III) What are SUPAC guidelines?

IV) How are swab samples collected during cleaning validation?

V) What is meant by specificity of a method?

VI) What is a pilot plant?

VII) What is vendor decertification?

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

   I) Why should computer systems be validated?

  II) Write the significance of scale-up studies.

 III) How is the pump performance evaluated during validation of HPLC instrument?

 IV) Explain the advantages of vendor certification.

  V) Write the IQ of dissolution test apparatus.

 VI) Enlist the IPQC tests for liquid oral dosage forms.

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

 A) What do you mean by computer systems validation? Describe the process of validation of computer systems.

                 OR

 A) What is SUPAC? Discuss the main points of SUPAC-IR guidelines.

 B) Describe how acceptance limits are established in cleaning validation.

                 OR

 B) What is ruggedness and robustness of a method? How are they determined?

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

 A) Discuss the prerequisites for a cleaning validation program.

 B) Discuss the design, development and in-process control in manufacture of aerosols.

 C) Discuss the important considerations in the design, development and process control of tablet manufacturing.