

UKA TARSADIA UNIVERSITY

M.Pharm. (Q.A.)(3rd Semester)

Subject :040030302- Validation and Product Development

Time : 10:00 am to 1:00 pm

Duration : 3 Hours

Date : **08/01/2014**

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) Do as directed.

[06]

- I. Differentiate Concurrent Validation and Revalidation.
- II. Explain D value.

OR

What is process validation? Discuss scope of validation.

Q-1 B) Define retrospective validation? How it can be conducted?

[05]

Q-2 Answer the following.

A) Discuss process validation of Coated Tablets.

[06]

OR

Write a note on Validation of Autoclave.

B) Describe the validation parameters of HVAC system.

[06]

Q-3 Answer the following in detail. (Any 2)

[12]

- A) Write a note on Calibration Master Plan
- B) Discuss URS and Qualification stages of Validation.
- C) Performance qualification of Purified Water system.

Section - 2

Q-1 A) Do as directed.

[06]

Explain following performance attributes and acceptance criteria for validation of UV- Visible spectrophotometer.

- I. Wavelength accuracy
- II. Stray light

OR

Enumerate different parameters used for analytical method validation in Assay and Impurities testing.

Q-1 B) Write a note on Validation of Dissolution test apparatus.

[05]

Q-2 Answer the following.

[12]

Discuss SUPAC guideline for modified release dosage form.

OR

Describe In-process controls in manufacturing process design and development of Aerosols.

Q-3 Answer the following in detail. (Any 2)

[12]

- A) Computer system validation
 - B) Vendor certification
 - C) Cleaning validation
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