

UKA TARSADIA UNIVERSITY

M.Pharm. (QA) (Semester III)

Subject : 040030302 Validation and Product Development

Time : 2.30 pm to 5.30 pm

Date : 15/05/2014

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 validation. Discuss its benefits and scope. 3

OR

- a** What are process characterization and ranging studies? 3
- b** Describe briefly different types of validation. 4
- c** Describe the content of a validation protocol. 4

Q.2 a In what cases can retrospective process validation be used? Explain with examples, the important considerations regarding selection of product and batches for retrospective validation study. 6

OR

- a** Describe the steps involved in qualification of a tablet compression machine. 6
- b** Explain the significance of user requirement specifications. Write the URS for FBD and Tray dryer. 6

OR

- b** Discuss the qualification of a pharmaceutical water system. 6

Q.3 Answer in detail (any 2)

- a** Discuss the validation of manufacturing and packaging process for oral liquids. 6
- b** Describe the validation of autoclave. 6
- c** Describe the prospective process validation of a tablet manufacturing process. 6

Section 2

Q.4 a Explain the terms Accuracy, Precision and Robustness of a method. 3

OR

- a** What are scale-up operations? What are SUPAC guidelines? 3
- b** Explain the performance qualification steps in validation of HPLC. 4
- c** Describe briefly the regulatory guidelines for computer system validation. 4

Q.5 a Describe the manufacturing considerations and in-process controls in the manufacturing of sterile parenterals OR ophthalmic preparations. 12

OR

- a** What is the importance of validation of cleaning procedures? Discuss the elements of a cleaning validation study. **12**

Q.6 Answer in detail (any 2)

- a** What is the difference between calibration and validation? Describe the validation of dissolution test apparatus. **6**
- b** Write a note on vendor certification. **6**
- c** How are the acceptable limits for cleaning validation program determined? **6**
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