*Seat No.:----------* *Enrolment No.:----------*

**UKA TARSADIA UNIVERSITY**

Maliba Pharmacy College

M. Pharm. Quality Assurance **3rd** Semester Internal Examination December 2013

**040030302 Validation and Product Development**

Time: 10:30 a.m. To 1:30 p.m. Max. Marks: **70**

Date: 12/12/2013

**Instructions:**

- Attempt all questions.
- Draw diagrams/figures where necessary.
- Figures to the right indicate full marks.

**Section 1**

**Q.1 Answer in brief:**

a Define validation. Write its advantages. **3**

OR

a What are process capability studies? **3**

b Differentiate between retrospective and concurrent validation. **4**

c When is revalidation required? What is change control? **4**

**Q.2 Answer the following: (Any 3)** **12**

a What are user requirement specifications? Differentiate between calibration and validation.

b Describe the content of a validation protocol.

c Write the validation of integrated lines by media fill test.

d How is a fluid bed dryer qualified?

**Q.3 Answer in detail: (Any 2)** **12**

a Describe the validation of a tablet OR oral liquid manufacturing process.

b Describe the qualification of an autoclave.

c Describe the OQ and PQ of HVAC system.

**Section 2**

**Q.4 Answer in brief:**

a What are SUPAC guidelines? **3**

**OR**

a Differentiate between ruggedness, robustness and reproducibility of a method. **3**

b Write the PQ tests of HPLC. **4**

c Describe the qualification of dissolution apparatus. **4**

**Q.5 Answer the following: (Any 3)** **12**

a Who are vendors? How are they certified?

b How is accuracy of analytical method determined?

c How are the limits for cleaning validation determined?

d Outline the different stages in the scale-up of a product.

**Q.6 Answer in detail: (Any 2)** **12**

a Discuss design, development and in-process controls of ophthalmic ointments OR aerosols.

b Discuss the important elements of cleaning validation.

c Write a note on computer system validation.

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