MALIBA PHARMACY COLLEGE

Internal Examination

M.Pharm. (QA) (Semester 3)

(040030302) Validation and Product Development

Date : 08/11/12
Duration: 3 Hours

Max. Marks: 70

Instructions:
1. Attempt all questions.
2. Figures to the right indicate full marks
3. Draw diagrams/figures where necessary.

Section-1

Q-1 (A). Answer the following: **[07]**

I) What is the difference between qualification and validation?
II) Why should equipments be qualified?
III) What are user requirement specifications?
IV) What is a HVAC system?
V) Why are three batches required for validation?
VI) What is microbial challenge test?
VII) Define the term calibration.

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

I) What is process qualification?
II) What parameters of a sterilization tunnel are checked at the time of its OQ and PQ?
III) Enlist the parameters checked during validation of compressed air.
IV) What is revalidation and change control?
V) Write the scope of validation.
VI) Enlist the critical parameters and measured responses in capsule filling operation.

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

A) Describe the validation of a tablet manufacturing process.

OR

A) Describe the validation of an ointment manufacturing process.
B) Describe the content of a validation master plan.

OR

B) Describe retrospective validation giving a suitable example.

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

A) Explain the principle behind media fill test. How is it performed?
B) Describe the qualification of a tablet compression machine.
C) Describe the validation of a water supply system.

Section-2

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

I) What is scale-up? Why should scale-up operations be monitored?
II) What is a validation report?
III) Enlist the in-process control parameters in aerosol manufacture.
IV) Enlist the performance verification tests for UV-visible spectrophotometer.
V) What is vendor decertification?
VI) Define linearity of a method.
VII) What are electronic signatures?

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

I) Classify the different types of vendors.
II) What are SUPAC guidelines?
III) Write the significance of cleaning validation.
IV) Explain the different levels of site changes as per SUPAC guidelines.
V) How are swab and rinse samples taken?
VI) How is specificity of a method determined?

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

A) How are vendors certified? Give the advantages and disadvantages of vendor certification.

OR

A) Write the procedure to determine accuracy and precision of an analytical method.

B) Describe the steps in computer system validation.

OR

B) Describe the content of a cleaning validation protocol.

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

A) Discuss the validation of a dissolution test apparatus.

B) Describe the OQ and PQ of a HPLC instrument.

C) Discuss the process design, development and controls in manufacture of parenterals.