UKA TARSADIA UNIVERSITY

Masters in Pharmacy (Quality Assurance)

Semester 1 – January 2012

Subject Code: 040030103 Good Manufacturing and Good Laboratory Practice

Instructions: **Max marks: 70**

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.
5. Draw diagrams/figures whenever necessary.

Section-I

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

I) Define QA.
II) What is meant by clean-in-place?
III) What is a master formula?
IV) What do FIFO and FEFO stand for?
V) What is Schedule M?
VI) Who is a vendor?
VII) What is vendor decertification?

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

I) What guidelines are given for consultants retained by manufacturer?
II) Name the equipments used to sample raw materials.
III) Enlist the in-process tests for ointments.
IV) What are control charts?
V) What are SOPs?
VI) What is plant layout?

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

A) Discuss the points to be considered when selecting a location for a pharmaceutical manufacturing unit.

OR

A) Explain the good sampling practices to be followed for raw materials.

B) Discuss the GMP guidelines followed in production area.

OR

B) Explain the guidelines for buildings and facilities for pharma manufacturing.

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

A) Write the benefits of making SOPs. Write an SOP for tablet coating operation.
B) Enlist the various documents required in a pharmaceutical company. Explain content of batch production records.
C) Discuss the responsibilities of personnel working in a manufacturing unit.

Section-2

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

I) Why is reconciliation of labels important?
II) What do WHO and GLP stand for?
III) What is meant by quarantine of rejected materials?
IV) What are stability studies?
V) What is quality review?
VI) What colour labels are used for on test, approved and rejected materials?
VII) Write the test to determine type of glass used as containers.

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

I) Name the climatic zones for stability studies as per ICH guidelines.
II) Give an example of bracketing in stability studies.
III) What information is recorded in distribution records?
IV) Name the methods for waste disposal.
V) Mention the various types of specifications.
VI) How are returned goods handled?

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

A) Discuss the procedure for complaint handling and product recall?

OR

A) Describe the procedure followed for conducting internal audits.
B) What good practices should be followed for printing, storing and issue of labels?

OR

B) Write a note on WHO certification.

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

A) Discuss the tests performed on plastic containers.
B) What are the duties and responsibilities of the Quality control department?
C) Describe the good practices to be followed in a pharmaceutical warehouse.

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