Seat No.:----------

Enrolment No.:----------

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M.Pharm (Pharm. Analysis) 2nd Semester Internal Examination 2012

Quality Control and Quality Assurance

Time: 1:30 to 4:30 p.m. Max. Marks: 70

Date: 23/04/2012

Instructions:

- Question no. **1 is compulsory.**
- From Q.2 to Q.6 attempt any **four** questions.
- Make suitable assumption whenever necessary.
- Figures to the right indicate full marks.

Q.1 (a) Answer the following: (any six) 06

1 What are SOPs?
2 What is line clearance?
3 Define specifications.
4 Write the full forms of cGMP, ICH.
5 What is shelf life?
6 What do you mean by container and closures?
7 What is schedule M?

(b) Describe in brief: (any four) 08

1 Explain the terms: Quality Assurance and Quality Control.
2 Write the significance of a good documentation system.
3 Explain the significance of GLP.
4 What is vendor certification?
5 Explain the terms: Prospective validation, Revalidation.

Q.2 (a) Describe the good practices to be followed during storage and sampling of raw materials. 04

(b) What points should be considered while constructing a building for pharma manufacturing? 05

(c) Write the responsibilities of the Quality control department. 05

Q.3 (a) Discuss the good manufacturing practices to be followed in the packaging and labeling stage. 04

(b) Write the content of a batch production record. 05

(c) Explain the GMP guidelines for the selection, location and use of equipment in pharma manufacturing. 05

Q.4 (a) What are the responsibilities of the QA unit as per GLP guidelines? 04

(b) Discuss applications of computers in QC laboratory. 05

(c) Describe protocol of stability testing. 05

Q.5 (a) Describe the good practices to be followed with respect to records and reports. 04

(b) Discuss presentation, recording and interpretation of stability data. 05

(c) Describe the minimum animal care facilities required as per GLP. 05

Q. 6 (a) Describe the testing frequency and storage conditions for long term and accelerated stability studies of a new drug as per ICH. 04

(b) Describe the different climatic zones as per ICH guideline. What is meant by 'significant change'? 05

(c) Describe GMP requirements for warehousing and distribution. 05