UKA TARSADIA UNIVERSITY

M.Pharm. (PA) (2nd Semester)

040060203 - Quality control & Quality assurance

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.
5. Draw diagrams/figures whenever necessary.

Section-1

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

I) Name the regulatory bodies of India and US.
II) What is ICH E6 guideline for?
III) Define shelf life.
IV) Define bioequivalence.
V) Who is a sponsor in a clinical study?
VI) What do you mean by CRO?
VII) What is ICH Q2 guideline for?

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

I) Explain the terms: Bracketing and Matrixing.
II) What are objectives and scope of ICH Q1A guideline?
III) Stability is an essential quality attribute for drug products. Justify.
IV) What are the reasons for conducting stability testing?
V) What do you mean by climatic hazards?
VI) What is GCP?

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

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

OR

A) Describe the testing frequency and storage conditions for long term and accelerated stability studies of a new drug as per ICH guideline.
B) Describe protocol of stability testing.

OR

B) Discuss presentation, recording and interpretation of stability data.

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

A) What are the responsibilities of IRB/IEC?
B) Describe contents of the investigator's brochure.
C) Classify impurities and give rationale for reporting and control of impurities as per ICH Q3A guideline.

Section-2

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

I) What are SOPs?

II) What is schedule M?
III) Define process validation.
IV) What is line clearance?
V) What are reserve samples?
VI) Define specifications.
VII) What is revalidation?

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

I) What is vendor certification?
II) Write the significance of a good documentation system.
III) Define Quality Assurance and Quality Control.
IV) What is change control?
V) What do you mean by container and closures?
VI) Differentiate between reports and records.

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

A) Explain the objectives and scope of GLP guidelines.

OR

A) Describe GMP requirements for warehousing and distribution.
B) What are the different records maintained in a pharmaceutical company? Describe the content of batch packaging record.

OR

B) Write note on Non-clinical testing.

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

A) Describe the responsibilities of QC Unit in pharma manufacturing.
B) Discuss the GMP guidelines for testing and approval/rejection of components, drug product containers and closures.
C) Discuss the GMP guidelines for design, construction, cleaning and maintenance of equipments used in pharmaceutical manufacturing.