UKA TARSADIA UNIVERSITY

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

040040203 - Global Regulatory Requirements & Validation

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) Do as directed: **[07]**

I) Define bioequivalence.

II) What are generic drugs?

III) What is the importance of labelling in NDA?

IV) What is an Orphan drug?

V) What is the full form of CDL? Where is it located in India?

VI) Write the full form of ICH & CTD.

VII) When level 3 changes in manufacturing process are made, it is necessary to perform in vivo bioequivalence studies as per SUPAC-MR guidelines. Say true or false.

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

I) What are Paragraph I to IV certifications?

II) What is meant by market exclusivity for generic drugs?

III) Enlist medicines which are not accepted as generics by ANVISA?

IV) Enumerate technical sections of review copy of NDA. Write their colour codes.

V) What is clinical hold? Give reasons of clinical hold.

VI) Enlist any four functions of Central Drugs Standard Control Organization, India

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

A) Discuss the role of USFDA as a regulatory body.

OR

A) Explain the objectives of Hatch-Waxman Act.

B) Describe the contents of form no. 356h.

OR

B) Why is a drug regulatory system required? write briefly about activities and responsibilities of WHO.

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

A) Discuss the composition and functions of ICH.

B) Mention different levels of changes as per SUPAC-IR guidelines.

C) Differentiate IND, NDA and ANDA.

Section-2

Q-4 (A) Do as directed: **[07]**

I) What is RLD?

II) Define revalidation.

III) What are open label studies?

IV) What is suprabioavailability?

V) Write full form of SAP & CDER.

VI) In how many volunteers is the standard bioequivalence study conducted?

VII) In which year was the first edition of the Orange book published?

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

I) What information should one include in requesting FOIA?

II) Explain the following terms: IQ, OQ & PQ?

III) Explain significance of cleaning validation.

IV) What is the use of biological indicators in validation of sterilizers?

V) Why should computer system be validated?

VI) What are pharmaceutical equivalents?

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

A) What are the different types of validation? Describe the validation of wet granulation process?

OR

A) Discuss the cases wherein steady state clinical studies are warranted. How do they differ from single dose studies? Discuss the importance of sampling time in these studies

B) Explain Orange book. Describe therapeutic equivalence evaluation codes.

OR

B) What is the need for validation? Describe the validation of tablet dissolution apparatus.

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

A) Describe in brief the content of Drug Master Files.

B) What is ERP? Discuss advantages and disadvantages of ERP.

C) Describe the Inactive Ingredient Guide.