UKA TARSADIA UNIVERSITY

M.Pharm. (PA) 2nd Semester

Subject 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.**

SECTION - I

Q.1 **a** What is ICH? What are the objectives of ICH? Name the constituent bodies of ICH. **5**

OR

a Describe the different ICH Quality guidelines applicable to pharmaceutical analysis. **5**

b Explain the terms: (i) Stress testing (ii) Bioequivalence (iii) Quality Assurance **6**

Q.2 **a** Describe the ICH stability testing guidelines for drug product with respect to selection of batches, testing frequency and storage conditions. List the content of a stability study protocol. **6**

OR

a What is meant by shelf life of a product? Explain the determination of shelf life based on stability studies. **6**

b What are impurities? Classify different impurities present in a drug substance. Write about determination and limits of residual solvents as impurities. **6**

Q.3 **Answer any 2 of the following:**

a Explain the principles behind ICH GCP guidelines. **6**

b Write the content of investigator's brochure. **6**

c Discuss the responsibilities of the Ethics Committee as per GCP. **6**

SECTION - II

Q.4 **a** Explain the concept of GMP. Name the different subparts of USFDA cGMP guidelines for finished products. **5**

OR

a Describe the GMP guidelines for personnel. **5**

b Write a brief note on: (i) Specifications (ii)Standard Operating Procedures **6**

Q.5 **a** Describe the good practices followed for storage, sampling and dispensing of raw materials. **6**

OR

a	Discuss the GMP followed during packaging and labeling operations.	**6**
b	Explain the importance of documentation. Describe the content of a master formula record.	**6**

Q.6 **Answer any 3 of the following:**

a	Discuss the scope and objectives of Good Laboratory Practices.	**4**
b	Write the qualifications and responsibilities of a study director.	**4**
c	Discuss the functions of the QA unit of a non-clinical testing laboratory.	**4**
d	Write a note on records maintained in a non-clinical testing laboratory.	**4**

****