E598-2

GUJARAT UNIVERSITY

M. Phil. (Chemistry) Examination May 2017

CHE 603 EA: Advanced Analytical Chemistry

All questions carry equal marks

[Time: 3 hours] **[Marks: 70]**

Q1. Answer the following: **14 marks**

(a) Write down the classification of whole blood and discuss in short some common determinants in clinical analysis. [7]

OR

(a) Define immunoassay and explain in detail radioimmunoassay. [7]

(b) State the fundamental differences between fluorescence and enzyme immunoassay. [7]

OR

(b) Describe in brief the procedures for collection and preservation of biological samples. [7]

Q2. Answer the following: **14 marks**

(a) What is a 'bioequivalence study'? Discuss various parameters of pharmacokinetic profile of drug with diagram. [7]

OR

(a) Explain in brief the three common extraction protocols used in bioanalytical method development. [7]

(b) Discuss various parameters of bioanalytical method validation according to USFDA guidelines. [7]

OR

(b) Explain the role of Incurred Sample Reanalysis (ISR) in bioanalysis. [7]

Q3. Answer the following: **14 marks**

(a) Write a short note on pharmaceutical method development. [7]

OR

(a) Discuss in brief bioavailability/dissolution requirement during drug discovery process. [7]

(b) Explain in detail degradation and impurity analysis of drug substances. [7]

OR

(b) State the activities followed in modern pharmaceutical analysis and discuss in brief pre-formulation studies of drug substances. [7]

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Q4. Answer the following: **14 marks**

(a) Define ICH guidelines. Discuss the issues covered under ICH guidelines. [7]

OR

(a) Explain in detail various phases of clinical trials. [7]

(b) Describe the salient features of regulatory considerations for clinical and regulatory aspects of drug discovery. [7]

OR

(b) Discuss the importance of global CMC NDA in clinical and regulatory aspects of drug discovery. [7]

Q5. Write short notes on any **two** of the following: **14 marks**

(a) Fundamental differences between UHPLC/UPLC and HPLC. [7]

(b) Principles of ICP-MS with its advantages and limitations. [7]

(c) Current state of technology for combining LC with NMR and MS. [7]

(d) Principle, merits and demerits of graphite furnace atomic absorption spectroscopy. [7]