Enrollment No:-_____ Exam Seat No:-_____

C.U.SHAH UNIVERSITY

Summer-2015

Subject Code: 5SC04ACC1 **Subject Name: Bio-Analytical Chemistry**

Course Name: M.Sc. (Chemistry) Date: 19/5/2015

Semester: IV Marks: 70

Time: 10:30 TO 01:30

Instructions:

1) Attempt all Questions in same answer book/Supplementary.
2) Use of Programmable calculator & any other electronic instrument prohibited.
3) Instructions written on main answer book are strictly to be obeyed.
4) Draw neat diagrams & figures (if necessary) at right places.
5) Assume suitable & perfect data if needed.

SECTION-I

Q-1 **a)** Give the full form of LLOQ and ULOQ. 2

b) What do you understand by NDA? 1

c) What are the components of blood? 1

d) What is stability study? 1

e) Give Clinical analysis of barbiturates. 2

Q-2 **a)** Explain in detail radioimmunoassay technique. 7

b) Discuss in detail Pharmaceutical Method development and validation. 7

OR

Q-2 **a)** Explain the composition of blood and discuss the collection and preservation of biological samples. 7

b) Explain in detail Pre-formulation Studies. 7

Q-3 **a)** Discuss in brief essential component of bioanalysis using appropriate examples. 5

b) Explain Regulatory compliances in modern pharmaceutical analysis. 5

c) What is ICH Guidelines? Discuss the issues which are covered under ICH guidelines. 4

OR

Q-3 **a)** Discuss Induced sample real analysis test for various samples. 5

b) Explain the procedure for identity and purity assessment of drugs in drug discovery. 5

c) Compare bioavailiblity and bioselectivity study. 4

SECTION-II

Q-4 **a)** Define Quality Assurance.

b) Give the formulae used to calculate accuracy. 1

c) Give the formulae to calculate % CV. 1

d) What is Immunoassay? 1

e) Give Full form of GMP and GLP. 1

f) Write full form of ELISA. 2

Q-5 **a)** Discuss the importance of regulatory filling in preclinical phase. 7

b) Discuss three extraction protocols used in bioanalysis. 7

OR

Q-5 **a)** Discuss Various biological method validation parameters in details. 7

b) Explain regulatory considerations in Pharmaceutical analysis. 7

Q-6 **a)** Discuss in brief degradation and impurity analysis of drug substances. 5

b) Explain in brief ELISA test. 5

c) Discuss non-regulated studies in drug discovery and development process. 4

OR

Q-6 **a)** Discuss in brief discovery of NCE and high throughput screening. 5

b) Discuss the clinical analysis of Serum electrolytes, blood glucose and blood urea nitrogen. 5

c) Give the entire set of documents to be provided for NDA filling at USFDA. 4