Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Summer Examination-2022

Subject Name: Bio-Analytical Chemistry
Subject Code: 5SC04BAC1 **Branch: M.Sc. (Chemistry)**
Semester: 4 **Date: 02/05/2022** **Time: 11:00 To 02:00** **Marks: 70**

Instructions:

(1) Use of Programmable calculator and any other electronic instrument is prohibited.
(2) Instructions written on main answer book are strictly to be obeyed.
(3) Draw neat diagrams and figures (if necessary) at right places.
(4) Assume suitable data if needed.

SECTION – I

Q-1 **Attempt the following questions** **(07)**

a. Why blood is red in color? **01**
b. Define Hematocrit. **01**
c. The volume of blood plasma is approximately_____lit. per 40-45 mL/kg of b. w. **01**
d. What do you mean by buffy coat? **01**
e. Which test methods are used to determine protein-bound nitrogen and Creatinine? **01**
f. Define impurity. **01**
g. What is called dissolution? **01**

Q-2 **Attempt all questions** **(14)**

a. Discuss the principles of immunoassay in detail. **08**
b. Explain the composition of blood and its function. **06**

OR

Q-2 **Attempt all questions** **(14)**

a. Explain the goals and types of preformulation study. **08**
b. Discuss the blood collection and preservation in detail. **06**

Q-3 **Attempt all questions** **(14)**

a. Explain the partition coefficient and its applications for preformulation solubility study. **05**
b. Write the classification of impurities. **05**
c. Give the ICH guidelines for stability study. **04**

OR

Q-3 **Attempt all questions** **(14)**

a. Discuss the influence of temperature, humidity, pH and oxygen on stability. **05**

b. Discuss the stability testing conditions for climate zone I to IV. **05**

c. Discuss the classification of residual solvents by risk assessment. **04**

SECTION – II

Q-4 **Attempt the following questions** **(07)**

a. Write the full form of PDUFA and PSUR. **01**

b. Define the term bioavailability. **01**

c. Give any two objectives of clinical trials. **01**

d. Define Bioanalysis. **01**

e. List out any two types of animal test. **01**

f. What do you mean by i*n-vivo* and *in-vitro* study*?* **01**

g. Define chemical equivalence. **01**

Q-5 **Attempt all questions** **(14)**

a. Write a note on different phases of clinical trial. **07**

b. Write a note on (i) types of validation and (ii) pharmaceutical equivalent. **07**

OR

Q-5 **Attempt all questions** **(14)**

a. Explain the role of Quality assurance (QA) in pharma industries. **07**

b. Discuss the measurement of bioavailability by plasma level time study. **07**

Q-6 **Attempt all questions** **(14)**

a. Discuss the bioanalytical method validation parameters. **05**

b. Explain in short drug products and drug substance section as per investigational new drug (IND) application. **05**

c. Give any six differences between Quality Assurance (QA) and Quality Control (QC). **04**

OR

Q-6 **Attempt all questions** **(14)**

a. Explain the measurement of bioavailability by urinary excretion study. **05**

b. Discuss the objectives of the bioavailability Study. **05**

c. Explain incurred sample reanalysis and give SOP for ISR study. **04**