Seat No.: _____ Enrollment No.: _____

PARUL UNIVERSITY

DOCTORAL STUDIES AND RESEARCH

PhD Summer 2022-23 Examination

Semester: 1 **Date: 24-06-2023**
Subject Code: 2324001 **Time: 2:00pm to 4:00pm**
Subject Name: Core 2: Research Methodology in QA, Analysis and RA **Total Marks: 50**

Instructions:
1. All questions are compulsory.
2. Figures to the right indicate full marks.
3. Make suitable assumptions wherever necessary.

Q.1 Multiple Choice Questions (MCQs) (1 Mark Each) **(10)**

1. Which of the following methods is used for characterization of impurities?
   a) Thin Layer Chromatography b) Potentiometry
   c) Mass Spectroscopy d) Column Chromatography
2. For conduct of forced degradation studies under acidic conditions, which of the following substance is used?
   a) Hydrochloric Acid b) Sulphuric Acid
   c) Nitric Acid d) Citric Acid
3. An example of sample preparation in bioanalysis is?
   a) Solid-solid extraction b) Liquid-solid extraction
   c) Solid-liquid extraction d) Liquid-phase extraction
4. The ICH guidelines which deal with Impurities: Guidelines for Elemental Impurities are
   a) ICH Q3A b) ICH Q3C
   c) ICH Q3B d) ICH Q3D
5. The degree of agreement amongst individual results is terms as ?
   a) Specificity b) Precision
   c) Sensitivity d) Accuracy
6. Guidelines on impurities in drug substances and drug products is given in guidelines?
   a) ICH Q1 b) ICH Q2
   c) ICH Q3 d) ICH Q4
7. QbD is a concept introduced by the international conference on harmonization as _____ guideline.
   a) ICH Q5 b) ICH Q6
   c) ICH Q7 d) ICH Q8
8. CTD developed by the European Medicines Agency (EMA, Europe), the Food and Drug Administration (FDA, US) and the Ministry of Health, Labour and Welfare (Japan)
   a) True b) False
9. Schedule ____ provides guidelines and requirements for clinical trials.
   a) Y b) M
   c) H d) X
10. Which is not factor for choosing adsorbent in HPTLC?
    a) Nature of the adsorbent b) Chemical Nature
    c) Solubility of the adsorbent d) Temperature

Q.2 Answer the following questions (Any 5 out of 6) (2 Marks Each) **(10)**

1. Define Precision.
2. Write about solid phase extraction (SPE)?
3. Define quality by design.
4. Write about validation process.
5. What is the principle of HPLC?
6. Name the modules of CTD.

Q.3 Answer the following questions (any 4 out of 5) (5 Mark Each) **(20)**

1. Discuss in detail about impurity identification and charcaterization process.
2. Enlist the various methods used for biological samples preparation.
3. Write about the registration process of drugs in India
4. Describe the method development of gas chromatography.
5. Write a short note on CTD.

Q.4 Answer the following question. **(10)**

1. Describe in detail about dossier preparation and submission process.

OR

2. Discuss in detail about analytical methods validation as per regulatory guidelines.