Duration: 3 Hours **Total Marks: 75**

N.B. : 1. All questions are compulsory
2. Figures to right indicate full marks

Q. 1 Choose the appropriate option for following multiple choice-based questions. (20)
Each question carries one mark.

1 What is a characteristic feature of descriptive modeling?
A) It involves the use of complex mathematical equations.
B) It aims to understand the causative relationships between variables.
C) It focuses on predicting future trends or outcomes.
D) It relies heavily on historical data for analysis.

2 Which modeling approach is more suitable for understanding the cause-effect relationships in a system?
A) Descriptive modeling
B) Population modeling
C) Statistical modeling
D) Machine learning modeling

3 What statistical parameter indicates the most frequently occurring value in a dataset?
A) Median
B) Mean
C) Mode
D) Range

4 What is a confidence region in statistics?
A) A range of values within which a parameter is estimated to lie with a certain probability
B) The region where the data points are expected to fall with high probability
C) The area under the curve representing the probability density function
D) A measure of the spread or dispersion of data points around the mean

5 In sensitivity analysis, a model is considered sensitive to a particular input parameter if
A) Small changes in that parameter result in large changes in the model's output.
B) Large changes in that parameter have minimal impact on the model's output.
C) The model's predictions are consistent regardless of variations in that parameter.
D) The model's assumptions are not affected by variations in that parameter.

6 Select a model to predict *in vitro* permeability
A) ClogP
B) PAMPA
C) SPARC online calculator
D) iDEA

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7 Which is NOT TRUE about biowaivers
- A) Test and Reference products must have f2 value less than 10.
- B) Test and Reference products should exhibit similar dissolution profile.
- C) Lowering regulatory burden provide regulatory relief without loss of drug product quality
- D) Product approval based on in vitro data

8 What is the role of Design of Experiments (DoE) in Quality-by-Design?
- A) To analyze clinical trial data.
- B) To identify potential drug targets.
- C) To systematically explore effects of formulation variables on product quality attributes.
- D) To expedite the regulatory approval process.

9 What is the role of critical quality attributes (CQAs) in ICH Q8?
- A) To define the limits of acceptable quality for a pharmaceutical product
- B) To identify the risks associated with the manufacturing process
- C) To establish the design space for the product
- D) To specify the quality requirements that ensure the product's safety and efficacy

10 What is the role of risk assessment in Quality by Design (QbD) for sustained-release (SR) tablet formulation?
- A) To ensure compliance with regulatory requirements
- B) To identify and prioritize critical process parameters
- C) To reduce tablet manufacturing costs
- D) To expedite the tablet approval process

11 What is the primary function of p-glycoprotein?
- A) Enhancing drug absorption
- B) Limiting renal excretion
- C) Transporting substrates into the cell
- D) Transporting substrates out of the cell

12 Which transporter is primarily involved in the uptake of di- and tri-peptides from the intestinal lumen into enterocytes?
- A) OCT
- B) ASBT
- C) hPEPT1
- D) BCRP

13 In factorial design, what is an interaction effect?
- A) The effect of one factor on the outcome variable
- B) The combined effect of two factors on the outcome variable
- C) The effect of random variability in the experiment
- D) The effect of the researcher's bias on the results

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14 How are factorial experiments denoted, such as "2^k" or "3^k"?
A) The number of factors being tested
B) The number of levels within each factor
C) The total number of experimental runs
D) The number of replicates for each experimental condition

15 Which aspect of formulation development is commonly addressed using computational methods?
A) Drug synthesis
B) Packaging design
C) Excipient selection and optimization
D) Regulatory compliance

16 The following is a qualitative approach used for computational modelling of drug disposition processes.
A) Simple multiple linear regression
B) Molecular pharmacophores
C) Multivariate partial least squares
D) Support vector machine

17 What role do modeling and simulation play in computer-aided gastrointestinal absorption simulation?
A) They provide visualizations of gastrointestinal anatomy
B) They allow for virtual testing of drug absorption profiles
C) They automate the experimental data collection process
D) They generate marketing materials

18 How does parameter sensitivity analysis contribute to model refinement?
A) By ignoring the influence of input parameters
B) By providing insights into which parameters are most influential
C) By increasing the complexity of the model
D) By reducing the number of parameters considered in the model

19 Is the example of independent variable in designing SMEDDS formulation.
A) average size of the droplets
B) emulsion viscosity
C) conductivity
D) mixing time

20 The situation where AI will grow uncontrollably, and eventually wipe out humanity is _____
A) AI monopoly
B) AI rule
C) AI singularity
D) AI Governance

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Q.2 Answer any two of the following three questions. (20)

1. Describe biowaivers. Give detailed account of in vitro in vivo correlation with relevant examples.
2. Explain the importance of QbD in developing a safe and efficacious drug product
3. Discuss in detail the Gastroplus simulation tool.

Q.3 Answer any seven of the following nine questions. (35)

1. Discuss 2^2 factorial design as an optimization technique in formulation development
2. Enlist screening designs. Explain in detail central composite design
3. Explain the ACAT model of GI absorption simulation
4. Write a detailed note on artificial neural network for product development.
5. Discuss importance of computational fluid dynamics and artificial intelligence.
6. Write a comparative short note on Descriptive versus Mechanistic modeling in pharmaceutical research.
7. Elaborate on ASBT and p-gp transporters.
8. Write a short note on prediction of food effects on drug absorption giving relevant examples.
9. Write a note on parameter sensitivity analysis.

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