

Time: Total

Marks – 80 M

Q. 1 Attempt all multiple-choice questions (MCQ)

20M

Sr No	Questions	Options
1.	The following is the preliminary stage of production planning	a capacity planning
		b material requirement planning
		c scheduling
		d product development and design
2.	Randomization, leave-one-out, bootstrapping are techniques used during QSPR for	a model validation
		b model building
		c model fitting
		d descriptor selection
3.	_____ is the example of independent variable in designing SMEDDS formulation.	a average size of the droplets
		b the emulsion viscosity
		c conductivity
		d mixing time
4.	Which of the following is not a stage of AI	a Cognitive analytics
		b Predictive analytics
		c Diagnostic analytics
		d All of the above
5.	Which of the following guidelines defines quality risk management	a ICH Q1
		b ICH Q5
		c ICH Q8
		d ICH Q9
6.	OATP can transport	a Mainly anionic drugs but can also transport cationic drugs
		b Only cationic drugs
		c Mainly cationic drugs but can also transport anionic drugs
		d Only neutral drugs
7.	ANA technique stands for	a Artificial Neural Networks
		b Artificial Neutral Networks
		c Architecture Neural Networks
		d Artificial Neural Naming

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8.	Which of the following is NOT TRUE	a	Nine compartments of ACAT Model are arranged parallel to each other
		b	A computer simulation or a computer model is a computer program that attempts to simulate an abstract model of a particular system
		c	Drug absorption process is a complex interplay between drug physicochemical properties, formulation related factors and body physiological factors.
		d	GastroPlus calculates regional solubilities on the basis of fraction of drug ionized at each compartmental pH.
9.	A typical QTPP of an immediate release solid oral dosage form would NOT include	a	Assay and Uniformity
		b	Purity/Impurity
		c	Hardness
		d	Dissolution
10.	These methods can be used to predict the log P of a compound except -	a	Docking methods
		b	Ab initio methods
		c	Fragment based methods
		d	Empirical methods
11.	Which of the following is a critical material attribute affecting the direct compression process	a	Crystalline structure of the API
		b	Solubility of excipients
		c	Color of API
		d	BCS class of API
12.	In IVIVC, deconvolution approach is used to estimate	a	In vivo dissolution profile
		b	Plasma concentration profile
		c	In vitro dissolution profile
		d	In vivo absorption profile
13.	To predict the volume of distribution for a new compound, which measurement are required	a	human plasma protein binding only
		b	experimental log D only
		c	pKa only
		d	Plasma protein binding, log D and pka

14.	Who is known as the Father of AI	a	John McCarthy
		b	Fisher Ada
		c	Alan Turing
		d	Allen Newell
15.	In Active Transport, OCT stands for	a	Organic Cation Transporter
		b	Organic Complex Transport
		c	Optical Cell Transmittance
		d	Optical Coherence Tomography
16.	What is artificial intelligence	a	Making a machine intelligent
		b	Using your own intelligence
		c	Putting your intelligence into Computer
		d	Playing a Game
17.	The Caco-2 assay is used to determine	a	Active transport of a compound
		b	Passive diffusion of a compound
		c	Solubility of a compound
		d	Metabolism of a compound
18.	Which of the following is INCORRECT about IVIVC	a	Promotes more testing in humans
		b	Dissolution testing and plasma drug concentration are identified as the most successful surrogate for safety and efficacy
		c	Reduction of regulatory burden
		d	Time/Cost savings during product development
19.	Commonly used Simulation Software package for estimation of Drug PK profile is	a	GastroPlus™
		b	SimCYP
		c	PK-Sim ®
		d	Cloe ® HIA
20.	As per Biopharmaceutics Drug Disposition classification system, Class 3 shows	a	High solubility, low permeability
		b	Low solubility, high permeability
		c	Low solubility, low permeability
		d	High solubility, high permeability

**Q.2 Answer any one of the following two questions.**

- i a. What are Confidence regions? Write its significance 6M  
b. Write a short note on the importance of computer simulations in pharmacokinetics and pharmacodynamics. Discuss computer simulations of whole organism. 6M
- ii a. Discuss optimization parameter using any screening design with example of a sustained release tablet 6M  
b. Write a note on Computational Fluid Dynamics 6M

**Q.3 Answer any four of the following five questions.**

- i a. Enlist the key elements of QbD and explain CQAs with examples. 6M  
b. Explain in detail gastrointestinal absorption simulation for computer-based biopharmaceutical characterization with special focus on the ACAT model. 6M
- ii a. Write a short note on In vitro dissolution and in vitro in vivo correlation with relevant examples. 6M  
b. Discuss applications of artificial intelligence and robotics in pharmaceutical drug development 6M
- iii a. Explain in brief OCT and ASBT transporters and describe any one method of their computational modeling. 6M  
b. Discuss computer simulations of isolated tissues and organ with suitable examples. 6M
- iv a. Discuss screening designs with one example 6M  
b. Discuss applications of machine learning in healthcare sector 6M
- v a. What are the steps involved in Parameter sensitivity analysis? Explain with suitable examples. 6M  
b. What is statistical modeling? Differentiate between mechanistic and Descriptive modeling 6M

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