

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.

12M

- 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.

48M

- 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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