Sem-II (Semester)
M PH 103 T 8/1/2024

Duration: 3 Hours **Total marks: 75**

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

Question No.	Question	Max. Marks
Q.I	Multiple Choice Questions (Answer all)	**20**
1	Drug in association with water molecules to produce crystalline forms is known as	**1**
a)	solvate	
b)	hydrate	
c)	coprecipitate	
d)	Polycrystal	
2	A thermal method of analyzing drug excipient compatibility is	**1**
a)	Differential scanning calorimetry	
b)	Thin layer chromatography	
c)	High pressure liquid chromatography	
d)	Vibrational spectroscopy	
3	Photolytic stress testing involves use of	**1**
a)	3% hydrogen peroxide	
b)	0.1N HCl	
c)	1 N HCL	
d)	Xenon or Halide metal lamp	
4	SMEDDS are isotropic mixture of	**1**
a)	oil, surfactant & cosurfactant forming O/ W microemulsion	
b)	oil, surfactant & cosurfactant forming W/O microemulsion	
c)	oil & surfactant forming W/O microemulsion	
d)	oil & cosolvent forming O/W microemulsion	
5	An example of a dependent variable is	**1**
a)	percent drug entrapment of microspheres	
b)	continuous phase volume	
c)	stirring speed (rpm)	
d)	concentration of ethylcellulose	

6	The problem type for a tablet to be prepared which has minimum friability is	1
a)	constrained	
b)	unconstrained	
c)	dependent	
d)	Independent	
7	A relationship between factors and their levels in an optimization design is called	1
a)	treatment	
b)	effect	
c)	response	
d)	Interaction	
8	To carry out operations for different samples and to check performance of the equipment is _____	1
a)	Performance qualification	
b)	Design qualification	
c)	Operational qualification	
d)	Installation qualification	
9	Documentation regarding the reception of date and time of equipment is _____	1
a)	Installation qualification	
b)	Design qualification	
c)	Performance qualification	
d)	Operational qualification	
10	Which of the following best describes the purpose of Operational Qualification (OQ) in equipment validation?	1
a)	Verifying that the equipment is installed correctly	
b)	Testing the equipment under extreme conditions	
c)	Ensuring that the equipment consistently performs according to specification	
d)	Evaluating the equipment's design and construction	

11	EOQ is the quantity of materials when	1
a)	quantity ordered is discounted	
b)	inventory quantity is equal to demand	
c)	order quantity is equal to profits	
d)	inventory carrying and ordering cost are equal	
12	Which of the following is a principle of TQM?	1
a)	customer focus	
b)	product focus	
c)	intermittent improvement	
d)	employer focus	
13	The first activity of material purchase is	1
a)	inspection of material	
b)	source selection	
c)	recognizing the need	
d)	communication with the purchase department	
14	A substance employed to minimize die-wall friction is referred to as _____	1
a)	glidant	
b)	flow promoter	
c)	lubricant	
d)	Plasticizer	
15	_____ is not a type of deformation of particles	1
a)	Elastic	
b)	Plastic	
c)	Brittle fracture	
d)	Decompression	
16	What is Poisson's ratio?	1
a)	The ratio of stress to strain in a material	
b)	The ratio of lateral strain to longitudinal strain in a material	
c)	The ratio of shear stress to shear strain in a material	
d)	The ratio of elastic modulus to yield strength in a material	

17	.....is the most frequently occurring value in a series of observations	1
a)	average mean	
b)	standard deviation	
c)	median	
d)	Mode	
18	A physicochemical factor affecting dissolution rate of drug	1
a)	motility pattern of GIT	
b)	gastrointestinal secretion	
c)	particle size	
d)	viscosity of luminal contents	
19	The apparatus consisting of a reservoir and pump for the flow of dissolution medium through the cell that holds the test sample is	1
a)	USP apparatus IV	
b)	USP apparatus III	
c)	USP Type II	
d)	USP TypeVI	
20	Drug release from porous matrix directly related to square root of time is indicated by	1
a)	Higuchi model	
b)	First order model	
c)	Hixon Crowell model	
d)	Korsemeyer Peppas model	

QII	Answer **any Two**	**20**
1.a	What are SMEDDS? Give an outline of the process for manufacturing of SMEDDS	**5**
1.b	Discuss use of similarity factor- f2 in dissolution profile comparison.	**5**
2.a	Give the key aspects of Production organization.	**5**
2.b	Explain the various methods of sales forecasting.	**5**
3.a	Elaborate on compaction profiles with the help of diagram.	**5**
3.b	Discuss the frictional forces involved in the compression process.	**5**

QIII	Answer **any Seven**	**35**
1	Write a note on drug excipient compatibility.	**5**
2	State the advantages of a Full Factorial design. Give the experimental layout for a three factor two level factorial design with an example.	**5**
3	Write the salient features of the validation protocol for tablets prepared by wet granulation method.	**5**
4	Describe the features of Total Quality Management.	**5**
5	Give the cGMP requirements of plant layout and services to be provided.	**5**
6	Discuss force porosity relationship for powders undergoing compression.	**5**
7	Discuss the Energy component involved in compaction process	**5**
8	Enlist the physicochemical factors affecting dissolution rate of drugs and discuss any two factors.	**5**
9	Explain the use of Higuchi and Peppas plot for studying drug release kinetics.	**5**

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