Time: 3 Hours **Marks: 75**

Q. 1 Attempt all multiple-choice questions (MCQ) **20M**

Sr No	Questions		Options
1	Materials that do not completely recover their original size when the deforming force is removed are said to exhibit	a	Pseudo-plastic deformation
		b	Elastic deformation
		c	Visco elasticity
		d	Plastic deformation
2	Poloxamer is available in various following common grades excluding the grade…….	a	20
		b	188
		c	407
		d	88
3	In matrix devices drug is ……..through out a polymer matrix.	a	Dispersed Abruptly
		b	Dissolved Homogenously
		c	Mixed Non Homogenously
		d	Dispersed Homogeneously
4	Nitro-Dur exhibits which type of controlled drug delivery	a	Polymer membrane permeation
		b	Activation modulated
		c	Micro-reservoir partition
		d	Polymer matrix diffusion
5	In activation modulated drug delivery systems which of the following is activated by Chemical process	a	Magnetically activated DDS
		b	pH activated DDS
		c	Osmotic pressure activated DDS
		d	Hydration activated DDS

6	Which of the following is a natural polymer	a	Collagen
		b	Poly D,L-lactic -co-glycolic acid
		c	Teflon
		d	Nylon
7	PLGA is a ……polymer used in the sustained/ controlled drug delivery systems	a	Natural polymer
		b	Natural copolymer
		c	Synthetic copolymer
		d	Synthetic polymer
8	Hollow microspheres, a non-effervescent approach for gastro retentive drug delivery system are also known as	a	Macroballs
		b	Floating balls
		c	Microballoons
		d	Microbeads
9	Which of the following GRDDS is also known as "Plug Type System"	a	Mucoadhesive system
		b	Floating system
		c	Pulsatile system
		d	Swelling system
10	An ocular device containing hydroxypropylcellulose is	a	Lacrisert
		b	SODI
		c	Minidisc
		d	Ocusert
11	.,…..,……. Is an example of natural polymer used in the formulation development of occular inserts .	a	Collagen
		b	Polyvinvyl Alcohol
		c	Hydroxypropyl methyl cellulose
		d	Ethyl cellulose

12	Dissolution apparatus for in vitro drug release from transdermal patches is	a	USP 5
		b	USP 1
		c	USP 2
		d	USP 3
13	Which of the following is an example of osmotic pressure activated drug delivery system	a	Progestasert
		b	Nitro-dur
		c	Compudose
		d	Alzet
14	Peel tack test for transdermal adhesives is carried out at	a	90 degrees and speed 12 inch / min
		b	120 degrees and speed 1 inch / min
		c	25 degrees and speed 9 inch / min
		d	45 degrees and speed 5 inch / min
15	The biological factor significantly affecting the bioavailability of Controlled release dosage form	a	Absorption
		b	Refractive index
		c	Surface tension
		d	Solubility
16	Crystallinity in a polymer leads to	a	low diffusion rate
		b	increased hydrolysis
		c	enhanced flexibility
		d	high diffusion rate
17	In the Reservoir system, the mechanism of drug release involves the drug…….	a	Dissolution
		b	In situ dissolution
		c	Diffusion
		d	Dissolution and Diffusion

18	Which of the following is used to produce effervescent Gastro retentive drug delivery system	a	Magnesium stearate
		b	Sodium bicarbonate
		c	Magnesium carbonate
		d	Sodium hydroxide
19	Which of the following is a wrong statement for Gastro retentive drug delivery systems	a	Useful to reduce first pass effect of the drug
		b	Useful to target site specific release of the drug
		c	Useful to increase gastric retention of the drug
		d	Useful to provide local and systemic effect of the drug
20	Bioadhesive delivery matrix helps to overcome which of the challenges for protein and peptide delivery	a	Denaturation
		b	Enzymatic activity
		c	Mucociliary clearance
		d	Absorption barrier

Q 2. Attempt any two questions

i. Enlist the ideal properties a drug candidate should possess for administering it through the transdermal route of drug administration. Discuss various approaches for delivering the drug through transdermal route 10M

ii. Explain the term Absorption window and discuss the evaluation of Gastro-retentive drug delivery systems. Enlist the types of GRDDS systems and explain any one in detail 10M

iii. Give the flow chart depicting the classification of osmotic drug delivery system. Discuss the various factors affecting the drug release through the osmotic drug delivery system 10M

Q 3. Attempt any seven questions

i. What are polymers? Discuss any two polymers and it's application in pharmaceutical formulation development. 5M

ii. Elaborate on the methods for formulation of Buccal Drug Delivery systems 5M

iii. Describe in details evaluation of transdermal drug delivery system 5M

iv. Discuss in detail pH activated and enzyme activated drug delivery systems 5M

v. How can one enhance the permeation of drugs through transdermal route of drug administration 5M

vi. What are Ocuserts? Which parameters are to be evaluated to obtain a therapeutically active Ocusert. 5M

vii. Discuss the mechanically activated drug delivery system 5M

viii. Differentiate between the proteins and peptides. Discuss any two approaches of Protein and peptide drug delivery system 5M

ix. Detail the salient features, merits and demerits of dissolution controlled drug release systems. 5M

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Time: 3 hrs **Marks:75**

Q. 1 Attempt all multiple-choice questions (MCQ) **20M**

Sr No	Questions		Options
1	What do you mean by a randomized design?	a	The subjects do not know which study treatment they receive
		b	Patients injected with placebo and active doses
		c	Randomly assigning subjects either for placebo or active dose
		d	Signed document of the recruited patient for the clinical trial procedures
2	CTD prescribes the organisation of dossier across	a	Four modules
		b	Five modules
		c	Six modules
		d	Two modules
3	Para III of filling is __	a	Patent will expire on a particular date.
		b	No listed patents
		c	Listed patent has expired
		d	Patent is invalid or will not be infringed by the drug, for which approval is being sought
4	Animal studies, clinical trials, bioavailability studies are part of which application process	a	ANDA
		b	IND
		c	BLA
		d	NDA
5	The CFR is divided into____titles that represent broad areas subject to federal regulation	a	40
		b	45
		c	50
		d	55
6	The Hatch Waxman Act provides how many days of market exclusivity?	a	185
		b	181
		c	182
		d	180

7	If an NDA is submitted under section 505 b of F D and C Act, it qualifies for exclusivity under this act and it is listed in	a	patent section
		b	exclusivity section
		c	Patent and exclusivity section
		d	Patent prior art part only
8	Deletion of colour or flavour comes under …… change	a	Level 1
		b	Level 2
		c	Level 3
		d	Level 4
9	Which is the Drug regulatory agency of country UK	a	TGA
		b	SAHPRA
		c	MHRA
		d	ANVISA
10	Group is the most lucrative, time consuming and expensive filling of ANDA.	a	Para IV
		b	Para II
		c	Para I
		d	Para III
11	What does CTD stands for	a	Current Technical Document
		b	Common Technical Document
		c	Current Technological Document
		d	Common Technological Document
12	IND and NDA application for FDA approval to Market a new drug (drug approval) comes under which part of 21CFR?	a	21 CFR part 201
		b	21 CFR part 316
		c	21 CFR part 314
		d	CFR part 50
13	Which of the following is not content of Master formula record	a	Formula
		b	Batch Number
		c	Name of the company
		d	Procedure
14	Drug Regulatory agency of India is	a	CDSCO

		b	TGA
		c	MHRA
		d	ANVISA
15	Which ICH guideline is concerned with design, safety, conduct and reporting of clinical trials?	a	Toxicity
		b	Multidisciplinary
		c	Quality
		d	Efficacy
16	After the completion of Phase III trials successfully the sponsor shall initiate _____ from 9-12 months before NDA submission.	a	BLA
		b	IND
		c	ANDA
		d	Pre-NDA
17	After how many days from announcing the IND, the sponsor shall submit reports of Clinical trials?	a	90 days
		b	30 days
		c	60 days
		d	20 days
18	ICH secretariat is based in_____?	a	Geneva
		b	Zurich
		c	Brazil
		d	Japan
19	Which one of the following is the last step of a clinical trial process	a	Investigator selection.
		b	Patient recruitment
		c	Statistical Analysis
		d	Data filed and registration
20	Hatch Waxman Amendments Act is also known as	a	Drugs Prices Control Order
		b	Essential Commodity Act
		c	Drug Price Competition And Patent Term Restoration Act 1984
		d	Amendments In Drug Price Control Order

Q 2. Attempt any two questions **20M**

i. Write a note on: Distribution records in Pharmaceutical Industry

ii. Explain in detail the various stages involved in FDA's new drug approval process.
iii. Discuss quality guideline Q1A (R2).

Q 3. Attempt any seven questions **35M**

i. Explain the regulatory guidelines of the documentation clinical study design with respect to various phases involved in clinical trials.
ii. What is Pharmacovigilance and explain its salient features.
iii. What are the regulatory requirements of TGA.
iv. Explain the approval process and timeline for an investigational new drug (IND) application.
v. Write a brief note on Regulatory process approval for Active Pharmaceutical Ingredient.
vi. What are the objectives of the International conference on harmonization (ICH)? Enlist safety guidelines
vii. Explain the non-clinical drug development for global submission of new drug application (NDA)
viii. Discuss the significance of Hatch Waxman Act.
ix. Write a brief note on CFR part 11

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

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

Question No.	Question	Marks
Q.I	Multiple Choice Questions (Answer all)	**20**
1	_____ cause Maillard reaction especially with amine containing drugs which is potentiated in presence of magnesium stearate.	**1**
a)	Starch	
b)	Lactose	
c)	Microcrystalline cellulose	
d)	Pre gelatinized starch	
2	Solubility of pure API is determined by	**1**
a)	diffusion study	
b)	partition co-efficient determination	
c)	permeability study	
d)	phase solubility study	
3	Which one of the following strategies would not normally be expected to reduce the rate of oxidation of an API?	**1**
a)	Replacing air ln package with nitrogen	
b)	Addition of heavy metal to the formulation	
c)	Protecting formulation from light	
d)	Reducing the temperature of the formulation	
4	Selection of surfactants for SMEDDS is based on	**1**
a)	high emulsification efficiency, high percentage transmittance and low flask inversions.	
b)	high emulsification efficiency, low percentage transmittance and high flask inversions.	
c)	low emulsification efficiency, highest percentage transmittance and high flask inversions.	
d)	low emulsification efficiency, low percentage transmittance and low flask inversions.	
5	In a factorial design	**1**
a)	two dependent variables are studied to determine their interactive effects	
b)	only one independent variable is studied to determine its effect on the dependent variable	
c)	two or more independent variables are simultaneously studied to determine their independent and interactive effects on the dependent variable	
d)	Only two independent variables are simultaneously studied to determine their interactive and independent effects on the dependent variables	

6	Factorial designs allow the study of _____ effects of independent variables on dependent variables.	**1**
a)	A rank order and correlation	
b)	dependent and independent	
c)	Symbiotic and dichotomous	
d)	main and interactive	
7	The following parameter is referred to as dependent variable in an optimization technique	**1**
a)	type of polymer	
b)	binder concentration	
c)	rpm of blender	
d)	content uniformity	
8	Benefit of validation is that it	**1**
a)	helps to label products	
b)	proves that the process is consistently doing what it is supposed to do	
c)	ensures role of the products	
d)	determines process variables and acceptable limits and thus sets up in-process control	
9	Operational Qualification checks and confirms	**1**
a)	all parts of the equipment are operating correctly	
b)	provision of user manual	
c)	place to fit the equipment	
d)	capacity of the equipment	
10	Documentation of date and time received is _____	**1**
a)	Installation qualification	
b)	Design qualification	
c)	Performance qualification	
d)	Operational qualification	
11	The following item falls under Direct labor element of cost control	**1**
a)	Electricity	
b)	cost of mechanics	
c)	salary of formulation scientist	
d)	equipment cleaning	
12	The following is categorized as finished goods inventory	**1**
a)	containers for packaging	
b)	saleable items	
c)	bulk tablets awaiting packaging	
d)	bulk capsules awaiting packaging	

13 Mean Absolute Deviation technique involves noting the differences between the actual and forecasted sales on following basis **1**

a) Weekly
b) Daily
c) Monthly
d) Quarterly

14 Radial die -wall forces arise as a result of tablet mass attempting to expand in _____ **1**

a) horizontal plane due to vertical compression force
b) vertical plane due to vertical compression force
c) horizontal plane due to horizontal compression force
d) vertical plane due to horizontal compression force

15 Coefficient of lubricant efficiency (R value) equal to 1 indicates_____ **1**

a) perfect lubrication
b) inadequate lubrication
c) moderate lubrication
d) high die-wall friction

16 Larger values of Ky in the Heckel Plot indicate formation of what quality of tablets? **1**

a) Softer
b) Brittle
c) Harder
d) Fluffy

17 % Drug release versus square root ot time is plotted for **1**

a) Higuchi model
b) Korsmeyer-Peppas plot
c) Hixson - Crowells plot
d) Second order

18 In a study, subjects are randomly assigned to one of three groups; control, experimental A or experimental B. After the treatment the mean score for the three groups are compared. The appropriate statistical test for comparing these means is _____ **1**

a) The ANOVA
b) The Correlation coefficient
c) The Chi-Square test
d) The t-test

19	For f2 analysis the percent coefficient of variation at the earlier time points for e.g., 15 mins should not be more than_____	**1**
a)	20%	
b)	25%	
c)	30%	
d)	35%	
20	The drug is considered highly permeable when the extent of drug absorption in humans is _____ or more of an administered dose based on a mass balance determination or in comparison to an intravenous reference dose.	**1**
a)	10%	
b)	50%	
c)	90%	
d)	60%	
QII	Answer **any Two**	**20**
1	a. Write a note on solid state stability of API.	**5**
	b Give ICH guidelines for Real time, intermediate and accelerated stability testing of new drug substances.	**5**
2	a) Explain the methods of inventory management and control.	**5**
	b Write a note on Total Quality Management.	**5**
3	a Write a note on Heckel's plot.	**5**
	b Comment on selection of dissolution media based on physicochemical properties of drug and dosage form.	**5**
QIII	Answer **any Seven**	**35**
1	Explain formulation strategy for SMEDDS using pseudo-ternary phase diagram.	**5**
2	Depict a 2^2 factorial design for a representative pharmaceutical SR tablet preparation and write a representative polynomial equation.	**5**
3	Discuss validation of process used for manufacturing of tablet dosage form prepared by wet granulation method.	**5**
4	Elaborate on cGMP requirements for services, equipment and maintenance.	**5**
5	Explain force porosity relationship for powders undergoing compression.	**5**
6	Enlist the pharmacokinetic parameters and discuss any two parameters	**5**
7	Explain the functions of material management.	**5**
8	With the help of a diagram explain the die wall lubrication	**5**
9	Write a short note on dissolution profile comparison by f1 and f2 Method	**5**

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Q.P.CODE:23192

Time: 3 Hrs **Marks : 75**

Note:

1. **Draw neat labeled diagrams wherever necessary**
2. **Figures to the right indicate full marks**

I.	Multiple choice questions	20
1.	The following quantitation methods in UV - Visible spectroscopy need a reference standard except	
a.	Standard curve method	
b.	Single point standardization	
c.	Double point standardization	
d.	Use of standard absorptivity	
2.	Michelson's interferometer is a component of	
a.	Atomic absorption spectrophotometer	
b.	X-ray diffractometer	
c.	GC	
d.	FTIR spectrophotometer	
3.	In flame photometry, as the energy gap between excited and unexcited metal atoms increases, the proportion of atoms in the ground state	
a.	Increases	
b.	Decreases	
c.	Remains unaffected	
d.	Increases or decreases	
4.	Fluorescence involves conversion from	
a.	Singlet excited state to ground state	
b.	Triplet excited state to ground state	
c.	Ground state to triplet excited state	
d.	Ground state to singlet excited state	

5. The signal for the methyl protons of n-butane is split into a

a. Quartet

b. Triplet

c. Singlet

d. Doublet

6. Coupling constant in proton NMR spectroscopy is:

a. Ratio of chemical shifts

b. Difference in Hz between adjacent peaks in a multiplet

c. Difference of chemical shifts

d. Ratio of absorption frequencies

7. Which of the following is used as an internal standard in ^{1}HNMR?

a. DMSO

b. $CDCl_3$

c. DMF

d. TMS

8. Nuclei having either the number of protons or neutrons as odd number have _____ spin

a. Integral

b. Half integral

c. One third

d. Zero

9. In mass spectrometry, the most intense peak is called the

a. Base peak

b. Fragment ion peak

c. Molecular ion peak

d. Metastable ion peak

10. Which of the following is used as a matrix in MALDI?

a. Acetic acid

b. Lactic acid

c. Benzoic acid

d. Citric acid

11. A mass spectrometer bombards molecules with a high energy electron beam in

a. Colloidal phase

b. Vapour phase

c. Solid state

d. Liquid phase

12. Which of the following is associated with mass spectrometry

a. Excitation of electron

b. Electron bombardment

c. Molecular vibration

d. Splitting of electrons magnetic energy

13. Gradient elution in HPLC involves_____

a. Changing the mobile phase composition with time

b. Successive injection of the sample

c. Changing the length of the column

d. Using constant mobile phase composition throughout the run time

14. Wall coated open tubular columns are used in_____.

a. GC

b. TLC

c. HPLC

d. Electrophoresis

15. Which of the following can be calculated using peak width at half peak height?

a. Asymmetry factor

b. Number of plates

c. Tailing factor

d. Resolution

16. The mechanism of separation in TLC is usually

a. Partition

b. Ion exchange

c. Adsorption

d. Size exclusion

17. Which of the following is associated with X-ray diffractometry

a. Miller's Indices

b. Retention indices

c. Magnetogyric ratio

d. Attenuated total reflectance

18. According to Bragg's Law constructive interference occurs at path difference of _____between two waves.

a. 2dSinϴ

b. Sinϴ

c. 2ϴSinϴ

d. 2ϴSind

19. In capillary electrophoresis _____ flow causes the movement of electrolytes through the tube.

a. Micro-osmotic

b. Macro-osmotic

c. Electro-osmotic

d. Reverse osmotic

20. In electrophoresis, as the particle size of analyte is increased,

a. rate of migration decreases

b. No change in the migration rate

c. rate of migration increases

d. Particle becomes immobile

II. Long answer questions (Answer any two out of three) 20

1. a. Give any two fragmentation pathways for 2-pentanone

   b. What is meant by spin-spin coupling? Relate and apply the concept to depict the splitting pattern for ^{1}H NMR spectrum of ethyl bromide.

2. a. A chromatogram shows an unretained solute eluting out at a dead time of 0.6 minutes. There are two more analyte peaks observed. Peak A starts at 4.4 minutes and ends at 4.7 minutes while peak B starts at 5.6 minutes and ends at 5.9 minutes. Assuming that peaks A and B are symmetric, calculate-

      i) - Adjusted retention time for peak A

      ii) - Capacity factor for peak B

      iii) - Selectivity factor

      iv) - Number of plates for peak B

      v) - Resolution between peaks A and B

   b. Explain the following terms with suitable examples:
   I. Shielding ii. Deshielding iii. Precessional frequency

3. a. Draw a typical mass spectrum showing different peaks seen in the same. Explain the following terms with suitable examples:
   i. Isotope peak ii. Metastable ion peak

   b. Enlist the methods for multicomponent analysis in UV - Visible spectroscopy.
   If a 12µg/ml solution of molecule $C_8H_9NO_2$ gives an absorbance of 0.86 at its λ_{max} in a 1cm cell, what is its molar absorptivity?

III. Short answer questions (Answer any seven out of nine) 35

1. Explain the terms -Gradient elution, Number of theoretical plates, Tailing factor

2. Enlist the reflectance methods used in IR spectroscopy. Explain any one in detail.

3. Enlist the detectors used in HPLC and explain the working of any one detector.

4. Write two points of distinction between AAS and AES. Explain principle of AAS.

5. Enlist the different ionization techniques used in mass spectrometry. Write a detailed note on MALDI or Chemical ionization.

6. Explain the term FT-NMR. Give three points of distinction between ^{1}H NMR & ^{13}C NMR.

7. Discuss principle involved in X-ray diffraction technique. State Bragg's law and its equation. Describe rotating crystal technique used in X ray Crystallography.

8. Explain the principle of paper electrophoresis. Comment on effect of factors affecting separation in the same.

9. Enlist quantitation methods used in HPLC. Discuss any one in detail.

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