

Vision – To emerge as a premier institute offering quality education in pharmaceutical sciences.

Mission – To create knowledgeable and ethical professionals capable of fulfilling the needs in health care systems.

SUBJECT: PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

(M PHARM SEMESTER I CBCS R 2019)

SAMPLE MCQS

Select the right option

Each correct answer carries two marks

SR NO

- 1 Which of these is exception for IND regulations?
 - a. Existing drug for new indication in humans
 - b. New drug molecule for clinical studies
 - c. Drug for preclinical studies
 - d. Higher dose for bioequivalence studies

- 2 Clinical investigation of drug metabolism and structure activity relationship is carried out in
 - a. Phase I
 - b. Phase II
 - c. Phase III
 - d. Phase IV

- 3 When an Indian firm wishes to manufacture new drug, it should apply to
 - a. DCGI
 - b. FDA
 - c. CDSCO
 - d. CAPA

- 4 Which study should be carried out before submission of IND?
 - a. Phase I
 - b. Phase II
 - c. Phase III
 - d. Preclinical

- 5 Which application is to be submitted if manufacturing site is to be changed post approval?
 - a. IND
 - b. ANDA
 - c. SUPAC
 - d. BACPAC

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- 6 Log partition coefficient of Alprazolam is 2.6. It is
- Polar
 - Non polar
 - Semi polar
 - Amphoteric
- 7 Enantiotropic forms of the drug have
- Transition temperature above melting point
 - Transition temperature at melting point
 - Transition temperature below melting point
 - Transition temperature near melting point
- 8 Which of these is a crystal growth retardant
- Starch
 - PVP
 - Glucose
 - Urea
- 9 In Noyes Whitney equation, D represents
- Dissolution parameter
 - Diffusion coefficient
 - Dispersion gradient
 - Disintegration time
- 10 At which temperature is dissolution of transdermal film studied?
- 32°C
 - 35°C
 - 37°C
 - 39°C
- 11 Which is model independent method of comparing dissolution profile?
- Hixson Crowell law
 - Higuchi model
 - Weibull model
 - Index of Rescigno

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- 12 Which type of glass is neutral?
- Sodalime glass
 - Treated sodalime glass
 - Borosilicate glass
 - Amber glass
- 13 Alu alu blister employs --- technology
- Thermo forming
 - Cold forming
 - Bending
 - Blow moulding
- 14 ASTM is abbreviation for
- American Society for Trial Methods
 - Alcovian Society for Testing and Materials
 - American Society for Testing and Materials
 - American Association for Testing and Materials
- 15 Which activity is carried out in pilot plant?
- Formulation development trials
 - QC testing
 - Batch manufacture for clinical trials
 - Stability testing
- 16 Thermocouples can be used for validation of
- Autoclave
 - Double cone blender
 - Compression machine
 - Scanning electron microscope
- 17 Store under refrigerated condition indicates
- Store below – 18°C
 - Store between -5 and -20°C
 - Store below 8°C
 - Store below -100°C

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- 18 Which of these works on the principle of fluidization of powders?
- Alpine airjet sieve
 - Coulter counter
 - Conductivity meter
 - Flame photometer
- 19 In Stokes law, g represents
- Gravitational factor
 - Gravitational constant
 - Viscosity
 - Centipoise
- 20 Which section of CFR contains regulations related to Pharmaceuticals?
- 24
 - 22
 - 210
 - 21
- 21 IND submitted by physician who initiates and conducts the study is
- Abbreviated IND
 - Emergency use IND
 - Treatment IND
 - Investigator IND
- 22 Module 4 of CTD asks for following information
- Administrative information
 - Summary
 - Non clinical study reports
 - Clinical study reports
- 23 Generic drug approval must be obtained by submitting ---- to FDA
- IND
 - NDA
 - SUPAC
 - ANDA

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- 24 In which form is import license issued in India?
- Form 10
 - Form 12
 - Form 16
 - Form 11
- 25 Conversion from crystalline to amorphous form leads to
- Decrease in solubility
 - Increase in solubility
 - Increase in disintegration time
 - Decrease in disintegration time

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ANSWERKEYS

QUESTION	CORRECT OPTION	QUESTION	CORRECT OPTION	QUESTION	CORRECT OPTION	QUESTION	CORRECT OPTION	QUESTION	CORRECT OPTION
1	c	6	a	11	d	16	a	21	d
2	a	7	c	12	c	17	c	22	c
3	a	8	b	13	b	18	a	23	d
4	d	9	b	14	c	19	b	24	a
5	c	10	a	15	c	20	d	25	b