

B.Pharm. (CBCS Pattern) Semester-VIII  
**BP812ET - Pharmaceutical Product Development**

P. Pages : 3

Time : Three Hours



**GUG/W/24/14157A**

Max. Marks : 75

- Notes :
1. All questions are compulsory.
  2. All questions carry equal marks.
  3. Diagrams and Chemical equation should be given wherever necessary.

**1. Multiple Choice Questions.**

**20**

- 1) Preclinical studies include.
  - a) Preformulation study
  - b) Formulation Development
  - c) Drug Disposition study
  - d) All of the above
- 2) Stages of pharmaceutical product development do not include.
  - a) Preclinical study
  - b) INDA
  - c) GLP
  - d) NDA
- 3) Which property measures the residence of a liquid to flow.
  - a) Density
  - b) Viscosity
  - c) Volume
  - d) Solubility
- 4) Full form of CFR.
  - a) Code of Federal Regulation
  - b) Center of Federal Regulation
  - c) Code of Formulation Regulation
  - d) Code of Federal Responsibility
- 5) Disintegration time for sugar coated tablet is-
  - a) 15 min
  - b) 60 min
  - c) 30 min
  - d) 5 min
- 6) Which of the following is a test for evaluation of suppositories?
  - a) Melting point
  - b) Solidification test
  - c) Freezing point
  - d) Drying point
- 7) Solute is not dissolved when it is added to-
  - a) Solvent
  - b) Solution
  - c) Mixture
  - d) Reaction
- 8) Which compound is used with 1, 2-dibromethane for the formation of glycol?
  - a)  $\text{Na}_2\text{CO}_3$
  - b)  $\text{NaHCO}_3$
  - c)  $\text{NaOH}$
  - d)  $\text{CH}_3\text{COONa}$

- 9) The HLB system is used to classify.
  - a) Flavors
  - b) Colours
  - c) Surfactants
  - d) Perfumes
- 10) Thiomersal belongs to which category of preservative.
  - a) Acidic
  - b) Neutral
  - c) Mercurial
  - d) Quaternary ammonium compound
- 11) Which is not an example of closure?
  - a) Crimp-on
  - b) Shrink wrapper
  - c) Press-on
  - d) Roll-on
- 12) Which is not an example of thermosetting material?
  - a) Polyvinylchloride
  - b) Polypropylene
  - c) Polyester
  - d) Bakelite
- 13) Risk analysis is a part of-
  - a) Risk control
  - b) Risk assessment
  - c) Risk communication
  - d) Risk review
- 14) What will be the method of choice in case of a situation having 2-4 factors?
  - a) Mixture design
  - b) Crossover design
  - c) Fractional factorial design
  - d) Full factorial design
- 15) Simultaneous optimization approach is a model----- technique.
  - a) Dependent
  - b) Independent
  - c) Both
  - d) None
- 16) Which of the following is not a method of preparation of glycol?
  - a) Shell's omega method
  - b) From carbon monoxide
  - c) From dimethyl
  - d) From nitrogen
- 17) Which of the following are widely used & excellent preservatives?
  - a) Mercurial
  - b) Quaternary ammonium compounds
  - c) Both a & b
  - d) Acidic
- 18) In any experiment, the variable that is manipulated is called the----
  - a) Independent variable
  - b) Dependent variable
  - c) Confounding variable
  - d) Both a & b
- 19) MLRA stands for-
  - a) Multiple linear regression analysis
  - b) Mean linear regression analysis
  - c) Multiple lagrangian regression analysis
  - d) Polyester

- 20) Which method is also known as downhill method?
- a) Simple method
  - b) Basic simplex
  - c) Lagrangian method
  - d) Modified simplex

**2. Solve any two.**

**10x2  
=20**

- a) Discuss various optimization techniques in detail.
- b) Explain in detail stages of product development.
- c) Write a note on risk assessment methodology with its tools and excipients use for formulation of NDDS.

**3. Solve any seven.**

**5x7  
=35**

- a) Write a note on excipients used in capsules.
- b) Write a note on coat material used in Tablet coating.
- c) Write physiochemical parameters of for product development.
- d) Write a short note on suspending & emulsifying agent.
- e) Explain non-ionic surfactants and their application as emulsifier.
- f) Write a note on solvent & solubilizers.
- g) Discuss the role of various excipients used in Aerosol preparation.
- h) Write about Quality control testing of packaging materials.
- i) Discuss the role of various excipients used in parenteral preparation.

\*\*\*\*\*

