

B.Pharm. - IV (CBCS Pattern) Semester - VIII
BP813ET - Pharmaceutical Product Development

P. Pages : 3

Time : Three Hours



GUG/S/23/14157A

Max. Marks : 75

- Notes :
1. Discuss the reaction, mechanism wherever necessary.
 2. All questions are compulsory.

1. Multiple Choice Questions.

**20x1
=20**

- 1) The ability of a substance dissolved in a given solvent system is depends on
 - a) Nature & intensity of forces present in the solute
 - b) Nature & intensity of the forces present in the solvent
 - c) Interaction between solute & solvent
 - d) All of the above
- 2) Which of the following substance have poor water solubility.
 - a) Weak electrolytes
 - b) Non polar molecules
 - c) Both
 - d) None
- 3) The span materials tend to be less water soluble than the----- materials. The same material could be a detergent, & a wetting agent.
 - a) Carboxylate
 - b) Tween
 - c) Ampholytic elements
 - d) Surfactants
- 4) Which of the following sugar has bitter taste?
 - a) Glucose
 - b) Sucrose
 - c) Saccharine
 - d) All of above
- 5) Direct compression formulation can be developed without using.
 - a) Diluents
 - b) Disintegrants
 - c) Lubricants
 - d) Antiadherents
- 6) Which of the following direct compression ingredient is prepared by chemical modification.
 - a) Tabletose
 - b) Beta lactose
 - c) Dibasic di calcium phosphate
 - d) Sodium carboxyl methyl cellulose
- 7) Which of the following is commonly used for direct compression?
 - a) Methyl cellulose
 - b) HPMC
 - c) Hydroxyl propyl cellulose
 - d) All
- 8) Spray crystallized maltose dextrose is also known as-
 - a) Dextrate
 - b) Emdex
 - c) Lactitol
 - d) Nutab
- 9) Which is not an example of thermoplastic material?
 - a) Bakelite
 - b) Polyvinyl chloride
 - c) Polypropylenes
 - d) Polyester

- 10) Characteristic of monolithic device.
 - a) Drug has large therapeutic index
 - b) Aqueous solution
 - c) Control drug release by portioning the drug from oil
 - d) Administration of emulsion.
- 11) Stages of pharmaceutical product development do not include.
 - a) GLP
 - b) Preclinical studies
 - c) INDA
 - d) NDA
- 12) Clinical trial phase 1 is also known as-
 - a)
 - b)
 - c)
 - d)
- 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 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) Shells 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
 - 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) Explain in detail regulatory consideration in packaging of the pharmaceuticals.
 - b) Discuss the optimization parameters & different optimization techniques in formulation 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 use in capsule.
 - b) Write a note on coat material used in Tablet coating.
 - c) What are directly compressible vehicle? Give its application.
 - d) Explain function and features of packaging.
 - e) Write a short note on QbD.
 - f) What are directly compressible vehicles? Give its application.
 - g) Enumerate different type of disintegrants. Discuss in brief about super disintegrants.
 - h) Write a short note on QbD.
 - i) What are directly compressible vehicles? Give its application.
