

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

P. Pages : 3

Time : Three Hours



GUG/S/23/14157A

Max. Marks : 75

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- 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) Tablettose
 - 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.
- Drug has large therapeutic index
 - Aqueous solution
 - Control drug release by portioning the drug from oil
 - Administration of emulsion.
- 11) Stages of pharmaceutical product development do not include.
- GLP
 - Preclinical studies
 - INDA
 - NDA
- 12) Clinical trial phase 1 is also known as-
- -
 -
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- 13) Risk analysis is a part of.
- Risk control
 - Risk assessment
 - Risk Communication
 - Risk review
- 14) What will be the method of choice in case of situation having 2-4 factors?
- Mixture design
 - Crossover design
 - Fractional factorial design
 - Full factorial design
- 15) Simultaneous optimization approach is a model ----- technique.
- Dependent
 - Independent
 - Both
 - None
- 16) Which of the following is not a method of preparation of glycol?
- Shells omega method
 - From carbon monoxide
 - From dimethyl
 - From nitrogen
- 17) Which of the following are widely used & excellent preservatives?
- Mercurial
 - Quaternary ammonium compounds
 - Both a & b
 - Acidic
- 18) In any experiment, the variable that is manipulated is called the-----
- Independent variable
 - Dependent variable
 - Confounding variable
 - Both a & b
- 19) MLRA stands for:
- Multiple linear regression analysis
 - Mean linear regression analysis
 - Multiple lagrangian regression
 - Polyester
- 20) Which method is also known as downhill method?
- Simple method
 - Basic simplex
 - Lagrangian method
 - 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.
