

Roll No.

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Total No. of Pages : 02

Total No. of Questions : 13

B.Pharmacy (Sem.-8)

PHARMACEUTICAL PRODUCT DEVELOPMENT

Subject Code : BP-813 ET

M.Code : 79776

Date of Examination : 12-01-2023

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A** is **COMPULSORY** consisting of **TEN** questions carrying **TWO** marks each.
2. **SECTION-B** contains **THREE** questions carrying **TEN** marks each and student has to attempt any **TWO** questions.
3. **SECTION-C** contains **NINE** questions carrying **FIVE** marks each and student has to attempt any **SEVEN** questions.

SECTION-A

1. Write briefly :
 - a) Incremental products
 - b) Roller compact
 - c) Design space
 - d) Similarity and dissimilarity factor in dissolution studies
 - e) Quality Target Product Profile
 - f) Name **any four** packages approved by FDA as tamper resistant packaging systems
 - g) Why cyclodextrins take the shape of a truncated cone or torus rather than a perfect cylinder?
 - h) Level 3 changes
 - i) Spans
 - j) Multiple emulsions.

SECTION-B

2. Discuss in detail the Directly compressible vehicles used for production of tablets.
3. What is the significance of QBD in new product development and discuss any one technique in detail.
4. Discuss the dissolution testing from regulatory point of view.

SECTION-C

5. Explain the process of new product development using a flow chart or through schematic representation.
6. Discuss quality control test of parenterals.
7. Discuss the non-ionic surfactants and their applications in pharma industry.
8. Classify emulsifying agents and discuss any one class in detail.
9. What are tonicity adjusters in parenterals? Discuss their significance and methods to adjust the tonicity.
10. Which excipients are used for formulation of nanoparticles, explain?
11. Discuss in brief the ICH Stability Testing Requirements for New Dosage Forms.
12. Discuss the quality control of rubber closures.
13. What are Pharmaceutical applications of binders?

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.