Roll No. | | | | | | | | | | | | **Total No. of Pages : 02**

Total No. of Questions : 13

B.Pharmacy (Sem-8)

PHARMACEUTICAL PRODUCT DEVELOPMENT

Subject Code : BP813 ET

M.Code : 79776

Date of Examination : 19-12-2023

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 short notes on :

a) Cyclodextrins as solubilizing agents

b) Types of suspending agents

c) Hydrophilic polymers

d) Examples of directly compressible agents

e) Optimization techniques

f) Half factorial designs

g) Preformulation studies

h) Objectives of pharmaceutical product development

i) Extractables and leachables testing

j) Quality control tests of packaging material.

SECTION-B

2. Explain the concept of factorial design in the context of pharmaceutical research. How does it help in studying multiple variables simultaneously?

3. Discuss the primary factors that influence the selection of packaging materials for different types of pharmaceutical products, such as solid oral dosage forms, sterile injectables or biologics?

4. Highlight the role of nonionic surfactants in pharmaceutical formulations and discuss their advantages over other types of surfactants.

SECTION-C

5. Explain the key stages involved in pharmaceutical product development from concept to commercialization.

6. How does stability studies help ensure the safety and efficacy of pharmaceutical products over their shelf life?

7. How do regulatory guidelines, such as Good Manufacturing Practices (GMP), impact the quality control testing of pharmaceutical dosage forms?

8. What are the primary functions of solvents in pharmaceutical formulations and how do they influence drug solubility and stability?

9. Describe the main components of aerosol formulations, and how do these excipients help in the production of aerosolized medications for inhalation?

10. Describe the role of excipients in the formulation of NDDS.

11. Highlight the role of excipients in ensuring the sterility and stability of parenteral formulations.

12. How do formulation scientists address issues related to drug solubility, stability and bioavailability during the formulation development stage?

13. What are some common response variables or quality attributes in pharmaceutical product development that can be optimized using factorial designs?

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.