Paper ID : 250315

Roll No: | | | | | | | | | | | | | |

BPHARMA
(SEM VIII) THEORY EXAMINATION 2024-25
PHARMACEUTICAL PRODUCT DEVELOPMENT

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define preformulation.
b.	How will you differentiate between manufacturing and quality control testing.
c.	Name any two solubilizers commonly used in pharmaceuticals.
d.	State any two regulatory considerations for packaging materials.
e.	Illustrate the concept of Quality by Design (QbD).
f.	Why is stability testing important in product development?
g.	Differentiate between directly compressible vehicles and conventional diluents.
h.	Evaluate the role of excipients in NDDS in enhancing drug delivery.
i.	Mention two key characteristics of a good semi-solid excipient
j.	What are non-ionic surfactants? Give one example.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Write a detailed note on packaging materials used for sterile dosage forms with relevant examples.
b.	Design a suitable formulation strategy for a poorly water-soluble drug.
c.	Evaluate the role of cyclodextrins in enhancing solubility and stability of APIs with examples.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Classify excipients used in parenteral formulations and explain any one class.
b.	Explain the application of surfactants in formulation of emulsions and suspensions.
c.	Discuss the objectives of pharmaceutical product development.
d.	Analyze the significance of optimization techniques in formulation development.
e.	List and explain key steps in manufacturing solid dosage forms.
f.	Evaluate the need for quality control in packaging material selection.
g.	Discuss the importance of emulsifying agents in pharmaceutical suspensions.