Paper ID : 250315

Subject Code: BP813ET

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

BPHARMA
(SEM VIII) THEORY EXAMINATION 2021-22
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.

Printed Pages: 01 **Sub Code: BP813ET**

Paper Id: 231053 **Roll No.**

B PHARM
(SEM VIII) THEORY EXAMINATION 2022-23
PHARMACEUTICAL PRODUCT DEVELOPMENT

Time:3 Hours ***Total Marks: 75***

Note: Attemptall Sections.

SECTIONA

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

(a) What do youunderstand about the term 'IPQC'?

(b)Give the classification of non-ionic surfactant.

(c) What is dissociation constant?

(d)Give any two examples of excipients specially used in semi solid dosage form.

(e) Define directly compressible vehicle with example.

(f) Define QbD.

(g)Write about LAL test.

(h)What is film forming agent used in coating technology?

(i) Define propellants used in aerosols.

(j) Define optimization.

SECTION B

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

(a) What are Preformulation Studies? Why these are important in development of new pharmaceutical products? Discuss objectives and regulations related to preformulation.

(b) Discuss the selection, quality control and regulatory considerations of packaging materials used for pharmaceutical preparations.

(c) What are the roles of pharmaceutical excipients in the development of pharmaceutical product in contextof cyclodextrins? Write theapplications of cyclodextrin.

SECTION C

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

a.

b. Whatis pharmaceutical product development?Givethe objectives of pharmaceuticalproduct development in details.

c. Explain various elements of QbD.

d. Explain factorial design with example.

e. Explain Non - ionic surfactants and their applications as emulsifier.

f. What do you mean by NDDS? Discuss in detail about various excipients used in the formulation of NDDS.

g. What are Coat materials? Describe the various excipients used in the formulation of tablets and capsules

Write about the glass packaging material for pharmaceutical product development.

Subject Code: BP813ET

PAPER ID-410621

RollNo: | | | | | | | | | | | | | |

BPHARM
(SEM VIII) THEORY EXAMINATION 2023-24
PHARMACEUTICAL PRODUCT DEVELOPMENT

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

Note: 1. AttemptallSections.Ifrequire any missing data; then choosesuitably.

SECTION A

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

a.	Define "product development".
b.	Write the ideal properties of tablet excipients.
c.	Write the packaging materials for syrups.
d.	Define glidants.
e.	Define suspending agents.
f.	Write a note on paper as packing material.
g.	Enlist some new drug delivery systems.
h.	Write the properties of an ideal aerosol.
i.	Write some excipients used in creams.
j.	Define directly compressible vehicles.

SECTION B

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

a.	
b.	Discuss the theory and application of Non-ionic surfactants.
c.	Enlist and describe excipients used in parenteral products.
	Write the role of QbD andits applicationinpharmaceutical product development.

SECTION C

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

a.	
b.	Discuss the propertiesofplastics as a packaging material.
c.	Enlist the capsule excipients. How the excipients help in stability?
d.	Write a note on emulsifying agents.
e.	Discuss the importance of glycols and sorbitol.
f.	Discuss the tablet granulation process.
g.	Write the quality tests foe tablet dosage form.
	Enlist the materials of tablet coating.

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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.

Paper ID : 261052

Subject Code:BP813ET

Roll No:													

BPHARM

(SEM. VIII) THEORY EXAMINATION 2025-26

PHARMACEUTICAL PRODUCT DEVELOPMENT

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

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

SECTION A

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

a.	Outline the objectives of pharmaceutical product development.
b.	State the significance of stability assessment.
c.	State the applications of non-ionic surfactants in pharmaceutical formulations.
d.	State the functions of two semi-solid excipients.
e.	Mention the types of tablet coating materials with examples.
f.	Define the components of pharmaceutical aerosols.
g.	Name two major optimization software used for pharmaceutical product development.
h.	State the applications of factorial designs.
i.	Name the quality control tests prescribed for pharmaceutical packaging materials.
j.	State the regulatory considerations of packaging materials for pharmaceutical product development.

SECTION B

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

a.	Elaborate on the role of cyclodextrins in pharmaceutical product development.
b.	Write in brief the types and applications of various pharmaceutical excipients used in the development of NDDS formulations.
c.	Analyze the merits, demerits, and applications of various optimization techniques for pharmaceutical product development with specific examples.

SECTION C

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

a.	Propose the regulatory aspects related to pharmaceutical formulation development.
b.	Describe the role and applications of polyethylene glycols in pharmaceutical product development.
c.	Explain the roles of suspending and emulsifying agents in pharmaceutical formulations.
d.	Justify the uses of directly compressible pharmaceutical vehicles with examples.
e.	Discuss the method of selection and applications of pharmaceutical excipients with specific industrial applications.
f.	Describe in brief the method of optimization by factorial designs and their applications.
g.	Explain the method of selection of packaging materials for pharmaceutical product development.