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

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

Note: Attempt all Sections.

SECTION A

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

(a) What do you understand 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 context of cyclodextrins? Write the applications of cyclodextrin.

SECTION C

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

a. What is pharmaceutical product development? Give the objectives of pharmaceutical product development in details.

b. Explain various elements of QbD.

c. Explain factorial design with example.

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

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

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

g. Write about the glass packaging material for pharmaceutical product development.

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