

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.