Seat No.: _____ Enrolment No. _____

PARUL UNIVERSITY

FACULY OF PHARMACY

M. Pharm. Winter 2022 - 23 Examination

Semester: 1 **Date: 15/03/2023**
Subject Code: MIP102T **Time: 10:00am to 1:00pm**
Subject Name: Pharmaceutical formulation development **Total Marks: 75**

Instructions:
1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) **(30)**

1. a) Define: Preformulation and Incompability. Write a detail note on drug-excipient compatibility studies.

   b) Explain role of formulation additives in formulation development and processing.

2. a) Enlist the factor affecting solubility. Discuss the role of pH in solubilization procedure

   b) i) Explain the following terminology: Dissolution, Sink condition, Bio-relevant media, and Controlled release.

   ii) What is IVIVC? Describe its importance and various phases of correlations.

3. Discuss the various aspects of pharmaceutical product stability.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) **(25)**

1. Write the importance of the following in Preformulation study i) Crystal morphology, and ii) Flow property
2. Explain the factorial design with suitable example relevant to pharmaceutical product developments.
3. Explain the following terminology: Solubility, Co-solvency, Micelle, Prodrug, Complexation
4. Discuss the factor affecting dissolution.
5. Comments on the states of matter effects on the stability of pharmaceutical formulations.
6. Enlist and discuss anyone dissolution theory.

Q.3 Short Answers. (2 Marks Each) **(20)**

1. Enlist Preformulation studies.
2. Explain any two methods of incompatibility study.
3. What are the formulation additives?
4. What is flow properties? What are the different additives used to enhance flow properties?
5. What is CMC? Discuss its role in formulation preparation.
6. Discuss the drawback of hydrophilic nature of drug in pharmaceutical formulation.
7. Enlist the dissolution test apparatus.
8. Discuss the different methods of drug release.
9. Describe the environmental factor affecting on the stability.
10. Discuss ICH guidelines relevant to solid state stability studies of API.