

**Department of Pharmaceutical Technology**  
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**M.Pharm (Industrial Pharmacy)/ 1<sup>st</sup> year/ 1<sup>st</sup> Sem/Time 3 hrs/ FM 75/ 2023-24**

**Course: Pharmaceutical Formulation Development      Code: MIP102T**

**Q1. Answer the following questions (Question 1 is Compulsory) 10x2M=20 Marks**

- a. What is phase solubility study? Why the study is important during preformulation studies?
- b. What do you mean by intrinsic solubility, kinetic solubility and equilibrium solubility?
- c. Write any three points on the importance of stability studies.
- d. Name the types of stability studies on drug substances.
- e. Why sink condition is maintained in dissolution study?
- f. Name any two theories for dissolution study.
- g. Define formulation additives.
- h. Explain "Maillard Reaction".
- i. Give the use of lactose, PVP, talc and Mg-stearate in tablet formulation.
- j. Yellow soft paraffin/ white soft paraffin----- which one is used to prepare eye ointment and why?

**Long Answer Questions      2 x 10Marks = 20Marks**

**(Answer 2 out of 3)**

Q2. Give a brief note on SALT form of drugs and its role in the improvement of solubility, give examples.

Q3. What are the different types of IVIVC? What are the different various parameters used in IVIVC depending on the level. How Level A IVIVC is done according to FDA?      2+5+3

Q4. Discuss in details the formulation additives needed to design solid dosage form.

[Turn Over

**Short Answer Questions**

**7 x 5Marks = 35Marks**

**(Answer 7 out of 9)**

- Q5. Write on the method of measurement of Intrinsic Dissolution Rate?      Marks 5
- Q6. (a) Why bulk density and true density are determined in Preformulation study? (b) What is the difference between plastic and elastic materials? (c) Why is it important to select excipients based on its plastic and elastic behaviour to improve compressibility? Marks 5
- Q7. According to USP monograph, write details on USP III dissolution apparatus.
- Q8. Define IVIVC. Write the utility of IVIVC.      2+3
- Q9. What is the acceptance criterion for formulation based on dissolution studies?
- Q10. Give some examples of instability in pharmaceutical products. Name three factors affecting stability of drug products.
- Q11. Give the functional roles of additives in dosage forms.
- Q12. Classify formulation additives with examples.
- Q13. Write a note on additives interactions in pharmaceutical products with suitable examples.