Birla Institute of Technology and Science, Pilani (Rajasthan)

First semester 2022-23

PHA G 542: Advanced Physical Pharmaceutics

Max. Marks: 25 **Mid Term Examination** **Closed Book**

Date: 31-10-2022 **Duration: 90 min**

Q1. Solubility of compound 'X' was determined with Nogami method with 30 min sampling intervals. All the concentrations at various intervals were measured in µg per ml. The slope and intercept were found to be 0.50 and 30.0 respectively when $\mathbf{C_t}$ (X axis) *vs* $\mathbf{C_{t+\gamma}}$ (Y axis) was plotted for 10 samples. Calculate the solubility of drug 'X' in gm/ml. [3M]

Q2. Distribution coefficient value of a weakly basic drug X was experimentally determined to be 7.5 when drug dissolved at pH 6.8 phosphate buffer. Calculate Log P of the drug at same pH (assuming that dissociation constant of drug is 3.16×10^{-8}). [3M]

Q3. What are the use of the information obtained from forced degradation studies of drug substance during stability studies? [2M]

Q4. (a) Draw the expected profile for Log D against pH for a unionized drug molecule. (b) Draw a solubility profile for weakly acidic drug (pKa= 4) vs Ph. Justify your answer. [3M]

Q5. Drug X is formulated as immediate release tablet dosage form with dose of 50 mg. Average weight of tablets were found to 300 mg. How will you evaluate uniformity of weight as per IP? Is it necessary to perform content uniformity? Why? Write the acceptance limits for content uniformity tests as per IP. [4M]

Q6. As a formulation scientist, suggest (with justification) a most suitable dosage form for a practically insoluble in water drug X, 50 mg dose three times in a day for women. Drug is liquid in state and having specific gravity 1.5 g/ml. Drug is not stable in water more than 30 days. Write appropriate composition of suggested dosage form. [3M]

Q7. (a) A formulator compressed the tablets of stable and metastable polymorphic form of drug X (85% w/w). He found the tablets of the metastable form were stronger at low pressures than those of stable form. Discuss the possible reasons for this. [2M]

(b) In comparison to crystalline polymorphs, the amorphous form of a drug is generally expected to be less chemically stable. Why? [2M]

Q8. Packaging of drug product is decided based on data obtained from preformulation studies. How? [3M]