Birla Institute of Technology and Science, Pilani (Rajasthan)

First semester 2023-24

PHA G 542: Advanced Physical Pharmaceutics

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

Date: 13-10-2023 **Duration: 90 min**

Q1. Why polymorphic studies need to be carried out during Preformulation? How does polymorph affect the drug bioavailability? Justify your answer with suitable examples. [5 M]

Q2. How co-crystals are differ from salt and solvates. In what situation, co-crystals formation for a drug is a good choice compared to salt and solvates? What are the disadvantage associated with amorphous and solvates when they are used in product development? [5 M]

Q3. Discuss the rational for conducting drug-excipient compatibility and forced degradation study prior to a controlled release tablet product development of a drug. Enlist the characterization or tests which are required to investigate the compatibility of samples for a suspension product. [5 M]

Q4. If a product is formulated without investigating the impact of drug particle size and surface area during preformulation then what are the possible issue may come during product development. Justify your answer with suitable examples. [3M]

Q5. The powder mix having bulk density 0.50 g/ml and tapped density 0.65 g/ml for capsule filling. Each 2 g of powder mix contains 500 mg of active drug. You need to fill the powder into suitable capsule with 50 mg of active dose. Suggest the suitable capsule size with justification. The capsules size and respective volume are: size 1: 0.5 ml; size 2: 0.37 ml; size 3: 0.30 ml; size 4: 0.21 ml, size 5: 0.13 ml). Write the max and min fill weight for the selected capsule. [2M]

Q6. P_{app} or 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 and Log D of the drug at same pH (assuming that dissociation constant of drug is 3.16×10^{-8}). [2M]

Q7. Partition coefficient of a drug in ethyl ether-water combination was found to be 3. A 500 mL aliquot of an aqueous solution containing 800 mg of drug X is extracted with 100 mL of ethyl ether. Calculate percentage extracted of drug X in single stage and double stage (equal portion) extraction with ethyl ether. Comments on your obtained values. [3M]