Birla Institute of Technology and Science, Pilani
PHA F 314 Pharmaceutical Formulation and Biopharmaceutics
First semester 2016-17 Endsem Examination

Time: 2hr **Date: 03/12/2016**

Part-A (50 Marks) Closed Book

Q1. Both hard and soft gelatin capsules are made from collagen. What makes soft gelatin capsules "soft"? For what type of drugs you would like to use a hard gelatin capsule over tablet (list the physicochemical and bio-pharmaceutical properties)? How enteric coating is done in capsules?

1+3+1

Q2. What are the drug related factors that affect drug absorption in general? If a drug show high absorption, irreversible plasma protein binding and slow metabolism, how would be the pharmacokinetic and biodistribution pattern of the drug?

3+2

Q3. What are the factors that control drug absorption after intra-muscular injection? Can mineral oil be used as a solvent in parenteral products? Why? Why parenteral formulations should not contain strong surfactants?

2+1+2

Q4. Why increasing viscosity is necessary for ophthalmic dosage forms? What viscosity enhancers are used in ophthalmic dosage forms? What are the disadvantages of ophthalmic dosage forms?

2+1+2

Q5. Drug X is only absorbed from the duodenum and has a good absorption rate. If you want to design a sustained release formulation of drug X, what would be the best approach? Justify. Can this be used if the drug X has a high first pass metabolism? Why?

2.5+2.5

Q6. A drug Y, which has very high first pass metabolism, needs to be given orally as a sustained release dosage form. Which strategy can be used for this? Why sustained release formulation designed by granule coating has different coating thickness? Give an example of a enzyme controlled sustained release dosage form.

2+2+1

Q7. Microcapsule produced by emulsion-solvent evaporation method would be mono-cored, poly-cored or matrix type? Can coacervation phase separation method be used with a core material which is soluble in the solvent? Discuss how air suspension technique can be used to make microcapsules for a sustained release formulation.

1+1+3

Q8. Write advantages and disadvantages of targeted drug delivery. Define active and passive targeting.

2.5+2.5

Q9. Write two mechanisms through which nano-carrier mediated drug delivery can evade multi-drug resistant cancer. If a non-biodegradable polymer is used for making a nanoparticle, what would be the problem?

4+1

Q10. What is EPR effect? Although non-viral carrier mediated gene delivery is less efficacious, why it is the preferred method? Can ultrasound be used for brain delivery? Why?

2+1+2

Birla Institute of Technology and Science, Pilani (Rajasthan)

First semester 2016-17

PHA F 314 Pharmaceutical Formulation and Biopharmaceutics

Comprehensive Examination

Time: 1 hr **Date: 03/12/2016**

Part B (20 marks): Open book

Q.1 Drug A and drug B, weak basic compounds have same Log P (3.2). pKa of drug A and B is 4.6 and 6.2 respectively. Calculate the Log D for drug A and B at pH 4.2. [4]

Q.2 You have formulated batch of immediate release tablets of drug X (dose 10 mg) and drug Y (dose 50 mg). During quality control testing you found that batch of drug X is failed in content uniformity test and batch of drug Y is failed to meet the disintegration test acceptance limit. Both the batches also failed to meet the dissolution acceptance limit and all other quality control (QC) test were complies as per IP. Suggest the possible reasons for failure in above QC tests for batch of drug X and Y individually. Write the acceptance limit and procedure for QC test for friability and disintegration test. [6]

Q.3 Write the specific answer for the following: [6]

a. With suitable example of ***marketed product*** discuss how the preformulation data of drug decide the dosage form.

b. With suitable example discuss how the preformulation investigation decide the ***process for formulation development***

c. With suitable example discuss how the preformulation investigation decide the ***mode of administration of drug***

d. With suitable example discuss how the preformulation investigation decide the ***packaging for pharmaceutical product.***

Example of drug for a,b,c and d should be different in each case.

Q.5 (a) Sometime physician instruct for the specific drugs **'to be taken *after* meal'** and **'to be taken *before* meal'.** Why? [2]

(b) Following is the plasma drug profile of an immediate release oral tablet of a drug. Draw the expected plasma drug profile if particle size of the drug is micronized (microfined) before formulation. Justify the reason of your drawn profile. Drug is known to be absorbed completely by oral route. [2]