Birla Institute of Technology and Science, Pilani (Rajasthan)

First semester 2022-23

PHA G 542: Advanced Physical Pharmaceutics

Comprehensive Examination

Max. Marks: 35 **Closed Book**

Date: 19-12-2022 **Duration: 3h**

Instruction: Write clear and legible answers. Avoid overwriting. Write the answers in the given sequence only.

Q.1 Write various steps involved to establish level A correlation (IVIVC). In what situations IVIVC can be used for biowaiver in regulatory submission. [5M]

Q2. (a) Define the term 'High soluble' and 'High permeable' as per the Biopharmaceutical classification systems. Give examples of any two drugs of BCS class I and II. [2M]

(b) What is 'significant change' as per ICH guideline? Suggest different storage conditions for stability testing of a liquid oral dosage form (general case) as per ICH guideline? [3M]

Q3. (a) Stability studies of above formulation was conducted and following data was obtained. Calculate the shelf life of product in this condition where the potency should not be less than 90%. [2M]

Time (months)	0	1	2	3	6	12	18	24	36
% Assay	100	94.4	89.0	84.0	70.6	49.9	35.2	24.4	12.4

(b) For preparation of o/w emulsion, 40% oil phase (density=0.92g/cm^3) dispersed in water. Oil phase contain 50% castor oil, 30% mineral oil and 20% cottonseed oil which RHLB values are 14, 10 and 7 respectively. Calculate the require quantity of surfactant mixture (density=1.2 g/cm^3) and require quantity of each surfactant for this emulsion. Surfactant mixture contain X (HLB=15) and Y (HLB=5) surfactants. [3M]

Q4. (a) What are the in-vitro dissolution documents and in-vivo bioequivalence documentation required when a company make following changes in approved immediate release tablet product of drug X: Case (i): change the RMG equipment capacity from 50 to 100 lit; Case (ii): change the binder concentration from 6 to 8%w/w. [3]

(b) Why drug-excipient compatibility study is important prior to formulation development. [2 M]

Q6. (a) Percentage cumulative drug release of sustained release tablets of drug from its Test and Reference formulations (dose 500 mg) are given below. Is test formulation similar to reference? Justify your answer with Similarity and Difference factor of drug release profiles. Also calculate Mean Dissolution Time (MDT) for both formulations.

Time (hrs)	Test formulation	Reference formulation
0.5	27.50	22.00
1	38.15	45.20
2	48.25	53.75
4	59.14	62.25
6	63.88	67.00
8	75.92	78.50
10	85.85	90.10
12	99.42	99.50

(b) Followings are the characteristics of two drugs:

Sr. N.	Parameters	Drug X	Drug Y
I	Mean dissolution time	120 min	6 hrs
Ii	Mean absorption time	90 min	360 min
iii	Max. dose (mg)	50	500
Iv	Solubility (g/L)	0.30	10

Suggest the BCS class of above drugs with complete justification. (Assume Mean Residence time in GI is 180 min). (6+4 M)

Q7. (a) Write selection criteria for dissolution methodology for a product development. Give explanation on your selection. [2M]

(b) Write the purpose of following ICH Q guidelines: [3M]

Q1 E; Q3C; Q9; Q2; Q1B; Q12