BIRLA INSTITUTE OF TECNOLOGY AND SCIENCE – PILANI

First Semester 2023– 2024

Course No.: **PHA G547** Closed Book

Course Title: **Quality by Design in Pharmaceutical Product Development**

Max. Marks: **25** Duration: **90 mins.** Date: **10/10/2023**

Instruction: Write clear and legible answers. Avoid overwriting. Write your answer in sequence of questions.

Q1. A formulator is asked to design and develop a Sustained release pellets to be coated with rate controlling polymers and required to be filled in capsules for a drug X (a new antiviral drug, BCS class I) to be administered through oral route for the treatment of viral infections using the principles of Pharmaceutical Quality by Design (QbD). The formulator has decided to prepare the pellets with extrusion-spheronization process and further drying and coating in fluidized bed processor.

As a part of designing the product by Pharmaceutical QbD, perform 'Risk Assessment' for the controlled release matrix pellets as per the details given below.

a) Using an appropriate 'Risk Identification' tool, identify the various process parameters that can affect the in-process CQAs' i.e. 'content uniformity' and 'in-vitro dissolution' of sustained release matrix pellets. [3M]

b) With an appropriate 'Risk Analysis and Risk Evaluation' tool, determine the Critical Process Parameters that can affect the 'CQAs' of the sustained release matrix pellets. The selected tool should generate quantitative values for comparing the effect of process parameters on the CQAs. [6M]

c) Write the specifications or quality control tests (with acceptance criteria if applicable) for sustained release pellets filled capsule dosage form as per IP. [3M]

Note: In the 'Risk Analysis and Risk Evaluation' tool, while assigning any quantitative value, you should consider the technology available as on date. Justify the value assigned where ever possible.

Q2. A drug was formulated as oral suspension product with strength of 50 mg/5mL. After 3 months of stability testing at long term conditions as per ICH, it was found that product showed poor content uniformity. Discuss the possible reasons related to material attributes which resulted in this risk. [3M]

Q3. Define and write significances of the followings in design of experiments: [10 M]

(a) Confounding

(b) Orthogonality

(c) Resolution IV

(d) Main Effects Designs

(e) Coding and transformation of the original measurement scale