Time: 3 Hours **Total Marks : 80**

N.B.: 1) All questions are compulsory.
2) Figures to the right indicate full marks.

Q.1 Answer the following.

a) What are the goals of tablet preformulation studies?	2
b) Write the steps in sugar coating process with a formula for each step.	2
c) Justify the addition of disintegrant in pre granulation and post granulation step.	2
d) Classify film coating polymers with suitable examples.	2
e) Differentiate between chewable and effervescent tablet.	2
f) Write various applications of soft gelatin capsules.	2
g) Give a flow chart for manufacturing of hard gelatin capsule shell.	2
h) Calculate shelf life of a product at 25°C given the following parameters: Ea= 12Kcal/mol R= 2 degradation rate at 60°C= 0.0156/min	2
i) Write the responsibilities of QA department.	2
j) Explain the importance of documentation.	2

Q.2 a) Elaborate on the formulation of chewable tablet.	4
b) Describe any one perforated coating pan.	4
c) Discuss the principle and methodology for accelerated stability testing in shelf life determination.	4

Q.3 a) Draw the layout for large scale manufacturing of tablets.	4
b) Discuss batch manufacturing record for any one solid oral formulation.	4
c) Explain the physics of tablet compression.	4

Q.4 a) State the causes of sticking and weight variation in tablet and suggest remedies for the same	4
b) Describe steps and mechanism involved in hard gelatin capsule filling machine based on independent dosing system.	4
OR	
b) Discuss the QC tests for hard gelatin capsules.	4
c) Elaborate on sampling and sampling plan.	4

Q.5 a) List out film coating defects of the coated tablets and suggest methods to rectify these defects.	4
b) Describe the Rotary Die process for large scale manufacture of soft gelatin capsules.	4
c) Explain hydrolytic degradation in pharmaceuticals and the methods for minimising/ preventing such degradation.	4

Q.6 a) Elaborate on packing of capsules.	4
OR	
a) Discuss DT and Dissolution testing of tablets.	4
b) Describe the process of fluidized bed coating.	4
c) Write a note on environmental and microbiological controls practised in a pharmaceutical manufacturing facility.	4
