[Time : 3 hours] **(Total Marks: 75)**

NB: (1) All Questions are Compulsory.

(2) Figures to the right indicate full marks.

(3) Draw neat and labelled diagram wherever necessary.

Q:1

(a) A drug solution has potency of 500 units /ml. When stored for 30 days its potency was found to be 200units/ml. Find the half-life of the drug if it undergoes zero order degradation. (2)

(b) Define Independent variables as per factorial design for optimization. Enlist any two independent variables for transdermal drug delivery system. (2)

(c) Enlist two factors affecting sink condition for dissolution testing of BCS-class-II drug containing matrix tablet. (2)

(d) Enlist two methods for characterization of Amorphous drugs (2)

(e) Define Glass transition temperature (Tg) of a polymer. Enlist any one important application of Tg of a polymer used for formulations development. (2)

(f) Give two significant characteristics of Level –A IVIVC (2)

(g) Name any two co-processed excipients with improvement of flow property. (2)

(h) Enlist two applications of USP flow through dissolution apparatus. (2)

(i) Name any two techniques used to study drug excipient compatibility. (2)

(j) Enlist parameters to define compressibility of powder. (2)

Q: 2.

(a) Discuss in brief, with example, importance of Pre-formulations studies of poorly soluble drug. (3)

(b) Explain importance and limitation of ICH stability study guidlines. (4)

(c) Explain V-graph for PH stability profile using a suitable example. (4)

Q: 3.

(a) Write a note on *in-vitro-in vivo* correlation. (3)

(b) Write a note on pre-formulations studies of poorly flowable drugs. (4)

OR

(b) Elaborate on role of complexing agents in BCS-class-II drugs formulations (4)

(c) Discuss the role of Biowaivers with reference to product development. (4)

Q: 4.

(a) Discuss Preformulationmethodology for parenteral suspension. (3)

(b) Give a first order polynomial equation and layout of three factors at two levels for optimizing a colon targeted tablet. (4)

OR

(b) Elaborate on significance of QbD during generic product development. (4)

(c) Write a note on temperature and PH responsive gelling agents. (4)

Q; 5.

(a) Discuss bulk characterization in preformulation. (3)

OR

(a) Write a note on enzyme degradable polymers used in colon targeted drug delivery system. (3)

(b) Discuss toxicity studies as of excipients with reference to oral route of administration. (4)

(c) Write a note on Simplex design of experiments for optimisation. (4)

Q: 6.

(a) Discuss in brief preformulation studies for protein and peptide drugs for nasal drug delivery. (3)

(b) Explain role of moisture in compressibility of granules. (4)

(c) Write a note on Hackle's plot. Explain its significance in product development. (4)

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