Q. P. Code : 27867

[Time : 3 hours] **(Total Marks: 80)**

NB: (1) All Questions are Compulsory.

(2) Figures to the right indicate full marks.

(3) Draw neat and labelled diagram wherever necessary.

1(a) Explain with an example depedent and independent variable in a factorial design. (2)

(b) Give an equation for Half life and Shelf life as per first order kinetics for a drug degrading with rate constant' K 'and initial concentration 'a'. (2)

(c) State Heckle's equation. (2)

(d) Name two techniques for determining melting point of a drug. (1)

(e) List four factors which will influence flow rate of a drug. (2)

(f) How many experiments will be required for a factorial design of three factors at two levels? (1)

(g) Write an equation stating relationship between aqueous solubility and melting point of a drug. (2)

(h) Give level B correlation in IVIVC. (2)

(i) What are superdisintegrants? Give suitable examples. (2)

(J) How does Cyclodextrin improve aqueous solubility of a drug? (2)

(k) Define 'significant change' for a drug product as per ICH. (2)

2 (a) Describe influence of packaging components on stability of drug products. (4)

(b) Discuss BCS classification of drugs. (4)

(c) Discuss accelerated and long term stability guidelines for dosage form as per ICH. (4)

3 (a) Outline validation protocol for USP Type II dissolution testing apparatus. (4)

OR

(a) Describe solubility analysis in preformulation of oral liquid containing poorly soluble drug. (4)

(b) Classify USP dissolution testing apparatus and discuss any one apparatus. (4)

(c) Discuss dissolution testing of topical products. (4)

4 (a) Give a layout of full factorial design of 3 factors at two levels for an oral suspension. (4)

(b) Write a note on preformulation consideration for a parenteral solution. (4)

(c) Discuss specialized lipids as drug carrier. (4)

OR

(c) Write a note on biocompatibility evaluation of polymers. (4)

5 (a) Write a note on Drug –excipient compatibility study. (4)

OR

(a) Discuss use of thermal analysis in preformulation studies. (4)

(b) Discuss central composite factorial design (4)

(c) Discuss colours and flavourants used in pharmaceutical products. (4)

6 (a) Write a note on derived properties of powder. (4)

(b) Describe Heckle's plot. (4)

(c) Give an account of deformation and bonding that occurs in the compaction of tablets. (4)

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