S/E

08-06-13 (Reg)

Total No. of printed pages = 4

48(M.Ph) 2·1

2013

DOSAGE FORM DESIGN AND PRODUCT DEVELOPMENT

Paper : 2·1

Full Marks - 80

Time - Three hours

The figures in the margin indicate full marks for the questions.

Answer any *six* questions taking *three* from each Section.

Question Nos. 1 and 5 are compulsory.

SECTION – A

Answer question No.1 and any *two* from the rest.

1. (a) Explain with schematic diagram, the various stages of tablet formation when external load is applied for consolidation of powder mass. 5

   (b) Deduce an equation for transmission of forces through powdered mass during compression cycle in tablet punch machine. 5

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(c) Explain the principle and formulation parameters in designing of mouth dissolving tablets. 4

2. (a) Describe the selection criteria of organoleptic additives for suspension dosage forms. How the suspension dosage forms are evaluated ? 7

(b) Describe a method for study of *in vitro* drug release from the semisolid dosage form. 6

3. (a) Write in brief about the recent advances made in development of Aerosol propellants. Give their advantages and limitations. 6

(b) Give the designing of a metered dose aerosol inhaler with a neat diagram. State the quality control tests for finished aerosol products. 7

4. (a) What are the recent developments in I.V. delivery systems ? Describe the physics o fluid flow in an I.V. control system. 8

(b) Explain a method used in microbiological air testing. 5

SECTION – B

Answer question No.5 and any *two* from the rest.

5. (a) Give the correlation of rheological parameters of dermatological vehicles with drug bioavailability. 5

(b) How the stability and integrity of soft gelatin capsule is assured during production process. 4

(c) State the parameters that should be considered in the pilot scale-up during development of a reliable method of manufacture. 5

6. (a) Explain the scale-up operations adopted for production of tablet dosage form. 7

(b) What is the need of new product development? Explain various obstacles in new product development. 6

7. (a) Do you think that *in vitro / in vivo* correlation is essential at every stage of product development ? If so, give reasons. Give the regulatory requirements in the *in vivo* evaluation of a pharmaceutical products. 9

(b) How the statistical methods are utilized in designing and optimization stages of product development ? 4

8. (a) What type of mixers would you recommend for blending cohesive and non-cohesive powder ? What are the ideal characteristics of powders prepared for inhalation dosage forms ? 7

(b) What are pharmaceutical drug interactions? Explain the consequences of drug interactions in bioavailability and therapeutics. 6