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B.Pharm. Semester—VI (C.B.S.) Examination

PHARMACEUTICAL VALIDATION

Paper—6

Time : Three Hours] [Maximum Marks : 80

N.B. :— (1) Question No. **1** is compulsory.

(2) Solve any ***four*** questions from remaining.

(3) Draw neat labeled diagram wherever necessary.

(4) Assume suitable data wherever necessary.

(5) Discuss the reaction, mechanism wherever necessary.

(6) Use of electronic calculator is permitted.

1. Solve any ***five*** of the following :

   (a) Give the composition of validation committee.

   (b) Write in short about repeatability parameter in analytical method validation.

   (c) Give the different conditions which require revalidation study in pharmaceutical processes.

   (d) Write the significance of raw material validation in solid dosage forms.

   (e) Give the different key physicochemical properties of the drug substance that need to be considered in developing tablet formulation.

   (f) What is retrospective validation ? Discuss in short about criteria for product to be considered for retrospective validation.

   (g) Write the rationale of prospective process validation. 5×4=20

2. Describe in brief about the following :

   (a) Validation protocol and report.

   (b) Preapproval inspection in pharmaceutical industry.

   (c) Product design and development stage of pharmaceutical process validation. 15

3. Discuss in detail process development program in prospective process validation. 15

4. Describe selection and evaluation of processing data of solution dosage form with reference to retrospective validation. 15

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Discuss in detail the following unit operations with reference to process evaluation and selection in process validation of tablet dosage forms :

(a) Mixing

(b) Drying

(c) Milling. 15

6. (a) Enlist the different parameters for analytical method validation. Discuss in detail about linearity parameter for analytical method validation. 7

(b) Discuss in detail selection and evaluation of processing data of soft gelatin capsules in reference to retrospective validation. 8

7. Write short notes (Any ***three***) :

(a) Finished product tests for validation of solid dosage forms.

(b) Selection and evaluation of packaging data in reference to retrospective validation.

(c) Factors to consider during encapsulation step in process validation of capsule dosage form.

(d) Limit of detection and robustness in analytical method validation. 3×5=15

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