NRT/KS/19/3178

B.Pharm. Sixth Semester (C.B.S.) Examination

PHARMACEUTICAL VALIDATION

Paper—6

Time : Three Hours] [Maximum Marks : 80

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

(2) Attempt any **FOUR** questions out of remaining.

(3) All questions carry marks as indicated.

(4) Draw neat labelled diagrams wherever necessary.

1. Solve any **FIVE** of the following :
   (a) How the preapproval inspection is done in Pharmaceutical Industry ?
   (b) Write about master documentation.
   (c) Define Accuracy, Linearity, Specificity and Recovery.
   (d) What are the product selection criteria for retrospective validation ?
   (e) What are the different guidelines for process validation of solid dosage form ?
   (f) Write about selection and evaluation of packaging data in reference to retrospective validation.
   (g) What are the different process validation options ? 5×4=20
2. (a) Describe in detail product design and development stage of pharmaceutical process validation. 8
   (b) Write in detail about validation protocol and preparation of report. 7
3. (a) What are the different parameters for analytical method validation ? 8
   (b) Discuss in detail about precision and reproducibility. 7
4. Describe selection and evaluation of processing data of compressed tablet dosage form with reference to retrospective validation. 15
5. (a) Discuss in detail about selection and evaluation of hard gelatin capsule. 8
   (b) Write different inprocess tests and finished product tests for solid dosage forms. 7
6. (a) Write in detail about pilot scale up and technical transfer. 8
   (b) Write in detail on selection and evaluation of processing data of solution dosage form. 7
7. Write notes on any **THREE** :
   (a) Validation committee
   (b) Limit of detection and robustness in analytical method validation
   (c) Selection and evaluation of packaging data in retrospective validation
   (d) Product development of pharmaceutical process validation. 3×5=15