NKT/KS/17/6575

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) Solve any **four** questions from the remaining.

(3) Draw neat labeled diagram wherever necessary.

1. Solve any **five** of the following :
   (a) What are various process validation options ? 4
   (b) Explain product development in prospective process validation. 4
   (c) Explain the various parameters to be considered during development and validation of dry granulation technique. 4
   (d) How do you select the product for retrospective validation ? 4
   (e) What are the different parameters for analytical method validation ? 4
   (f) What are the different guidelines for process validation of solid dosage form ? 4
   (g) Write in short about validation committee. 4
2. (a) Discuss in detail about pre approval inspection and pilot plant scale up. 8
   (b) Write in detail about validation protocol and report. 7
3. (a) Explain in detail about product development of prospective process validation. 10
   (b) Write about organisation of prospective process validation. 5
4. (a) Explain in detail about accuracy and recovery in analytical method validation. 8
   (b) What do you mean by precision, linearity and robustness in analytical method validation ? 7
5. (a) Discuss in detail selection and evaluation of processing data of compressed tablets with relation to retrospective validation. 10
   (b) Write about computer aided analysis of data. 5
6. What are the different in-process tests and finished product test of solid dosage form ? 15
7. Write notes on any (**two**) : 15
   (a) Selection and evaluation of processing data of solutions.
   (b) Master documentation.
   (c) Process validation of hard gelatin capsules.