

B.Pharm Semester–VI (C.B.S) Examination**PHARMACEUTICAL VALIDATION****Paper—6 (6T6)**

Time : Three Hours]

[Full 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) Define process validation. Comment on its various options.
- (b) Draw flow diagram showing different steps involved in selection of candidates for retrospective validation.
- (c) Discuss the various parameters to be considered during development and validation of wet granulation technique.
- (d) Explain cause and effect diagram.
- (e) Discuss the various factors to consider during encapsulation step in process validation of hard gelatin capsules.
- (f) Give the different critical process steps and quality control test in process validation of compressed tablets.
- (g) Draw typical process flow diagram for granulated product. 5×4=20

2. Briefly describe the various stages of validation. 15

3. Explain in detail about the following parameters for analytical method validation :

- (a) Selectivity and specificity. 5
- (b) Precision and reproducibility. 5
- (c) Accuracy and recovery. 5

4. (a) Briefly comment on validation of raw materials for solid dosage forms. 8
- (b) Write in brief about various in-process tests required for solid dosage forms in process validation. 7
5. Explain selection and evaluation of processing data of coated tablets with reference to retrospective validation. 15
6. Write briefly about :
- (a) Experimental design and analysis. 7
- (b) Full-scale product/process development in prospective process validation. 8
7. Write short notes on (any **three**) :
- (a) Pilot plant scale-up and technology transfer.
- (b) Physicochemical properties of the drug in developing tablet formulation.
- (c) Selection and evaluation of processing data of semisolid dosage forms in retrospective validation.
- (d) Linearity and calibration curve. 3×5=15