

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. $3 \times 5 = 15$