

**Sixth Semester Examination for the Degree
of Bachelor of Pharmacy**

PHARMACEUTICAL VALIDATION

6 T 6

Time : Three Hours]

[Max. Marks : 80

- N. B. : (1) Question No. 1 is compulsory.
(2) Attempt any **four** questions from the remaining.
(3) Draw neat labelled diagram wherever necessary.

1. Answer any **five** questions from following

- (a) Write brief account on – process validation options. 4
- (b) Explain in brief — The validation committee. 4
- (c) Enlist components of validation Master plan. 4
- (d) Write brief account on validation protocol. 4
- (e) Write short note on preapproved inspection. 4
- (f) Explain in brief – Technical transfer. 4
- (g) Write short note on Pilot Plant Scale up. 4

Answer any **four** questions from following.

2. Discuss in detail :—

- (a) Different stages of validation.
- (b) Change control validation process. 15

3. Discuss prospective process validation. 15

- 4. Explain parameters for analytical method validation. 15
- 5. Write detailed account of product selection criteria for retrospective validation. 15
- 6. Explain validation of raw materials for solid dosage form. 15
- 7. Write brief account on :—
 - (a) Selection and evaluation of processing data soft gelatin capsules.
 - (b) Finished product tests for solid dosage form. 15