

TKN/KS/16–7004

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. 15
(b) Change control validation process. 15
3. Discuss prospective process validation. 15

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Contd.

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

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