

1071

M.Sc. (Applied Chemistry/Pharmaceutical)
Fourth Semester
Paper – 404: Quality Control and Quality Assurance

Time allowed: 3 Hours

Max. Marks: 60

NOTE: Attempt five questions in all, including Question No. I which is compulsory and selecting one question from each Unit.

x-x-x

I. Write the following in brief:-

- a) What do you mean GLP?
- b) Explain TQM.
- c) Sampling plans
- d) Define non-clinical testing.
- e) Mentioned the step about the material management.
- f) ICH

(6x2)

UNIT - I

II. What is the need of training programmes? Briefly explain the concept. (12)

III. Write notes on:-

- a) Environmental control in the sterile area.
- b) ISO 9000 series.

(2x6)

UNIT - II

IV. Discuss the various step involve for purchase specification, equipment selection. (12)

V. Write a notes on the following:-

- a) Good warehouse practice
- b) Guidelines for cleaning and maintenance of equipment

(2x6)

UNIT - III

VI. Discuss the various sample plans employed in quality control laboratory. (12)

VII. What are the procedures required for evaluation for complaints and recalled distributed finished products. (12)

P.T.O.

(2)

UNIT - IV

- VIII. Briefly discussed US-FDA guideline regarding to pharmaceuticals and bulk drug manufacture. (12)
- IX. Explain the qualification and validation of equipments. (12)

x-x-x