

1056

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. Attempt the following:-

- a) Brief the significance of ISO 9000 series.
- b) Define patents. What do you understand by PCT?
- c) What are SOPs?
- d) Enlist good warehousing practices.
- e) Differentiate between clinical and non-clinical testing.
- f) Define validation of equipments.

(6x2)

UNIT - I

- II. Discuss in details the principle of GLPs for attaining total quality management? (12)
- III. Illustrate and explain in detail the design and plan layout of the sterile premises. (12)

UNIT - II

- IV. Discuss the selection and procedures involved for cleaning of the equipment? (12)
- V. What do you understand by the term purchase specifications? Detail the process of selection of vendors and control on raw materials. (12)

UNIT- III

- VI. Discuss in detail the responsibilities of the personnel in a quality control laboratory. Also brief the various sampling plan used? (12)
- VII. What are various complaints and recalls during the testing procedures? How is the evaluation of complaints and recalls done? (12)

P.T.O.

(2)

UNIT - IV

VIII. Briefly explain the following

- a) Principles of CPMP
- b) Process of patenting in India
- c) ICH Guidelines

(3x4)

IX. a) WHO certification

- b) Calibration of equipments

(2x6)

x-x-x