

1058

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. Explain the following:-

- a) TQM
- b) Sampling plans
- c) TDM
- d) ISO 9000 series
- e) WHO certification
- f) Master formula records

(6x2)

UNIT – I

- II. Explain the design and layout of sterile areas. Discuss the measurement for the control of contamination. (12)
- III. Discuss in detail the Concepts and Philosophy of GMP and GLP. (12)

UNIT – II

IV. Write note on:-

- a) Guidelines for cleaning and maintenance of equipment
- b) Selection of vendors

(12)

- V. What do you mean by term warehousing? Explain the good warehousing practices detail. (12)

UNIT – III

VI. Discuss the importance of:-

- a) Documentation in quality control
- b) Control on animal house

(12)

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

P.T.O.

(2)

UNIT - IV

- VIII. Name the different regulatory bodies for pharmaceutical products. Briefly describe the guidelines of any two.
- IX. Explain the following:-
- a) Define and classify Patent. Name few national and International patent agencies. Give a flow chart describing the various steps involved in it.
 - b) Validation and calibration of equipment
- (12)

X-X-X