

2072

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. Answer the following in brief:-

- a) What is GLPS?
- b) Explain ISO 9000.
- c) Warehousing.
- d) Importance of material management
- e) Evaluation of complaints

(12)

UNIT - I

II. Explain the basis of location, design and plan layout of any pharmaceutical plant. (12)

III. Write notes on:-

- a) Control of contamination.
- b) Personal responsibilities

(2x6)

UNIT - II

IV. What are various factors which affect material management? (12)

V. Write a note on the following:-

- a) Control on raw material
- b) Selection of vendors

(2x6)

UNIT - III

VI. Discuss in details about the good laboratory practices. (12)

VII. Discuss in brief following:-

- a) Data generation and storage
- b) Sample retention

(2x6)

P.T.O.

(2)

UNIT - IV

VIII. Write notes on:-

- a) WHO certification
- b) ICH guideline

(2x6)

IX. Describe the regulatory aspects of pharmaceuticals and bulk drug manufacture. (12)

x-x-x