

2056
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. 1 which is compulsory and selecting one question from each Unit.

x-x-x

I. Explain following in brief :-

- (a) What is ICH?
- (b) Explain DRA.
- (c) WHO certification.
- (d) Control of contamination.
- (e) Importance of good warehouse.
- (f) Sampling plans

(6x2)

UNIT - I

II. Explain the philosophy of GLPS in pharmaceutical plant.

(12)

III. (a) Plant Layout.

(b) Maintenance of sterile area.

(2x6)

UNIT - II

IV. What is preventive maintenance of equipments?

(12)

V. (a) Control on raw material.

(b) Warehousing.

(2x6)

UNIT - III

VI. Discuss in details about the patent application.

(12)

VII. (a) Control of animal house.

(b) Evaluation of Complaints.

(2x6)

UNIT - IV

VIII. Write in details about the regulatory aspect of pharmaceuticals.

(12)

IX. (a) Calibration of instruments.

(b) Drug approval process.

(2x6)

x-x-x