

[LJ 355]

OCTOBER 2016

Sub. Code: 2916

**M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE**

Q.P. Code : 262916

Time : Three hours

Maximum : 100 Marks

I. Elaborate on:

(2 x 20 = 40)

1. a) Write in detail about the Quality control procedures for finished product.
b) Impact of Globalization in Indian Pharmaceutical Industry.
2. a) Explain the packaging and labeling controls for the plastics used in pharmaceutical manufacturing and its modification by drugs.
b) Write a note on good warehousing practice.

II. Write notes on:

(10 x 6 = 60)

1. Principles of GMP.
2. Hygiene control in organization.
3. Purchase specifications for raw materials.
4. Quality audits of manufacturing processes.
5. Standard operating procedure for drying.
6. Quality control protocols for animal house.
7. Steps in evaluation of complaints.
8. General principles of recall procedures.
9. Regulatory issues in pharmaceutical drug manufacturing.
10. Objectives and functions of the purchase committee.
