

[LG 355]

APRIL 2015

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. What are the different types of packaging material used in a Pharmaceutical industry? Add a note on quality control of packaging materials.
2. a) Write a detailed note on concepts and philosophy of Total quality Management.
b) Give a detailed account on location and building requirements for Pharma industry.

II. Write notes on:

(10 x 6 = 60)

1. Good Laboratory Practice (GLP)
2. Quality audits of manufacturing processes
3. Consumer Protection Act
4. Quality review
5. Handling of returned goods
6. Scrap disposal procedure and records
7. Sterilization area
8. Concepts and Philosophy of TQM
9. Patent regimen
10. Controls on animal house
