

[LK 355]

MAY 2017

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) Explain in detail the regulatory affairs of UKMCA.
b) Give a detailed account on location and building requirements for pharma industry.
2. Discuss the different types of closures and closure liners. Explain quality control of packaging material and filling equipment.

II. Write notes on:

(10 x 6 = 60)

1. What is quality audit? Explain the quality auditing of laboratories.
2. Controls on animal house.
3. Sterilisation of area.
4. When pharmaceutical products are recalled from market?
5. Good Laboratory Practice (GLP).
6. Write the note on certification.
7. Write the concept of loan license auditing.
8. Write the significance of environmental protection act.
9. Import policy.
10. Therapeutic Goods Administration (TGA).
