

[LI 355]

APRIL 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) Describe the details of standard operating procedure for compression and coating of pharmaceutical dosage form.  
b) Write a note on the spectrum and functions of regulatory affairs.
2. a) Write in detail concepts and philosophy of TQM.  
b) Describe the procedure for getting loan license and auditing.

**II. Write notes on:**

**(10 x 6 = 60)**

1. Patent filing procedure.
2. Import procedures for pharmaceutical products.
3. Role of Medicines and Healthcare products Regulatory Agency (MHRA).
4. Pharmaceutical waste management guidelines for listed wastes.
5. Classification and Handling Procedures of Returned goods.
6. Types and description of auditing.
7. Tests assuring quality of glass.
8. Design of premises.
9. Administration of the Drugs and Cosmetics Act 1940 and relevant rules.
10. Objectives & Salient features of Consumer Protection Act.

\*\*\*\*\*