

GUJARAT TECHNOLOGICAL UNIVERSITY**M. PHARM. - SEMESTER- II. EXAMINATION – SUMMER 2016****Subject Code: 2920108****Date: 19/05/2016****Subject Name: Industrial Pharmacy Practice - III****Time: 10:30 AM To 1:30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

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| Q.1 | (a) | Discuss procedural requirements for obtaining manufacturing license for liquid department. | 06 |
| | (b) | Discuss approval formalities for pharmaceutical industry as per Factory act. | 05 |
| | (c) | Describe the legislative requirements as per D & C act for obtaining manufacturing licenses for oral products. | 05 |
| Q.2 | (a) | Discuss aims, objects and salient features of Pollution control act. | 06 |
| | (b) | Discuss aims, objects and salient features of Prevent of Food Adulteration Act 1954. | 05 |
| | (c) | Discuss aims, objects and salient features of Industrial Development and Regulation Act 1951. | 05 |
| Q.3 | (a) | Draw a neat sketch of blister packaging machine; discuss its advantages and disadvantages. | 06 |
| | (b) | Enlist factors affecting selection of strip packaging materials. How are strip packs evaluated? | 05 |
| | (c) | Enlist and discuss factors affecting selection of primary and secondary packaging material. | 05 |
| Q.4 | (a) | Differentiate between Oriented and Non-oriented films for flexible packages giving suitable advantages and disadvantages for it. | 06 |
| | (b) | Differentiate between Stretchable films and laminates giving suitable advantages and disadvantages for it. | 05 |
| | (c) | Enlist various evaluations parameters of strip and blister packaging. | 05 |
| Q.5 | (a) | Enlist and discuss various types containers used for sterile products. | 06 |
| | (b) | Enlist and discuss evaluation parameters of the sterile products. | 05 |
| | (c) | Draw a flowchart for manufacture of oily steroid injection with suitable IPQC tests. | 05 |
| Q. 6 | (a) | Write a note on nano suspension giving suitable evaluation parameters. | 06 |
| | (b) | Discuss aerosols filling processes in details. | 05 |
| | (c) | Discuss environmental controls and design consideration for small volume parenteral products. | 05 |
| Q.7 | (a) | Enlist and discuss factors affecting release of drugs from semisolid dosage forms. | 06 |
| | (b) | Discuss stability protocol for liquids. | 05 |
| | (c) | Discuss SUPAC guidelines for Immediate release dosage forms. | 05 |
