Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharm. – SEMESTER – II • EXAMINATION – WINTER • 2015**

**Subject Code: 2920108** **Date: 07-12-2015**

**Subject Name: Industrial Pharmacy - III**

**Time: 10:30 am - 01:30 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)** | Define stability study. Enlist the various ICH guidelines as they have been classified with codes. | **06** |
| | **(b)** | Design the stability protocol for fast release tablets. | **05** |
| | **(c)** | Give SUPAC guidelines for modified release dosage forms. | **05** |
| **Q.2** | **(a)** | Enlist and discuss the legislative requirements of WHO GMP certification scheme. | **06** |
| | **(b)** | Explain the procedural requirements for obtaining manufacturing license for liquid department. | **05** |
| | **(c)** | Give the approval formalities for pharmaceutical industry as per factory act. | **05** |
| **Q.3** | **(a)** | Enlist evaluation parameters for sterile products packages. Discuss any two in details. | **06** |
| | **(b)** | Enlist the provisions of Consumer Protection Act. | **05** |
| | **(c)** | Enlist the provisions for Preservatives as per Food Adulteration Act 1954. | **05** |
| **Q.4** | **(a)** | Enlist aims, objects and salient features of Industry – Pollution Control Act. | **06** |
| | **(b)** | Classify various types of packaging material. Enlist factors affecting selection of packaging material. | **05** |
| | **(c)** | Write a note on BACPAC guidelines for API. | **05** |
| **Q.5** | **(a)** | Draw a neat sketch of the blister packing machine. Give advantages and disadvantages of blister packing over strip packaging. | **06** |
| | **(b)** | Enlist the factors affecting selection of strip packaging materials. How are strip packs evaluated? | **05** |
| | **(c)** | Write a note on FFS (Form Fill Seal) Technology. | **05** |
| **Q. 6** | **(a)** | Describe In-process quality control tests for solid injectable in vial pack. | **06** |
| | **(b)** | Write a note on formulation & evaluation of nanosuspensions. | **05** |
| | **(c)** | Enlist IPQC parameters for aerosols and discuss any two in details. | **05** |
| **Q.7** | **(a)** | Draw a detailed flowchart for manufacture of oily injection containing corticosteroids with details of IPQC tests. | **06** |
| | **(b)** | Enlist the factors affecting drug release from semisolids and enlist list of equipments required for a semisolid manufacturing department. | **05** |
| | **(c)** | Write a note on bracketing and matrixing used in stability studies. | **05** |

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