

GUJARAT TECHNOLOGICAL UNIVERSITY**M.PHARM- SEM-II-EXAMINATION – JULY 2012****Subject code: 2920108****Date: 06/07/2012****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.

- Q.1** (a) Describe the legislative requirements of WHO GMP certification scheme. **06**
- (b) Explain the procedural requirements for obtaining manufacturing license for tablet department. **05**
- (c) Give the approval formalities for pharmaceutical industry as per factory act. **05**
- Q.2** (a) Describe various types of wastes generated in a liquid oral manufacturing facility and plan its disposal. **06**
- (b) Explain the provisions of Consumer Protection Act. **05**
- (c) Explain the provisions for Preservatives as per Food Adulteration Act 1954. **05**
- Q.3** (a) Discuss the powers and procedures followed by food inspectors. **06**
- (b) Give the penalties listed in Industrial Development & Regulation Act 1951 for contravention of provisions. **05**
- (c) Write a note on BACPAC guidelines for API. **05**
- Q.4** (a) With a neat sketch explain the strip packing machine. Give disadvantages of strip packing. **06**
- (b) Explain the factors affecting selection of blister materials. How are blister packs evaluated? **05**
- (c) Write a note on FFS (Form Fill Seal) technology. **05**
- Q.5** (a) Describe in-process quality control tests for liquid injectables in vial pack. **06**
- (b) Write a note on formulation & evaluation of nanoemulsions. **05**
- (c) Describe the pharmacopoeial parameters for evaluation of aerosols. **05**
- Q. 6** (a) Explain SVP and LVP. Draw a detailed flowchart for manufacture of corticosteroid oily injection with details of components, processing equipments, and IPQC tests. **06**
- (b) What are the factors affecting drug release from semisolids? Give a list of equipments required for a semisolid manufacturing dept. **05**
- (c) Write a note on bracketing and matrixing used in stability studies. **05**
- Q.7** (a) Give the CFR 21 considerations for stability studies. Enumerate the various ICH guidelines as they have been classified with codes. **06**
- (b) Design a stability protocol for tablets. **05**
- (c) Give SUPAC guidelines for Immediate release dosage forms. **05**