Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2014

Subject Code: 2920108 **Date: 29-05-2014**

Subject Name: Industrial Pharmacy-III

Time: 02:30 pm - 05:30 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)**	Explain the procedural requirements for obtaining manufacturing license for Parenteral department.	**06**
	(b)	Give the approval formalities for pharmaceutical industry as per factory act.	**05**
	(c)	Give the objects and salient features of legislations governing Pharmaceutical Industry-Pollution control act.	**05**
Q.2	**(a)**	Give the penalties listed in Industrial Development & Regulation Act 1951 for contravention of provisions.	**06**
	(b)	Describe on Prevention of Food Adulteration Act 1954.	**05**
	(c)	Discuss on Factors affecting selection of packaging components.	**05**
Q.3	**(a)**	With a neat sketch explain the strip packing machine. Give economics and limitation of strip packing.	**06**
	(b)	How will you evaluated sterile product packages?	**05**
	(c)	With a neat sketch explain the ampoule filling and sealing machine.	**05**
Q.4	**(a)**	Discuss on formulation and evaluation of nanosuspension.	**06**
	(b)	Write a note on recent advances in disperse system technology with emphasis on suspensions and emulsions.	**05**
	(c)	Describe the pharmacopoeial parameters for evaluation of aerosols.	**05**
Q.5	**(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? Describe the Quality control of semisolid dosage forms.	**05**
	(c)	Design a stability protocol for liquid dosage form.	**05**
Q. 6	**(a)**	Discuss the SUPAC guideline for Modified release Dosage form with equipments amendment.	**06**
	(b)	Give the CFR 21 considerations for stability studies. Enumerate the various ICH guidelines as they have been classified with codes.	**05**
	(c)	Discuss the production and evaluation of Oriented and non-Oriented films for flexible packages.	**05**
Q.7	**(a)**	With a neat sketch explain blister packing machine. How are blister packs evaluated?	**06**
	(b)	Describe in-process quality control tests for liquid injectables in vial pack.	**05**
	(c)	Write a note on BACPAC guidelines for API.	**05**

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