Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920108 Date: 24-12-2014

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)	Give the approval formalities for pharmaceutical industry as per factory act.	**06**
	(b)	Explain the provisions for Preservatives as per Food Adulteration Act 1954.	**05**
	(c)	Explain the provisions of Consumer Protection Act.	**05**
Q.2	(a)	Describe the legislative requirements of Pharmaceutical Industry-Pollution Control act.	**06**
	(b)	With a neat sketch explain the strip packing machine. Give disadvantages of strip packing.	**05**
	(c)	Give the significance of blister packing with limitations. .	**05**
Q.3	(a)	With a neat sketch explain the ampoule filling and sealing machine.	**06**
	(b)	Describe in-process quality control tests for liquid injectables in vial pack.	**05**
	(c)	Discuss on formulation and evaluation of nanosuspension.	**05**
Q.4	(a)	Describe the pharmacopoeial parameters for evaluation of aerosols. .	**06**
	(b)	Write a note on bracketing and matrixing used in stability studies.	**05**
	(c)	Give the SUPAC Guideline for Modified release Dosage form.	**05**
Q.5	(a)	Give the CFR 21 considerations for stability studies. Enumerate the various ICH guidelines as they have been classified with codes.	**06**
	(b)	Explain the procedural requirements for obtaining manufacturing license for tablet department.	**05**
	(c)	What are the factors affecting drug release from semisolids? Give a list of equipments required for a semisolid manufacturing dept.	**05**
Q. 6	(a)	Explain the factors affecting selection of blister materials. How are blister packs evaluated?	**06**
	(b)	Design a stability protocol for tablets.	**05**
	(c)	Give the penalties listed in Industrial Development & Regulation Act 1951 for contravention of provisions.	**05**
Q.7	(a)	Write a note on BACPAC guidelines for Active Pharmaceutical Ingredients.	**06**
	(b)	Write a note on Stretchable films and laminates.	**05**
	(c)	Describe the legislative requirements of WHO GMP certification scheme.	**05**

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