Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – II • EXAMINATION – SUMMER • 2015

Subject Code: 2920108 Date: 14-05-2015

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.**

Q.1	**(a)**	Which act regulates manufacturing activities of drugs and cosmetics in India? What is the outlined requirements for this purpose?	**06**
	(b)	Suggest the basic infrastructural facilities for manufacturing drugs and cosmetics can be made compliable as per factory act, excise act and pollution control act.	**05**
	(c)	Suggest additional requirements for WHO-GMP certification scheme to be complied by manufacturer after getting license from state drugs control.	**05**
Q.2	**(a)**	What are the provisions in process to implement PFA Act and how does it will affect the basic market structure in India?	**06**
	(b)	Which food, drug, cosmetic commodity can be challenged by consumer protection act? Explain scenario in India about public awareness.	**05**
	(c)	What is the repurcations of industrial development in Indian society? How does Industrial development and regulation Act 1951 helps to overcome adverse effects of it?	**05**
Q.3	**(a)**	Define and explain package is a part of product in pharmaceuticals. Discuss the factors affecting selection of Pharmaceutical package material.	**06**
	(b)	What is primary/secondary/tertiary packaging? Discuss the types of packages and classify them.	**05**
	(c)	How does the package contribute in maintaining shelf quality and expiry date of Pharmaceutical product?	**05**
Q.4	**(a)**	Differentiate films/strips and blister packing in pharmaceutical product.	**06**
	(b)	Discuss different materials used to prepare films and strips.	**05**
	(c)	Write a note on blister pack.	**05**
Q.5	**(a)**	Write a note on sterile package.	**06**
	(b)	Discuss IPQC parameters in packaging development.	**05**
	(c)	What is sterilization compatibility and its evaluation criteria in case of sterile packaging?	**05**
Q. 6	**(a)**	What do you mean by disperse system? Classify them giving illustration in each class.	**06**
	(b)	Write a note on aerosol formulation, which propellants can be used as environment friendly system?	**05**
	(c)	Draw neat and labeled diagram for MDI and how will you evaluate them?	**05**
Q.7	**(a)**	Discuss vehicles for parenteral and how do they affect the stability?	**06**
	(b)	Write a note on design and environmental control aspects of in-situ sterilization area.	**05**
	(c)	Discuss SUPAC guideline for release from semisolid dosage form.	**05**

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