Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2920204 Date: 16-05-2015

Subject Name: Regulatory Affairs and New Drug Application

Time: 10:30 am to 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 constitution and functioning of the Pharmacy Council of India and state pharmacy councils.	**06**
	(b)	What is meant by Registered pharmacists and what are their privileges and responsibilities?	**05**
	(c)	Describe the responsibilities of pharmacist under Consumer Protection Act.	**05**
Q.2	**(a)**	Describe the quality attributes for any three cosmetics.	**06**
	(b)	Write a note on regulatory aspects of herbal products in India.	**05**
	(c)	What are the chemical and microbiological aspects of testing safety of herbal products?	**05**
Q.3	**(a)**	What are the regulations controlling air and water pollution? Describe the standards of effluents permitted in pharmaceutical industry.	**06**
	(b)	Describe the main features of Industrial Development & Regulation Act.	**05**
	(c)	Describe the licensing procedure for biotechnology derived products in India.	**05**
Q.4	**(a)**	Name the drug regulatory agencies in India,US, EU and Japan & briefly describe their functioning.	**06**
	(b)	Describe the types of DMF and its significance in NDA/ANDA application.	**05**
	(c)	Describe the role of Bureau of Indian Standards and ASTM in prescribing and certifying the standards.	**05**
Q.5	**(a)**	Differentiate between General Monographs and Individual Monograph. Enlist various tests prescribed under drug substance and drug product monographs.	**06**
	(b)	Write a note on evolution of Indian Pharmacopoeia. Write the current edition and publisher of Indian Pharmacopoeia.	**05**
	(c)	How is manufacture and sales of drugs regulated in India?	**05**
Q. 6	**(a)**	Define the terms: NDA, ANDA, CDER, Exclusivity, Electronic Orange Book, ICH.	**06**
	(b)	What is Common Technical Document? Describe five modules thereof.	**05**
	(c)	Define New Drug as per Drug & Cosmetics Act. Describe the procedure for new drug approval from CDSCO in India.	**05**
Q.7	**(a)**	Describe the procedure for new drug approval (NDA) in US.	**06**
	(b)	Describe the contents of investigator brochure used in clinical studies.	**05**
	(c)	What is meant by reference listed drug product & generic product? Describe how Waxman-Hatch Act has simplified and facilitated approval of generic products in US?	**05**

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