GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM - SEMESTER–II • EXAMINATION – SUMMER-2016

Subject Code:2920204   **Date: 21/05/2016**
Subject Name: REGULATORY AFFAIRS AND NEW DRUG APPLICATION
Time:10:30 AM To 1:30 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 of Pharmacy Council of India and explain how PCI regulates Pharmacy profession.	**06**
	(b)	Write in detail about Common Technical Document.	**05**
	(c)	Write in short about Drug Master File.	**05**
Q.2	**(a)**	Give in detail WHO guideline for Quality Control of Herbal Drug.	**06**
	(b)	What are the regulations controlling environmental pollution for Pharma industries?	**05**
	(c)	Write in short about Consumer Protection Act.	**05**
Q.3	**(a)**	Write in detail about drug regulatory agencies of India.	**06**
	(b)	How Drug and Cosmetic Act regulates sale of drugs and cosmetics?	**05**
	(c)	Compare and contrast IP, BP and USP.	**05**
Q.4	**(a)**	Define new drug as per Drug and Cosmetic Act. Discribe the procedure for new drug approval from CDSCO in India.	**06**
	(b)	Write in short about USFDA.	**05**
	(c)	Write in short about Industrial Development and Regulation Act 1951.	**05**
Q.5	**(a)**	Write in detail about MSDS preparation.	**06**
	(b)	Which are different certification agencies? Write briefly about ISI.	**05**
	(c)	Describe regulatory aspects of biotechnologically derived products.	**05**
Q. 6	**(a)**	Describe contents of Investigator brochure used in clinical trial.	**06**
	(b)	Writ e in short about ICH.	**05**
	(c)	What are the guidelines for filing in European countries?	**05**
Q.7	**(a)**	What is monograph? Give different contents of drug substance and drug product monograph.	**06**
	(b)	Write briefly about Protection of Food Adulteration Act 1954.	**05**
	(c)	Define IND, NDA and ANDA. Explain when they are filled.	**05**

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