Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM - SEMESTER–2 EXAMINATION – SUMMER-2019

Subject Code: MRA201T Date: 27/05/2019

Subject Name: Regulatory Aspects of Drugs & Cosmetics

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)**	Discuss about Drug Master File system in US.	**06**
	(b)	Discuss procedure for changes to an approved NDA.	**05**
	(c)	Draw the organization chart and structure of EMA.	**05**
Q.2	**(a)**	Describe the content and approval process for Supplemental New Drug Application as per USA.	**06**
	(b)	How is manufacture and sale of cosmetics regulated in India?	**05**
	(c)	Discuss about Marketing authorization application via the Mutual recognition in EU.	**05**
Q.3	**(a)**	Discuss about 21 CFR Part 211 for packaging and labeling requirements of Pharmaceuticals in USA.	**06**
	(b)	Discuss the regulatory requirements for Oral Combination Products in USA.	**05**
	(c)	Give the information required for CoPP application in South Africa.	**05**
Q.4	**(a)**	Describe how Waxman-Hatch Act has simplified and facilitated approval of generic products in US?	**06**
	(b)	Discuss Marketing authorization requirements for drugs in CIS Countries.	**05**
	(c)	Describe in brief regulatory aspects of Active Substance Master File as per EMA.	**05**
Q.5	**(a)**	Give organization structure, activities and responsibilities of Drug regulatory Agency of Japan.	**06**
	(b)	Discuss the certificate of compliance with the European Pharmacopoeia.	**05**
	(c)	Describe types of DMFs in detail as per Japan.	**05**
Q. 6	**(a)**	Discuss about regulatory requirements for Generic drug approval process as per ASEAN region.	**06**
	(b)	Write a note on Content and approval process of IMPD.	**05**
	(c)	Discuss the regulatory requirements for manufacturing of cosmetic products in Canada.	**05**
Q.7	**(a)**	Discuss about Post approval requirements in China.	**06**
	(b)	Discuss the Post marketing safety measure as per PMDA guideline of Japan.	**05**
	(c)	Discuss briefly about Purple Book	**05**

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