Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: MRA202T Date: 29/05/2019

Subject Name: Regulatory Aspects of Herbal & Biologicals

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)**	Write briefly about Market Authorization Application Data Requirements for Similar Biologics as per CDSCO.	**06**
	(b)	Write a note on Preclinical studies as per CDSCO.	**05**
	(c)	Write a note on Assessment of clinical safety and efficacy in the preparation of EU herbal monographs for well-established and traditional herbal medicinal products.	**05**
Q.2	**(a)**	Discuss Guidelines for IND application for Biosimilars as per USA.	**06**
	(b)	Differentiate Biosimilars products and Biologics products.	**05**
	(c)	Write a note on Pre-market approval process for Biologics in USA.	**05**
Q.3	**(a)**	Discuss about general requirements for 510(k) application for Biologics as per USA.	**06**
	(b)	Write a note on Content and requirements of Plasma master file as per EU.	**05**
	(c)	Describe labelling and packing requirements for Blood products in EU.	**05**
Q.4	**(a)**	Describe various steps involved in obtaining an EU marketing authorisation.	**06**
	(b)	Discuss about control, monitoring and diagnosis of TSE as per EU.	**05**
	(c)	Discuss about pre-clinical development of Biologics as per EU.	**05**
Q.5	**(a)**	Write briefly about guidelines on GDP for Biological products as per CDSCO.	**06**
	(b)	Discuss general format and content for post-authorisation safety studies as per EMA.	**05**
	(c)	Discuss Pharmacovigilance requirements for biological products as per CDSCO.	**05**
Q. 6	**(a)**	Discuss Schedule T for GMP requirements of herbal medicine in INDIA.	**06**
	(b)	Discuss the role and responsibilities of IHN.	**05**
	(c)	Discuss Good Agriculture and Collection Practices guideline as per AHPA.	**05**
Q.7	**(a)**	Enlist documents required for application of Herbal drug products in India.	**06**
	(b)	Discuss standardization and quality evaluation of herbal products.	**05**
	(c)	Discuss about preclinical data requirements for similar biologics.	**05**

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