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GUJARAT TECHNOLOGICAL UNIVERSITY

M. Ph. II SEMESTER • EXAMINATION – SUMMER -2018

Subject Code:MRA202T **Date: 16/05/2018**

Subject Name: REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Time: 10:30AM TO 01:30PM **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)	Differentiate Biosimilars drugs with Generic drugs.	06
	(b)	Write a note on toxicological studies as per CDSCO.	05
	(c)	Define: a) Sponsor b) LR (Legal Representative)	05
Q.2	(a)	Discuss various phases for clinical development for Biosimilars.	06
	(b)	Discuss Good agricultural and collection practice for starting materials of herbal origin as per EU.	05
	(c)	What are TSE (Transmissible Spongiform Encephalopathy)? Write a note on diagnostic tests to detect TSE.	05
Q.3	(a)	Discuss Guidelines for the Scientific Data Requirements for Plasma Master as per EU.	06
	(b)	Write general requirements for A 351(k) application for Biosimilars as per USA.	05
	(c)	Write a note on Pharmcovigilance study as per CDSCO.	05
Q.4	(a)	Describe labelling and packing requirements for Biologics.	06
	(b)	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
	(c)	Discuss the Industry guidance for Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications as per USFDA.	05
Q.5	(a)	Write a note on Content of BLA (Biologics License Applications).	06
	(b)	Write briefly about Post-Market Data for Similar Biologics.	05
	(c)	Discuss the role and responsibilities of ISBT.	05
Q. 6	(a)	Discuss ICH Q5C guidelines on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products.	06
	(b)	Discuss Schedule T for GMP requirements of herbal medicine in INDIA.	05
	(c)	Discuss the Choice of Reference Product for Biosimilars.	05
Q.7	(a)	Write a note on Principles for Development of Similar Biologics as per CDSCO.	06
	(b)	Discuss standardization and quality evaluation of herbal products.	05
	(c)	Discuss Good Agriculture and Collection Practices guideline as per AHPA.	05

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