Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM – SEMESTER -1 - EXAMINATION –WINTER - 2018

Subject Code: MRA104T Date: 07/01/2019

Subject Name: Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights

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 guidelines and standard for Regulatory filling of Medical devices in India.	**06**
	(b)	Discuss role of Bureau of Indian Standards and certifying its standards.	**05**
	(c)	Discuss ICMR-DBT Guidelines for Stem Cell Research.	**05**
Q.2	**(a)**	Discuss regulation guidelines and standard for Regulatory filling of herbals in European countries.	**06**
	(b)	Write brief note on Indian Patent Scenario.	**05**
	(c)	Describe organizational chart & responsibilities for State Licensing Authority.	**05**
Q.3	**(a)**	Discuss standard for Regulatory filling of neutraceutical in India.	**06**
	(b)	Describe format and contents of Regulatory dossier filing for solid dosage form in India.	**05**
	(c)	What are objective & offences of Prevention of Cruelty to Animals Act.	**05**
Q.4	**(a)**	Describe organization & functions for Central Drug Standard Control Organization.	**06**
	(b)	Discuss objective & functions of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.	**05**
	(c)	What is the Rationale for conducting animal testing studies?	**05**
Q.5	**(a)**	Discuss ICH Regulatory Requirements for Bioequivalence studies.	**06**
	(b)	Write short note on Intellectual Property Right.	**05**
	(c)	What are CPCSEA Ethical guidelines for human participants?	**05**
Q. 6	**(a)**	Write objectives & function of Pharmacy Act 1948.	**06**
	(b)	Describe briefly design and conduct of bioequivalence study.	**05**
	(c)	Describe ISO and other relevant standards in certifying the standards.	**05**
Q.7	**(a)**	Write note on DPCO & NPPA.	**06**
	(b)	Discuss history of Indian Pharmacopoeia. Describe content of current edition of Indian Pharmacopoeia.	**05**
	(c)	Write short note on Trademark & Copyright.	**05**

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