Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: MRA104T **Date: 09/05/2018**

Subject Name: REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Time: 02:30PM TO 05:30PM **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)**	Discuss rules, regulation guidelines and standard for Regulatory filling of Medical devices in India.	**06**
	(b)	Describe ISO and other relevant standards in certifying the standards in pharmaceutical product.	**05**
	(c)	What are CPCSEA Ethical guidelines for human participants?	**05**
Q.2	**(a)**	Describe role of Bureau of Indian Standards in prescribing and certifying the standards for pharmaceutical industry.	**06**
	(b)	Discuss ICMR-DBT Guidelines for Stem Cell Research.	**05**
	(c)	Write short note on new applications of Intellectual Property Right.	**05**
Q.3	**(a)**	Write objectives & function of The Pharmacy Act 1948	**06**
	(b)	Discuss rules, regulation guidelines and standard for Regulatory filling of herbals in India.	**05**
	(c)	Discuss history of Indian Pharmacopoeia. Write the current edition and publisher of Indian Pharmacopoeia.	**05**
Q.4	**(a)**	Discuss ICH Regulatory Requirements for Bioequivalence studies.	**06**
	(b)	Write note on Indian Patent Scenario.	**05**
	(c)	Discuss objective & function of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.	**05**
Q.5	**(a)**	Discuss rules, regulation guidelines and standard for Regulatory filling of neutraceuticals in India.	**06**
	(b)	Describe organization & responsibilities for Central Drug Standard Control Organization.	**05**
	(c)	What is the role of NPPA in fixing retail price of pharmaceutical products?	**05**
Q. 6	**(a)**	Describe organization & responsibilities for State Licensing Authority.	**06**
	(b)	Discuss rationale for conducting Preclinical Studies in animals	**05**
	(c)	What are provision & offences for Prevention of Cruelty to Animals Act?	**05**
Q.7	**(a)**	Describe Format and contents of Regulatory dossier filing for clinical trial in India.	**06**
	(b)	Discuss Guidelines for Drug testing in animals preclinical Studies.	**05**
	(c)	Describe brief layout & design for conduct of bioequivalence study.	**05**

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