Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: MPH104T **Date: 09/05/2018**
Subject Name: REGULATORY AFFAIRS
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)**	Write a note on ANDA. Explain the concept of PARA I to IV filling.	**06**
	(b)	What is DMF? Write a short note on Type of DMF.	**05**
	(c)	Write a note on NDA.	**05**
Q.2	**(a)**	Give the concept of ANDA & prepare flow chart showing ANDA review process.	**06**
	(b)	Describe various components of FDA.	**05**
	(c)	Write a note on Post Marketing Surveillance.	**05**
Q.3	**(a)**	Explain regulation for medical devices.	**06**
	(b)	Define CTD & eCTD. Explain modules of CTD.	**05**
	(c)	Explain Regulatory requirements of EU.	**05**
Q.4	**(a)**	Write a note on MHRA.	**06**
	(b)	Explain Investigation of medicinal products dossier (IMPD).	**05**
	(c)	Explain Guidelines of ICH-M.	**05**
Q.5	**(a)**	Explain the scope of TGA regulations. Discuss the TGA guidelines for OTC product.	**06**
	(b)	Explain export registration of pharmaceuticals in rest of world countries.	**05**
	(c)	Write a note on HIPAA.	**05**
Q. 6	**(a)**	Explain pharmacovigilance safety monitoring in clinical trials.	**06**
	(b)	Write note on ANVISA.	**05**
	(c)	Describe various activity regulated by CDER.	**05**
Q.7	**(a)**	Explain CFR 21(code of federal regulation).	**06**
	(b)	Discuss Drug Price Competition and Patent restoration act of 1984 and WAXMAN-HATCH ACT are the same and its economics on the society is important.	**05**
	(c)	Define ‘Orange Book’, ‘Green Book’ and ‘Blue Book’. Explain statistical criteria for Bio-equivalence in context to orange book.	**05**

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