Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: MPA102T Date: 03/01/2019

Subject Name: Advanced Pharmaceutical Analysis

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)**	Explain Selection of batches, sampling frequency, specifications and storage condition with respect to stability testing protocols.	**06**
	(b)	Give a short note on handling of degradation product.	**05**
	(c)	Describe in brief the procedure to study stability of the natural products.	**05**
Q.2	**(a)**	Give a note on photo stability testing guidelines.	**06**
	(b)	Discuss various Potential Sources of Elemental Impurities.	**05**
	(c)	Give applications of Immunoassay in relation to quantification.	**05**
Q.3	**(a)**	Why it is important to control residual solvent? Classify residual solvents in detail along with their limits and reporting levels.	**06**
	(b)	Discuss HPTLC/HPLC finger printing interactions.	**05**
	(c)	Describe method for separation of bound and unbound drug in Immunoassays.	**05**
Q.4	**(a)**	What is gene regulation? Explain principle and procedures of PCR studies for gene regulation.	**06**
	(b)	Give effects of impurities in new drug products in terms of degradation.	**05**
	(c)	Write biological tests and assays of Rabies Vaccine.	**05**
Q.5	**(a)**	Define immunoassay. Explain basic principle of IA and production of antibodies.	**06**
	(b)	Discuss ICH guidelines laid down for stability studies for biological products.	**05**
	(c)	What is oxytocin? Give principle and procedure for the bioassay of Oxytocin.	**05**
Q. 6	**(a)**	Discuss the regulatory requirements and protocols for phyto-pharmaceuticals	**06**
	(b)	Classify impurities in API. And its effects on stability of sample.	**05**
	(c)	Describe various factors which affect the stability of samples.	**05**
Q.7	**(a)**	Define impurity and give detail notes of quantification of impurities as per ICH guideline.	**06**
	(b)	Give Safety Assessment of Elemental Impurities for Oral, Parenteral and Inhalation Routes of Administration.	**05**
	(c)	Discuss in detail shelf life calculation and stability zones.	**05**

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