Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – 8 EXAMINATION – SUMMER-2025

Subject Code: BP806TT **Date: 14-05-2025**

Subject Name: Quality Control and standardization of Herbals

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)**	For New Drug application of a novel phyto-constituent; provide list of submissions.	**06**
	(b)	Describe how different regulations help in streamlining manufacturing and uniform quality of natural products.	**05**
	(c)	Enumerate parameters of WHO guidelines for quality assessment of crude drugs.	**05**
Q.2	**(a)**	Describe in detail; 1. Extractive value 2. Ash value 3. Bitterness value	**06**
	(b)	Explain how a pure phyto-pharmaceutical can be asses for quality by WHO guidelines?	**05**
	(c)	Provide full form and objectives of following GACP guidelines.	**05**
Q.3	**(a)**	Describe in detail from GACP guidelines; 1. Propagating material 2. Irrigation 3. Pest control	**06**
	(b)	Provide Good Collection practice for roots and bark.	**05**
	(c)	Write in detail about Post harvesting primary processes practices.	**05**
Q.4	**(a)**	Differentiate EU guidelines from ICH guidelines for quality and stability study of medicinal constituent.	**06**
	(b)	What stability study practice is required to prove stability of a plant constituent?	**05**
	(c)	Provide definition, significance and Process of Phyto-pharmacovigilance.	**05**
Q.5	**(a)**	Write a note on OECD 420 and OECD 425 guidelines for drug safety.	**06**
	(b)	Write detailed classification of markers with examples.	**05**
	(c)	Provide all the components of Adverse Drug Reaction report.	**05**
Q. 6	**(a)**	Enlist guidelines GMP given in Schedule T of Drugs and Cosmetics Act of India.	**06**
	(b)	Describe details of prescribed Good Laboratory Practice with emphasis on record keeping.	**05**
	(c)	Describe Indian EXIM policy in brief and give details o document required for import of medicinal plant product.	**05**
Q.7	**(a)**	Write role of different Herbal Pharmacopoeias in Herbal Drug market.	**06**
	(b)	As per current Good Manufacturing Practice, describe ideal practice for STORE, STORAGE AREA and EQUPMENTS HANDLING for a herbal drug Industry.	**05**
	(c)	Write a note on efficacy study of herbal drugs.	**05**

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