Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 8 EXAMINATION – SUMMER -2023

Subject Code: BP806TT Date: 30/06/2023

Subject Name: Quality Control and standardization of Herbals

Time:10.30 a.m. to 1.30 p.m. 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)**	Narrate in brief about WHO guidelines for quality control of herbal drugs.	**06**
	(b)	Differentiate Herbals versus Pharmaceutical Drugs.	**05**
	(c)	Enlist various herbal formulations available in market and explain in detail about herbal syrup.	**05**
Q.2	**(a)**	Discuss in detail about challenges in monitoring the safety of herbal medicines with reference to GMP.	**06**
	(b)	Write a note on comparison of various Herbal Pharmacopoeias.	**05**
	(c)	Discuss about requirement of infrastructure, staff and equipment for herbal drug industry.	**05**
Q.3	**(a)**	Discuss in brief stability criteria for herbal drugs.	**06**
	(b)	Write a note on role of chemical markers in standardization of herbal products.	**05**
	(c)	Define: Herbal Medicine, Traditional Medicine, Bio-logical markers, Adverse Reaction, Therapeutic activity	**05**
Q.4	**(a)**	Enumerate various steps used for preparation of documents for filing new drug application and export registration.	**06**
	(b)	Classify Ayurvedic Dosage form. Discuss various evaluation parameters of Bhasma.	**05**
	(c)	Discuss Application of HPTLC for standardization of herbal drugs.	**05**
Q.5	**(a)**	Narrate in brief about EU guidelines for quality control of crude drugs.	**06**
	(b)	Classify Modern Dosage form. Discuss various evaluation parameters of emulsion.	**05**
	(c)	Discuss in detail about WHO Guidelines on GACP for Medicinal Plants.	**05**
Q. 6	**(a)**	Define Pharmacovigilance. How does Pharmacovigilance operate?	**06**
	(b)	Write a note on shelf life of herbal medicine.	**05**
	(c)	Describe importance of standardization and problems involved in the standardization of herbs.	**05**
Q.7	**(a)**	Describe about guidelines used for toxicity investigation of herbal medicines.	**06**
	(b)	Enumerate various parameters to validate Herbal products.	**05**
	(c)	How herbal extract is evaluated - Explain with different parameters.	**05**

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