

GUJARAT TECHNOLOGICAL UNIVERSITY**B.PHARM - SEMESTER- 8 EXAMINATION – SUMMER-2024****Subject Code:BP806TT****Date: 03/05/2024****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)	Discuss the WHO guidelines for quality control of herbal drugs.	06
	(b)	Discuss various documents are needed for the export registration.	05
	(c)	Enlist various evaluation methods for herbal drugs and describe in details any one method of evaluation.	05
Q.2	(a)	What is the role of AYUSH department in regulation of herbal medicine?	06
	(b)	Explain WHO guideline on safety monitoring of herbal medicine in pharmacovigilance system.	05
	(c)	What is the role of biological markers in standardization of herbal products?	05
Q.3	(a)	Discuss quality control parameters for c-GMP of traditional medicine.	06
	(b)	Explain stability testing of new active substance.	05
	(c)	Write a note on GLP in traditional system of medicine.	05
Q.4	(a)	Explain research guideline for evaluation efficacy of herbals.	06
	(b)	Discuss qualitative and quantitative parameters of active substances of herbal products.	05
	(c)	Write a note on international drug monitoring program.	05
Q.5	(a)	Describe ICH guidelines for quality control of herbal drugs.	06
	(b)	Discuss about the documents needed for new drug application.	05
	(c)	Explain the role of HPTLC in standardization of herbal products.	05
Q. 6	(a)	Describe GACP guidelines for medicinal plants.	06
	(b)	Discuss GMP requirement & Drug and Cosmetic Act provision of herbal medicine.	05
	(c)	Explain good collection methods for herbal medicine.	05
Q.7	(a)	What are the regulatory requirements of herbal medicine?	06
	(b)	Write a note on factors affecting stability of herbal drugs.	05
	(c)	Explain various test procedure for hrbal drug substances.	05
