

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 8 EXAMINATION – WINTER -2024

Subject Code:BP806TT**Date: 26-11-2024****Subject Name: Quality Control and standardization of Herbals****Time:02.30 PM TO 05.30 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) What is evaluation? Explain the Various method used for the evaluation of Herbal drug. **06**
(b) Explain the WHO guideline for evaluation of Herbal Drug & their preparation. **05**
(c) Explain the common test used for the evaluation & quality control for Medicinal plants & Relate substance. **05**
- Q.2** (a) Describe the ICH guideline for the evaluation of Herbal drug. **06**
(b) WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines. **05**
(c) WHO Guidelines on good agricultural practice & GACP for Medicinal Plants. **05**
- Q.3** (a) Describe the EU and ICH guidelines for quality control of herbal drugs & related product. **06**
(b) Explain the various parameter used for standardization of herbal drug and its preparation. **05**
(c) Explain the role of Various chromatographic & Spectroscopic techniques used for Standardization of Herbal Extract. **05**
- Q.4** (a) Explain the role of Regulatory requirements for herbal medicines safety & stability. **06**
(b) Describe the Role of chemical and biological markers in standardization of Herbal products. **05**
(c) Preparation of documents for new drug application and export registration. **05**
- Q.5** (a) Explain the role of separation techniques in standardization of Herbal Extract. **06**
(b) Describe the Regulatory requirements for Production, Sale & export & herbal medicines. **05**
(c) WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. **05**
- Q. 6** (a) Describe the GMP & CGMP Requirements for Drugs & Cosmetics Act 1945. **06**
(b) Elaborate Good Laboratory Practice in traditional system of medicine or AYUSH. **05**
(c) Write the Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines & related product. **05**
- Q.7** (a) Explain Role & Comparison of various Herbal Pharmacopoeias used for standardization of Herbal Drug preparation. **06**
(b) Write on hypanated analytical methods used for Chemical evaluation of Herbal. **05**
(c) Explain the various quality attributes commonly used for Evaluation & Standardization of herbal. **05**