

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM – SEMESTER – VIII EXAMINATION – WINTER-2025**

**Subject Code: BP806TT****Date:17-11-2025****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) Enlist various evaluation parameters for commercial crude drugs. Discuss Microscopical evaluation for crude drugs **06**
- (b) Enumerate Quality control parameters for herbal drugs as per WHO guideline. Explain importance and determination of Ash value & Foreign matters. **05**
- (c) Discuss the determination of Extractive value and volatile oils in details. **05**
- Q.2** (a) Define Pesticide. Explain determination of pesticide residue in detail **06**
- (b) Discuss the basic chemical tests for alkaloids and glycosides. **05**
- (c) Explain importance of Good agricultural practices for medicinal plants. **05**
- Q.3** (a) Write a note on requirement of Premises, Equipment and Materials in cGMP for herbal medicines. **06**
- (b) Discuss Good practices in quality control in herbal drug manufacturing. **05**
- (c) Explain the importance of GLP in traditional system of medicine. **05**
- Q.4** (a) Discuss EU guidelines for quality control of herbal drugs. **06**
- (b) Explain clinical trials using herbal medicine. **05**
- (c) Explain importance of Good collection practices for medicinal plants **05**
- Q.5** (a) Write a brief idea on ICH guidelines for quality control of herbal drugs. **06**
- (b) How the Safety and efficacy is evaluated for Herbal Medicines? Discuss in detail. **05**
- (c) Explain Export registration procedure for Herbal drugs. **05**
- Q.6** (a) Write a note on standardization of crude drugs by HPLC and HPTLC with suitable examples. **06**
- (b) Explain in detail stability testing guideline for finished product. **05**
- (c) Discuss NDA summary formats and content for herbal drugs. **05**
- Q.7** (a) What is phytopharmacovigilance? Discuss the importance of phytopharmacovigilance in safety monitoring of herbal medicines. **06**
- (b) Compare and discuss monograph of herb from various pharmacopoeias. **05**
- (c) Define Markers. Explain the role of chemical and biological markers in Standardization of herbal products. **05**

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