

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Ph. SEMESTER VIII • EXAMINATION – WINTER -2022**

**Subject Code: BP806TT****Date: 23/12/2022****Subject Name: Quality Control and Standardization of Herbals****Time: 02:30PM TO 05:30PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

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|-------------|--|-----------|
| <b>Q.1</b>  | (a) Explain Physical evaluation for the quality control of herbal drugs.   | <b>06</b> |
|             | (b) Describe HPTLC techniques in the standardization of herbal products.   | <b>05</b> |
|             | (c) Discuss WHO Guidelines on GACP for Medicinal Plants.   | <b>05</b> |
| <b>Q.2</b>  | (a) Discuss the WHO Guidelines on cGMP of Herbal drugs.  | <b>06</b> |
|             | (b) What is stability testing? Explain the different methods for stability testing of herbal drugs in detail.          | <b>05</b> |
|             | (c) Explain the WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.                  | <b>05</b> |
| <b>Q.3</b>  | (a) Explain the role of markers in the standardization of herbal products.   | <b>06</b> |
|             | (b) Write a note on GLP in the traditional system of medicine.   | <b>05</b> |
|             | (c) Describe the pharmacological and toxicological evaluation of herbal drugs.   | <b>05</b> |
| <b>Q.4</b>  | (a) Discuss ICH guidelines for quality control of herbal drugs.  | <b>06</b> |
|             | (b) Explain in brief about good agriculture practice of herbal drugs.  | <b>05</b> |
|             | (c) Write a note on the document preparation for new drug applications.  | <b>05</b> |
| <b>Q.5</b>  | (a) Write a note on the document preparation for export registration.  | <b>06</b> |
|             | (b) Compare and contrast between Ayurvedic and herbal pharmacopeia.  | <b>05</b> |
|             | (c) Explain the research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines in Brief.               | <b>05</b> |
| <b>Q. 6</b> | (a) Define: standardization, Shelf life, swelling index, chromatographic fingerprinting, Pesticide residue, Ash Value. | <b>06</b> |
|             | (b) Write the chemical tests for identification of secondary plant metabolite.   | <b>05</b> |
|             | (c) Discuss EU guidelines for quality control of herbal drugs.   | <b>05</b> |
| <b>Q.7</b>  | (a) Write a note on the Microscopic evaluation of crude drugs.   | <b>06</b> |
|             | (b) Describe TLC and HPLC techniques in the standardization of herbal products.  | <b>05</b> |
|             | (c) Discuss regulatory requirements of herbal medicines in India.  | <b>05</b> |

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