

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER-8 EXAMINATION – WINTER -2023

Subject Code: BP806TT**Date: 06/12/2023****Subject Name: Quality Control and standardization of Herbals****Time:02.30 p.m. to 5.30 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.

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| Q.1 | (a) Write in detail about basic tests for analysis of a pure pyto-pharmaceutical. | 06 |
| | (b) Suggest assessment criteria of a powdered herb drug using WHO guidelines. | 05 |
| | (c) Give specifications of following parameters with their limits suggested by WHO guidelines; Microbial limit, Heavy metal residues. | 05 |
| Q.2 | (a) Elaborate Good cultivation practice criteria for cultivation of medicinal plants; site selection, Ecological environment social impact and soil selection | 06 |
| | (b) Write a note on Good Collection Practice for Wild medicinal plants. | 05 |
| | (c) Explain in detail about ideal Post Harvesting processes suggested by WHO guidelines. | 05 |
| Q.3 | (a) Write in brief about ICH guidelines for stability studies of new dosage form. | 06 |
| | (b) Explain in detail how EU guideline differs from ICH guidelines. | 05 |
| | (c) Write applications of HPLC and HPTLC techniques in standardization of herbal products. | 05 |
| Q.4 | (a) Enlist the documents required for New Drug Application of a plant bio-active. | 06 |
| | (b) Write detailed OECD guidelines for acute toxicity study of unknown herb. | 05 |
| | (c) Explain LD ₅₀ determination study guidelines for pyto-constituent. | 05 |
| Q.5 | (a) Write a short note on Phyto-pharmacovigilance. | 06 |
| | (b) Enlist types of markers and their significance in Medicinal plant studies. | 05 |
| | (c) Write detailed frame work of Adverse Drug Reporting. | 05 |
| Q.6 | (a) Describe following subparts of cGMP;
1. Building 2. Equipments 3. Personell | 06 |
| | (b) Enlist suitable WHO and Indian guidelines for Records and report maintenance in Herbal Drug Industry. | 05 |
| | (c) Suggest Good Laboratory Practice guidelines for a Natural Product Industry. | 05 |
| Q.7 | (a) List out different Herbal Pharmacopoeias with their comparative components of monograph. | 06 |
| | (b) Give details of requirements for Export approval of a Herbal supplement. | 05 |
| | (c) Write a short note on guidelines for Efficacy evaluation given by CDSCO. | 05 |
