

**BP806ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS
(Theory)**

45 Hours

Course Content

Unit-I

10 hours

Basic tests for drugs– Pharmaceutical substances, Medicinal plants materials and dosage forms.
WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use.

Unit-II

10 hours

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit-III

10 hours

EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.

Unit-IV

08 hours

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit-V

07 Hours

Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems
Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products.