

Unit I

Chapter 1: QUALITY CONTROL AND STANDARDIZATION OF HERBALS

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Abstract: 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.

Keywords: Pharmaceutical substances, Medicinal plant materials, Dosage forms, WHO quality control guidelines, Evaluation of crude drugs, Commercial herbal drugs

1 Introduction

Essential preliminary drug evaluation tests are critical to ensure the identity, purity, quality, and safety of raw materials, plant material, and finished product (dosage) of pharmaceutical products. Basic tests provide the initial quality assurance evaluation to determine if the raw materials have been contaminated, degraded, or adulterated prior to processing or procurement. Due to limited access to sophisticated equipment, basic tests can be a useful tool for conducting field testing, testing in developing countries, and conducting preliminary screenings at the quality control laboratory.

The main purpose of basic tests is to validate the authenticity of the tested substance through confirmation of its inherent physical and chemical characteristics. Organoleptic assessments (e.g., determination of color, smell, taste, and texture), which are commonly employed to evaluate raw plant materials and identify significant adulteration, can be used for this purpose. Basic physical tests (melting point, boiling point, solubility, and moisture) will provide information regarding whether the substance has met all applicable standards, while ash values and extractive values will provide information regarding the possible presence of inorganic or non-herbal drugs in herbal medicines.

Chemical tests are the final primary evaluation test category for basic evaluations. Chemical tests include various simple color tests or precipitation tests which are used to determine the presence of specific chemical classes of compounds (alkaloids, glycosides, tannins, etc.) in addition to limit tests