

WHO (WORLD HEALTH ORGANIZATION) GUIDELINES FOR STANDARDIZATION OF HERBAL DRUGS

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ABSTRACT

Herbal drugs are being used as medicines from ancient period. The increased use of herbal drugs, and concerns over their safety and efficacy have certainly augmented the need of standardization of these herbal drugs. WHO has set up guidelines for standardization of these drugs, which are used as a standard by the majority of countries. The standardization includes the external (macroscopy/microscopy) as well as internal examination/ash values, extractive values and many other parameters to identify, authenticate and study its chemical composition. Standardization of the medicinal plants will ensure indirectly that the plants are conserved for their medicinal and nutritive value. Standardization confirms the safety of the medicinal plant but efficacy has to be judged clinically or in the laboratory. There is a thin line between efficacy and the presence of chemical compounds in the drug. The major hurdle in standardization of the batch to batch variation in the plant compounds. Addition of finer analytical methods of the chemical compounds may help to minimize the variation and give a better resolution of the plant drug. Importance of toxicological examination has increased manifolds as contamination can occur at various stages, from collection, storage, analysis or processing to extraction of active principles. These parameters should be recorded for years together; their database should be generated, recorded and analyzed statistically to see the difference in quality and quantity of the chemical compounds.

Keywords: Standardization, herbal drug, botanical, pharmacological, toxicological, parameters

INTRODUCTION

Medicinal plants are in use for the purpose of treatment of different ailments since centuries. There has been an immense increase in sales of herbal OTC (Over the counter drugs. This is growing to a billion dollar industry. The need for safety and efficacy has also escalated since the western interest has grown. Thus the need for standardization has come into view. The process of evaluation of the quality and purity of

crude drugs by means of various parameters like morphological, microscopical, physical, chemical and biological observations is called standardization.¹Standardisation of the herbal drug begins from the collection of the herbal drug to its packaging/use as medicine. The impediments in standardization of herbal drugs-

- Variability in the chemical composition of the soil and changes in the climate in-

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