

COMPONENTAL TESTING METHODS FOR HERBAL CRUDE DRUGS***K. Malleswari, D. Rama Brahma Reddy G. Baby Syamala, M. Kavitha and J. Somasekhar**

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ABSTRACT

Uncaria rhynchophylla (Miq.) Jacks (Rubiaceae) is a component of the Chinese crude drug Gou-teng, which is widely used as a remedy for several ailments including cerebrovascular diseases, hypertension, eclampsia, and epilepsy. In chapter, we review the phytochemistry and pharmacological attributes of *U. rhynchophylla*, with a focus on the neuroprotective activity of the plant. The plant is reported to exert antioxidant, anti-inflammatory, antihypertensive, antiarrhythmic, anticancer, anticonvulsive, and neuroprotective properties, which are related to the presence of various classes of bioactive compounds, predominantly indole alkaloids such as rhynchophylline and isorhynchophylline. In vitro and in vivo studies have provided strong evidence that the bioactive compounds present in *U. rhynchophylla* may potentially be useful in treating neuronal disorders through different modes of action. For instance, with respect to Alzheimer's disease, constituents of the plant have been showed to play significant roles in inhibiting acetylcholinesterase, A β aggregation, counteracting oxidative stress and neuroinflammation, and increasing neuronal survival and synaptic plasticity. This chapter advocates for further investigations into *U. rhynchophylla* as a novel source of therapeutic agents to prevent and/or manage Alzheimer's disease.

KEYWORDS: Crude drug, evaluation, standardization, qualitycontrol, quality assurance.**INTRODUCTION**

Standardization is a code of conduct that ensures the correct substance in correct amount for desired therapeutic effect (safety, quality and efficacy) is known as standardization. It describes all measures taken during manufacturing process and quality control leads to reproducible quality of particular product. Standardization confirms drug identity (authentication) and determines the quality and purity. The herbal raw material prone to a lot of variation in phyto constituents due to several factors different places of collection (indigenous and naturalized plants), time and season of collection, different environmental conditions, (primary causes like light, moisture, temperature, oxygen etc. secondary causes as involvement of living organisms like bacteria, molds, mites, nematodes, worms, insects etc.), genotypic and chemotypic variation, presence of xenobiotics (foreign chemical substances found within an organism that is naturally not expected to be present within that organisms).

HERBAL MEDICINE

Herbal medicine (HM) is the fulcrum of complementary and alternative medicine, which in recent times is increasingly gaining widespread popularity all over the world and gradually streaming toward integration into the mainstream healthcare systems. The use of HM cuts across gender, social and racial classes in both

developing and developed countries of the world. Due to the increasing popularity of HM, stakes in the world markets (local and international) are also rapidly increasing and the annual sale is rapidly approaching US \$62 billion. An important driver in this upsurge in patronage and use includes low cost, the wide acceptance due to its status of being a natural product with the acclaim of low toxicity, efficacy in certain challenging diseases, flexibility in its accessibility, preparation and use.

HEALTH BENEFITS OF HERBAL MEDICINES

Correspondingly to conventional medicines, the indications of folk HMs are diverse, being employed for the treatment of a wide range of diseases. The indications spread from simple health conditions such as cold, pain, surface wounds to serious conditions such as psychosis, diabetes, malaria, sickle cell disease, tuberculosis, cancer, hypertension, infertility, and so on. In certain communities, HM is a major component of the primary healthcare. Indeed, up to 80% of the rural population in Africa use herbal-based traditional medicines for most of their healthcare. In Ghana, Mali, Nigeria and Zambia, the first line of treatment for 60% of children with high fever resulting from malaria and other diseases is HM, which are often administered at home. Rural South Africa also has a strong culture of traditional medicine that is based on HM. In China and India, HM accounts for about 50%

of the total health product consumption. With the increasing attention to HM all over the world, the list of medicinal herbs and products is increasing so also is the consumption rate even in societies where conventional healthcare is available and easy to access. Also, in the USA, about 40% of the adult population has used herbal medicine. The sales output of HM in Canada, Australia and Europe especially in Germany and France is rapidly increasing.

METHODS OF HERBAL CRUDE DRUGS

Authenticated raw material is the basic starting point in developing a botanical product. In addition, each step of harvest, storage, processing and formulation may dramatically alter the quality and consistency of final product. Therefore methods to ensure quality control in manufacturing and storage are requisite tools to ensure optimal efficacy and safety of these products. Furthermore, such controls are critical for the evaluation of pharmacological, toxicological or clinical studies involving botanical products. Authentication is especially useful in cases of drugs that are frequently substituted or adulterated with other varieties which are morphologically and chemically indistinguishable. Several herbal drugs in the market still cannot be identified or authenticated based on their morphological or histological characteristics. Use of wrong drugs may be ineffective or it may worsen the condition.

TAXONOMIC METHODS

The initial step in the identification and authentication of botanical materials. The botanical origin of the drug is identified and its scientific Latin binomial (i.e. genus species) name is determined based on this method. Information such as botanical name, vernacular names, site of collection of plant material, details of collector, habitat, season of collection, altitude and part collected etc. are the essential prerequisites even before authentication.

The herbal preparations thus obtained include extracts, decoctions, tinctures, essential oils and others.

The processes involved include.

- Extraction.
- Distillation.
- Fractionation.
- Concentration.
- Fermentation.
- Chemical and biological methods.

FORMULATION STUDIES

1. Content Herbal formulation: Challenges in herbal formulation, Constraint in herbal formulation, Ayurvedic formulations, Concept of detoxification.
2. Herbal formulation: Herbal formulation shall mean a dosage form consisting of one or more herbs or processed herb(s) in specified quantities to provide specific nutritional, cosmetic benefits, and/or other benefits meant for use to diagnose treat, mitigate diseases

of human beings or animals and/or to alter the structure or physiology of human beings or animals.

3. Herbal formulation: Herbal preparations are obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

4. Challenges in Herbal formulation: A key challenge is to objectively assess conflicting toxicological, epidemiological, and other data and the verification of herbal materials used. Management within ranges of risk, Communication of uncertainty • Pharmacological, toxicological, and clinical documentation • Pharmacovigilance.

5. Challenges in Herbal formulation: Understanding why addition of harmful additives works evaluating “drug” interactions. Constraints with clinical trials and people available, Standardization, Safety, and efficacy assessment.

6. Factors affecting safety and Quality: Quality of starting materials, Complexity of nomenclature of herbal ingredients, Chemical contamination by Heavy metals, Choice of chemical markers, Adulteration with synthetic chemical drugs.

7. Constraints of herbal formulation: Indiscriminate harvesting and poor post-harvest treatment practices. Lack of research on the development of high-yielding varieties, domestication etc. Poor agriculture and propagation methods. Inefficient processing techniques leading to low yields and poor quality products. • Poor quality control procedures.

8. Constraints of herbal formulation: Lack of current good manufacturing practices. Lack of R & D on product and process development. Difficulties in marketing. • Lack of trained personnel and equipment. Lack of facilities to fabricate equipment locally. Lack of access to latest technological and market information.

9. Factors affecting herbal formulation preparation, Incorrect storage, Gross exhausted drugs.

10. Drug adulteration, Faulty collection, Imperfect substitution with plant material, Substitution with.

EVALUATION OF CRUDE DRUGS

1. Crude drugs: Vegetable or animal drugs that consist of natural substances that have undergone only the processes of collection and drying. Natural substances: 1- Plant origin: leaves, flowers, seeds and barks. Or vegetable saps, extracts and secretions. 2- Animal origin: whole animals, glands or organs, extracts and secretions. Crude drugs: Vegetable or animal drugs that consist of natural substances that have undergone only the processes of collection and drying. Natural substances: 1- Plant origin: leaves, flowers, seeds and barks. Or vegetable saps, extracts and secretions. 2- Animal origin: whole animals, glands or organs, extracts and secretions.

2. Drug evaluation may be defined as the determination of identity, purity and quality of a drug. Identity –

identification of biological source of the drug. Quality – the quantity of the active constituents present. Purity – the extent of foreign organic material present in a crude drug. Importance of evaluation of crude drugs. Determination of Biochemical variation in the drugs. Identification of deterioration due treatment and storage. Reporting Substitution and adulteration, as result of carelessness, ignorance and fraud Drug evaluation may be defined as the determination of identity, purity and quality of a drug. Identity – identification of biological source of the drug. Quality – the quantity of the active constituents present. Purity – the extent of foreign organic material present in a crude drug. Importance of evaluation of crude drugs. Determination of Biochemical variation in the drugs. Identification of deterioration due treatment and storage. Reporting Substitution and adulteration, as result of carelessness, ignorance and fraud.

METHODS OF DRUG EVALUATION

To evaluate means to identify it and to determine its quality and purity, the identity of a drug can be established by actual collection of the drug from a plant or animal that has been positively identified. The evaluation of drug involves a number of methods that may be classified as follows.

1. Organoleptic and morphological evaluation

Evaluation by means of organs of senses knowing the color, odor, taste, size, shape and special features like texture.

3. Microscopic

For identification of the pure powdered drug. This method allows more detailed examination of a drug and their identification by their known histological characters. Microscope by the virtue of its property to magnify, permits minute sections under study to enlarge so that leaf constants, stomatal index, palisade ratio can be determined.

3. Biologic

Pharmacological activities of drugs are evaluated by bioassays. When the estimation of potency of crude drug or its preparations are done by means of measuring its effect on living organisms like bacteria, fungal growth, or animal tissue, it is known as biological effect of the drug, compared to the standard drug. By these methods, a crude drug can be assessed and further clinical trial can be recommended.

4. Chemical

Chemical assays are best to determine potency and active constituents. It comprises different test and assays. The isolation, purification and identification of active constituents are the methods of evaluation. Quantitative chemical test such as acid value, saponification value etc are also covered under these techniques.

5. Physical

Physical constants are applied to active principles. These are helpful in evaluation with reference to moisture content, specific gravity, density, optic rotation etc.

CONCLUSION

Plant materials are used throughout the developed and Developing world as home remedies, in over-the-counter Drug products, and as raw material for the Pharmaceutical industry, and they represent a substantial Proportion of the global drug market. Therefore, it is Essential to establish internationally recognized Guidelines for assessing their quality. Certain herbs have Become popular over the years, but the general public, Medical practitioners and the media still have a poor Understanding of safe and effective use of herbal Medicine. Evidence is emerging on the dangers of Indiscriminate use of some of these herbs. As in most Situations, the truth lies hidden under the media hype, Poorly understood science, an exaggerated claim. The Need for standardization of herbals is now very essential Given the global acceptance of herbal products as Remedies for various diseases and ailments. The deployment of modern analytical tools in testing The various quality parameters for an effective quality Control herbal product cannot be over emphasized. The Assurance of the safety and efficacy of a herbal drug Requires monitoring of the quality of the product from Collection through processing to the finished packaged Product. It is recommended that various government Agencies should follow a more universal approach to Herbal quality by adopting the WHO guidelines and also Developing monographs using the various quality Parameters outlined above. This will strengthen the Regulatory process and minimize quality breach.

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