WWJMRD 2019; 5(10): 01-04
www.wwjmrd.com
International Journal
Peer Reviewed Journal
Refereed Journal
Indexed Journal
Impact Factor MJIF: 4.25
E-ISSN: 2454-6615

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A Study on Herbal Plants Medicine for Human Beings

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Abstract
World Health Organization (WHO) encourages, recommends and promotes traditional/herbal remedies in natural health care programmes because these drugs are easily available at low cost, safe and people have faith in them. The WHO assembly in number of resolutions has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and applying suitable standards. Quality control for efficacy and safety of herbal products is of paramount importance. Quality can be defined as the status of a drug that is determined by identity, purity, content, and other chemical, physical, or biological properties, or by the manufacturing processes. In this paper different researchers research work is studied. The different herbal medicines are studied.

Keywords: WHO, herbal plants, remedies, drugs etc

1. Introduction
Standardization of herbal formulations is essential in order to assess of quality drugs, based on the concentration of their active principles, physical, chemical, phytochemical, and standardization, and In-vitro, In-vivo parameters. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicine [1]. One of the major problems faced by the herbal industry is the unavailability of rigid quality control profiles for herbal materials and their formulations. In India, the department of Ayush, Government of India, launched a central scheme to develop a standard operating procedures for the manufacturing process to develop pharmacopeial standards for ayurvedic preparations. The subject of herbal drug standardization is massively wide and deep. There is so much to know and so many seemingly contradictory theories on the subject of herbal medicines and their relationship with human physiology and mental function. India needs to explore the medicinally important plants. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization. World Health Organization (WHO) encourages, recommends and promotes traditional/herbal remedies in natural health care programmes because these drugs are easily available at low cost, safe and people have faith in them. The WHO assembly in number of resolutions has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and applying suitable standards [2].

Standardization of raw materials includes the following steps:-
Authentication- Each and every step has to be authenticated, area of the collection, parts of the plant collection, the regional situation, as phytomorphology botanical identity, microscopic and histological analysis(characteristic features of cell walls, cell contents, starch grains, calcium oxalate crystals, hairs, fibers, vessels etc.) Several studies of the histological parameters are list of palisade ratio, vein islet number, vein termination, stomatal number, stomatal index, trichomes, stomata, quantitative microscopy, taxonomic identity, foreign matter. Loss on drying, swelling index, foaming index, ash values and extractive values, Chromatographic and spectroscopic evaluation, Determination of heavy metals, pesticide residues, Microbial contamination, Radioactive contamination. The parameter stability of herbal formulations that includes pharmacognostic parameters, physicochemical parameters, phyto-chemical parameters, microbiological assay, chromatographic analysis.

Pharmacognostic evaluation
It includes color, odor, taste, texture, size, shape, microscopical characters, and histological parameters.

Physico-chemical parameters
It includes foreign matter, total ash, acid-insoluble ash, swelling and foaming index, assay, successive extractive values, moisture content, viscosity, PH, Disintegration time, friability, hardness, flow capacity, flocculation, sedimentation, alcohol content.

Chemical parameters
It includes limit tests, chemical tests etc.

Chromatographic and spectroscopic analysis
It includes TLC, HPLC, HPTLC, GC, UV, IR, FT-IR, AAS, LC-MS, GC-MS, fluorimetry etc.

Microbiological parameters
It includes the full content of viable, total mould count, total coliforms count. Limiters can be used as a quantitative tool or semi-quantitative to determine and control the amount of impurities, such as reagents used in the extraction of various herbs, impurities ships directly from the manufacturing and solvents etc.

2. Who Guidelines for Quality Standardized Herbal Formulations

1. Quality control of crude drugs material, plant preparations and finished products.
2. Stability assessment and shelf life.
3. Safety assessment; documentation of safety based on experience or toxicological studies.
4. Assessment of efficacy by ethno medical information's and biological activity evaluations. The bioactive extract should be standardized on the basis of active principles or major compounds along with the chromatographic fingerprints (TLC, HPTLC, HPLC, and GC).

1. Quality Control of Herbal Drugs
Quality control for efficacy and safety of herbal products is of paramount importance. Quality can be defined as the status of a drug that is determined by identity, purity, content, and other chemical, physical, or biological properties, or by the manufacturing processes. Quality control is a term that refers to processes involved in maintaining the quality and validity of a manufactured product. The term "herbal drugs" denotes plants or plant parts that have been converted into phytopharmaceuticals by means of simple processes involving harvesting, drying, and storage [3]. Hence they are capable of variation. This variability is also caused by differences in growth, geographical location, and time of harvesting. A practical addition to the definition is also to include other crude products derived from plants, which no longer show any organic structure, such as essential oils, fatty oils, resins, and gums. Derived or isolated compounds (e.g. strychnine from strychnous nux-vomica) or mixtures of compounds (e.g. abrin from Abrus precatorius).

In general, quality control is based on three important pharmacopeial definitions

- Identity- it should have one herb
- Purity – it should not have any contaminant other than herb
- Content or assay-the active constituents should be within the defined limits.

It is obvious that the content is the most difficult one to assess, since in most herbal drugs the active constituents are unknown. Sometimes markers can be used which are, by definition, chemically defined constituents that are of interest for control purposes, independent of whether they have any therapeutic activity or not [4]. Identity can be achieved by macro and microscopical examinations. Voucher specimens are reliable reference sources. Outbreaks of diseases among plants may result in changes to the physical appearance of the plant and lead to incorrect identification [5,6]. At times an incorrect botanical quality with respect to the labeling can be a problem. Purity is closely linked with safe use of drugs and deals with factors such as ash values, contaminants (e.g. foreign matter in the form of other herbs), and heavy metals. However, due to the application of improved analytical methods, modern purity evaluation also includes microbial contamination, aflatoxins, radioactivity, and pesticide residues. Analytical methods such as photometric analysis, Thin layer chromatography (TLC), High performance liquid chromatography (HPLC), High performance thin layer chromatography (HPTLC), and Gas chromatography (GC) can be employed in order to establish the constant composition of herbal preparations. Content or assay is the most difficult area of quality control to perform, since in most herbal drugs the active constituents are unknown. Sometimes markers can be used. In all other cases, where no active constituents or marker can be defined for the herbal drug, the percentage extractable matter with a solvent may be used as a form of assay, an approach often seen in pharmacopeia [7,8]. A special form of assay is the determination of essential oils by steam distillation. When active constituents (e.g. sennosides in senna) or markers (e.g. alkydamides in Echinacea) are known, a vast array of modern chemical analytical methods such as ultraviolet/visible spectroscopy(UV/VIS), TLC, HPLC, HPTLC, GC, mass spectrometry, or a combination of GC and MS(GC/MS), can be employed [9].

2. Stability Assessment and Shelf Life
The past decade has seen a significant increase in the use of herbal medicines. As a result of WHO‟s promotion of traditional medicine, countries have been seeking the assistance of the organization in identifying safe and effective herbal medicines for use in national health care systems. Prolonged and apparently uneventful use of a substance usually offers testimony of its safety. In a few instances, however, investigation of the potential toxicity of naturally occurring substances widely used as ingredients in these preparations has revealed previously unsuspected potential for systematic toxicity, carcinogenicity and teratogenicity. Regulatory authorities need to be quickly and reliably informed of these findings. They should also have the authority to respond promptly to such alerts, either by withdrawing or varying the licences of registered products containing suspect substances, or by rescheduling the substances to limit their use to medical prescription [10].

Assesement of quality
All procedures should be in accordance with good manufacturing practices.

Crude plant material
The botanical definition, including genus, species and authority, description, part of the plant, active and characteristics constituents should be specified and, if possible content limits should be defined. Foreign matter, impurities and microbial content should be defined or limited. Voucher specimens, representing each lot of plant material processed, should be authenticated by a qualified botanist and should be stored for at least a 10-year period. A lot number should be assigned and this should appear on the product label.

Plant preparations
The manufacturing procedure should be described in detail. If other substances are added during manufacture in order to adjust the plant preparation to a certain level of active or characteristics constituents or for any other purpose, the added substances should be mentioned in the manufacturing procedures. A method for identification and, where possible, assay of the plant preparation should be added. If identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances to ensure consistent quality of the preparation.

Safety assessment:
Herbal medicines are generally regarded as safe based on their long-standing use in various cultures. However, there are case reports of serious adverse events after administration of herbal products. In a lot of cases, the toxicity has been traced to contaminants and adulteration. However, some of the plants used in herbal medicines can also be highly toxic. As a whole, herbal medicines can have a risk of adverse effects and drugdrug and drug-food interactions if not properly assessed. Assessment of the safety of herbal products, therefore, is the first priority in herbal research. These are various approaches to the evaluation of safety of herbal medicines. The toxic effects of herbal preparation may be attributed mainly to the following: Inherent toxicity of plant constituents and ingredients and Manufacturing malpractice and contamination. Evaluation of the toxic effects of plant constituents of herbal formulation requires detailed phytochemical and pharmacological studies. It is, however, safe to assume that, based on human experiences in various cultures, the use of toxic plant ingredients has already been largely eliminated and recent reports of toxicity could largely ne due to misidentification and overdosing of certain constituents [11]. Substitution and misidentification of herbal substances, documented or regulatory approaches, development of monitoring and surveillance systems, assessment of toxicity, risk assessment approach. The evaluation of new herbal products consists of six steps, which define the following: Characteristics of new substances, history and pattern of use, any adverse reaction, biological action, toxicity and carcinogenicity, and clinical trial data. The presence of impurities is either an intended addition, or accidental contamination via processing. The substitution of plants arises because of similar plants/ wrong identification, or the use of cheaper alternatives.

3. Literature Survey
Arun Rasheed et.al. [2012] have studied Herbal medicines are not a simple task since many factors influence the biological efficacy and reproducible therapeutic effect. Standardized herbal products of consistent quality and containing well-defined constituents are required for reliable clinical trials and to provide consistent beneficial therapeutic effects. Pharmacological properties of an herbal formulation depend on phytochemial constituents present therein. Development of authentic analytical methods which can reliably profile the phytochemical composition, including quantitative analyses of market/bioactive compounds and other major constituents, is a major challenge to scientists. An overview covering various techniques employed in extraction and characterization of herbal medicines as well as herbal nanomedicines standardization is reported. In addition, phytosomes increased bioavailability, bhasma as ametal nanobarrier drug delivery system, potential of metabolomics in the development of improved phytotherapeutic agents, DNA based molecular markers in adulterants, and SCAR markers for authentification and discrimination if herbs from their adulterants are reported. Nanotechnology based herbal drugs possess improved solubility and enhanced bioavailability. [1]

Ghiware Nitin B. et.al. [2010] have studied the present investigation, three orally administrable dosage forms of fruits of Piper nigrum (Maricha) and leaves of Nyctanthes arbortristis (Parijataka), in combination, were developed. Tablet form of drugs from solid dosage form and two formulations from liquid class were designed and developed. By considering difficulty of solubility of herbal drugs in a vehicle, in one of the liquid class, decoction form of drugs in specific vehicle was used. This form of drugs hereafter considered as Liquid Oral Dosage Form of drugs. To prepare a liquid form with suspended particles of drugs, Suspension form was also designed. Formulated dosage forms then subjected to evaluation of production quality by different methods stated as per official compendia. Such evaluation has unique position in development of new formulations. [2]

Margret Chandira et.al.[2010] have studied Medicinal plants have curative properties due to the presence of various complex chemical substance of different composition, which are found as secondary plant metabolites in one or more parts of these plants. Ipomoea digitata Linn., Convolvulaceae is a annual extensive perennial climber with large ovoid and tuberous roots herb indigenous to India and widely used in the treatments of hypolipodemic, hypogycemic, for debility, to increase secretion of milk, to increases milk, poor digestion, tuberculosis, enlarged liver etc. It was also found to have alterative, aphrodisiac, cholagogue, demulcent, diuretic, rejuvenative actions. The present paper deals with formulation and evaluation of anti-diabetic activity of tablets prepared from aqueous extract of the selected plant. A solid pharmaceutical dosage formulation using a novel dry plant extract (tuberous roots) using various excipients viz., carbopol, ethylcellulose, MCC, dibasic calcium phosphate and PEG-4000 by direct compression was reported to be statically significant as anti-diabetic activity. The present communication also deals with the evaluation of formulated tablets (weight variation, friability, hardness and disintegration time). [3]

Chew Oon Sim et.al. [2004]Pharmacognosical analysis of medicinal herbs remain challenging issues for analytical chemists, as herbs are a complicated system of mixtures. Analytical separation techniques for example high performance liquid chromatography (HPLC), gas chromatography (GC) and mass spectrometry (MS) were among the most popular methods of choice used for quality control of raw material and finished herbal product. The application of infrared (IR) spectroscopy in herbal analysis is still very limited compared to its applications in other areas (food and beverage industry, microbiology, pharmaceutical etc). This article attempts to expand the use of FTIR spectroscopy and at the same time creating interest among prospective researcher in herbal analysis. A case study was conducted by incorporating appropriate chemometric methods (Principal Components Analysis, PCA and Soft Independent Modelling of Class Analogy, SIMCA) as tools for extracting relevant chemical information from the obtained infrared data. The developed method can be used as a quality control tool for rapid authentication from a wide variety of herbal samples.[4]

Seraina Caprez [2005] Traditional Chinese medicine (TCM) enjoys great popularity in western countries. The distribution of TCM products has much increased and become a lucrative business. The prospect of fast profit attracts dubious companies, which act only via the internet. This market is nearly uncontrollable and implicates several risks. In general the quality of such products is not ensured. Contamination with chemicals, heavy metals, banned pesticides and microbes are a known problem in Asian herbal medicines. But there are also cases of adulteration with synthetic agents. The aim of this diploma thesis was to develop simple and rapid high performance thin-layer chromatographic methods for the detection of synthetic adulterants in herbal preparations.[5]

4. Objectives and Plan of Work

Main is using formulation also called physiotherapy since the beginning of record history. Ayueveda is the oldest known physiotherapy, which is now a day of great demand due to the adverse side effect in allopathic system of medicine.

Herbal formulation are prepared from the plant source and the activity of these formulations is mainly due to the active constituent present in them. There are number of herbal formulation available in market, but very few methods have been reported for the quantitative determination of active constituents present in them.

Clove is the herbal drug mainly used in dental analgesic,stimulant, aromatic flavoring agent and antiseptic agent.These actions are due to its active constituent .Which is found in its volatile oil content known as clove oil .The main active constituent is Eugenol(60-90%).

The main Objective of this study is develop analytical method for the quantitative determination of eugenol. i.e. the active constituent of clove oil, which is present in various herbal formulations.

Plan of Work

1. Identification test of Supplied of Eugenol.
- Determination of density.
- Determination of Boiling point.
- Thin layer Chromatography.
2. Determination of number of Hydroxy group.
3. Development of Spectrophotometric method by using different reagent.
4. Application of the successful method for the estimation of the drug in herbal formulation.
5. Compilation of work.

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