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A COMPREHENSIVE REVIEW ON NEED OF QUALITY EVALUATION OF AYURVEDIC MEDICINES

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ABSTRACT

In ancient times collection, identification and preparations of Ayurvedic formulations were strictly followed by the *Vaidyas* themselves, later with the passage of time the collection, preparation were done by pharmaceutical industry. Worldwide need of alternative medicine has resulted in growth of natural product markets and interest in traditional systems of medicine. There is a growing focus on the importance of medicinal plants in the traditional health care system (*viz*. *Ayurveda*, *Unani*, *Homoeopathy*, *Yoga*) in solving health care problems Nowadays in market, lots of Ayurvedic preparations are there. So many preparations are found to be hazardous for human being. Some of the manufacturers have engaged themselves to earn more money by supplying substandard drugs. Some of the plants used in Ayurvedic medicines can also be highly toxic, so assessment of the safety of herbal products is necessary. To check the malpractices by the suppliers and the manufacturing units the standardization of formulation is highly needed. The efficiency and quality of an Ayurvedic preparation can be only judged by drug standardization. To achieve this goal one should follow the path of drug standardization. Therefore standardization i.e. to develop the pharmacopeia standards is the only tool which provides as authentic Ayurvedic preparation in the present science age. Present paper highlights the need of quality evaluation of Ayurvedic medicines by using modern tools for their standardization.

KEYWORDS: Herbal drugs, Ayurvedic medicines, Quality evaluation, Physico-chemical Analysis.

INTRODUCTION

India is a mother hub for development of *Ayurveda,Yoga, Unani, Siddha, Homoeopathy* and other natural herbs based health science (AYUSH). As we all know in our Ayurvedic system of medicines, drug standardization of Ayurvedic formulation is a big challenge. Clear cut guidelines have not been developed so far. World Health Organization (WHO) stresses the importance of the qualitative and quantitative methods for characterizing the samples, quantification of the biomarkers and or chemical markers and the fingerprint profiles. In recent years more people throughout world are turning to use medicinal plant products in healthcare system. Proper integration of modern scientific techniques and traditional knowledge is important. Systematic approach and well-designed methodologies for the standardization of herbal raw materials and herbal formulations are developed. Evaluation of the parameters based upon chemical, physical, microbiological, therapeutic and toxicological studies can serve as an important tool in quality evaluation. Standardization of herbal drugs means confirmation of its identity, Quality and purity.

The development of the methodologies of various types of formulations has greater importance in quality assurance and efficacious character of the drug. This need various pharmacopeia parameters for different formulation described in Ayurvedic literature which are categorized as *Vati, churna, Avleha, asava, Arishta, Gutika, Bhasmas, taila* etc. Standardization as defined by American Herbal Product association: "Standardization refers to the body of information and control necessary to product material of reasonable consistency. This achieved through minimizing the inherent variation of natural product composition through quality assurance practices applied to agricultural and manufacturing processes.[1]

MATERIAL AND METHODS

Medicines prepared by our *Acharyas* were more efficacious but in present scenario many manufacturers are adding adulterants in Ayurvedic formulations which render them less effective. The Ayurvedic medicines contains single plant materials or combination of several plants some plants are poisonous also and some preparations contain metals, minerals.

The problems encountered procurement of authentic plant materials are mainly due to the following:

1. Collection from wildly growing plants from forests and waste lands.

2. Suppliers of plant materials are generally traders who have limited knowledge of medicinal plants collected from various regions sources of the country.
3. Non-homogeneity of the plant materials due to the collection from wild and even different geographical locations and then pooled together.
4. Adulterated or substituted plant materials due to collection by person not fully acquainted with the differences in various species of the specific plant.

Though poisons are harmful and dangerous to life, *Ayurveda* has mentioned the use of poisonous drug therapeutically as a medicine after *Shodhana Sanskara*. The medicinal poisonous substances if consumed in excessive quantity or in impure form it may fatal so, our *Aacharyas* told *Shodhana Sanskara* i.e. method of purification. There are the well designed processes through which the therapeutics of the drug can increase." Shodhanam Gunvardhanam" itself signifies the enhancing effect of therapeutics of the drug.

In modern era, every toxic drug is used after its analytical study. They used different modern advanced machineries and technologies to indentify the consistencies in the crude drugs. They prefer different techniques as physico-chemical analysis, Thin Layer Chromatography (T.L.C.), High Performance Thin Layer Chromatography (H.P.T.L.C.) to identify the toxic material.

In Ancient time-such types of technique and machineries were not available. So our *Aacharya* studies on experimental and observational basis. It is the observational study by which they identify the toxic food Material.[2],[3]

- Changes the voice of crow.
- Eyes of Chacor turns whitish pale.
- Peacock dances to see the toxic substance.
- If flies ate toxic material it dies.

In ancient times *Aacharya* own collect raw material from forest. They had knowledge of identification of drugs and its purification. Some ancient methods for quality evaluation of herbal drug:[4]

***Rutu*:** i.e. collection time some drugs are seasonal as well as some parts of herb should collect in specific *Rutu*.

***Desha*:** Availability of some drugs in specific area e.g. *Himalaya*, so geographical distribution is important one.

***Nakshtra*:** Collection of some drugs should be collected on specific *Nakshtra*.

Now days, if someone want to prepare a drug; he buys the material from market which is not reliable. That's why in today's professional world qualitative examination as well as analytical study of medicinal preparation is essential. In ancient days *Rekhapurnatva*, *Sukshmatva*. Examination was done after preparation of medicines, which are totally based on laboratorial observation. So there is need to apply modern methods of qualitative standardization.

Who Guidelines For Quality Evaluation of Ayurvedic Medicines[5]

- Quality control of crude drugs material, plant preparations and finished products.
- Stability assessment and shelf life.
- Safety assessment; documentation of safety based on experience or toxicological studies.
- Assessment of efficacy by ethno medical information and biological activity evaluations.

Methods of Standardisation of Ayurvedic Medicines[6]

Methods of standardization should take into consideration all aspects that contribute to the quality of the herbal drugs, namely correct identity of the sample, pharmacognostic evaluation, volatile matter, quantitative evaluation (ash values, extractive values), physiochemical evaluation, toxicity testing, and biological activity. Physiochemical standardization encompasses all possible information with regard to the chemical constituents present in an herbal drug. Hence, the physiochemical evaluation for standardization purpose includes the following:

1. Preliminary testing for the presence of different chemical groups.
2. Quantification of chemical groups of interest (*g.*, total alkaloids, total phenolics, total tannins).
3. Multiple marker-based fingerprint profiles.

PHYSICOCHEMICAL ANALYSIS

Determination of Foreign Matter: Herbal drugs should be prepared from the confirmed part of the plant. They should be totally free from insects or moulds, including visible and excreta contaminant such as stones, sand, harmful and poisonous foreign matter and chemical residues. Animal objects such as insects and invisible microbial contaminants, which produces toxins, as well as the potential contaminants of herbal medicines. Macroscopic

evaluation can easily used to determine the presence of foreign matter, although microscopy is essential.

Chemical Evaluation: Qualitative chemical test used to identify drug quality and purity. The identification, isolation and purification of active chemical constituents is depends chemical methods of evaluation. [7],[8]

Chromatographic Fingerprinting and Marker Compound Analysis: A chromatographic fingerprint is a chromatographic pattern of the extract of some common chemical components of pharmacologically active constituents.

Physical Evaluation: Each monograph contains detailed botanical, macroscopic and microscopic descriptions with detailed illustrations and photographic images which provide visual documentation of accurately identified material. A microscopic analysis assures the identity of the material and as an initial screening test for impurities. [9]

Determination of ash: The ash remaining following ignition of medicinal plant materials is determined by three different methods which measure total ash, acid-insoluble ash and water-soluble ash. The total ash method is designed to measure the total amount of material remaining after ignition. This includes both "physiological ash", which is derived from the plant tissue itself, and "non- physiological" ash, which is the residue of the extraneous matter adhering to the plant surface. Acid-insoluble ash is the residue obtained after boiling the total ash with dilute hydrochloric acid, and igniting the remaining insoluble matter. This measures the amount of silica present, especially as sand and siliceous earth. Water soluble ash is the difference in weight between the total ash and the residue after treatment of the total ash with water.

Determination of extractable matter: This method determines amount of active constituents extracted with solvents from a given amount of medicinal plant material. [10]

1. Water Soluble extractives
2. Alcohol Soluble extractives
3. Ether Soluble extractives

TLC: Thin layer chromatography is simply known as TLC. It is one of the most popular and simple chromatographic technique used of separation of compounds. In the physiochemical evaluation of herbal drugs, TLC is being employed extensively for the following reasons:

1. It enables rapid analysis of herbal extracts with minimum sample.
2. It provides qualitative and semi quantitative information of the resolved compounds.
3. It enables the quantification of chemical constituents.

In TLC fingerprinting, the data that can be recorded using high-performance TLC (HPTLC) scanner includes the chromatogram, retardation factor (R_f) values, the color of the separated bands, their absorption spectra, λ_{max} and shoulder inflection/s of all the resolved bands.

All of these, together with the profiles on derivatization with different reagents, represent the TLC fingerprint profile of the sample. The information so generated has a potential application in the identification of unauthentic drug, in excluding the adulterants and in maintaining the quality and consistency of the drug.

HPTLC: HPTLC technique is widely employed in pharmaceutical industry in process development, identification and detection of adulterants in herbal product and helps in identification of pesticide content, toxins and in quality control of herbs and health foods.[11] It has been well reported that several samples can be run simultaneously by use of a smaller quantity of mobile phase than in HPLC. [12] Another advantage of HPTLC is the repeated detection (scanning) of the chromatogram with the same or different conditions. Consequently, HPTLC has been investigated for simultaneous assay of several components in a multi-component formulation. [13] With this technique, authentication of various species of plant possible, as well as the evaluation of stability and consistency of their preparations from different manufactures.

HPLC: Preparative and analytical HPLC are widely used in pharmaceutical industry for isolating and purification of herbal compounds.

Liquid Chromatography - Mass Spectroscopy: (LC-MS) LC-MS has become method of choice in many stages of drug development. [14] Recent advances includes electro spray, thermo spray, and ion spray, ionization techniques which offer unique advantages of high detection sensitivity and specificity.

Liquid Chromatography-Nuclear Magnetic Resonance (LCNMR): LC-NMR improves speed and sensitivity of detection and found useful in the areas of pharmacokinetics, toxicity studies, drug metabolism and drug discovery process. It is one of the most powerful and time saving method for the separation and structural elucidation of unknown compound and

mixtures. These new hyphenated techniques are useful in the areas of pharmacokinetics, toxicity studies, drug metabolism and drug discovery process.[15]

Gas Chromatography (GC-MS): GC equipment can be directly interfaced with rapid scan mass spectrometer of various types. GC and GC-MS are unanimously accepted methods for the analysis of volatile constituents of herbal medicines, due to their sensitivity, stability and high efficiency. Especially, the hyphenation with MS provides reliable information for the qualitative analysis of the complex constituent.[16]

DNA Fingerprinting: Deoxyribonucleic acid DNA analysis has been proved as an important tool in herbal drug standardization. This technique is useful for the identification of phytochemically indistinguishable genuine drug from substituted or adulterated drug. Adulterants can be distinguished even in processed samples, enabling the authentication of the drug.[17]

Determination of Arsenic and Heavy Metals: Contamination of medicinal plant materials with arsenic and heavy metals can be attributed to many causes including environment pollution and traces of pesticides.[18]

DISCUSSION

In today's competitive world the mentality of professionalism is increasing day by day. As the demand for medicine is increasing rapidly, the pharma companies are responsible for maximum production in minimum time. Hence the quality of medicine is degraded. The quality assessment of herbal formulation is important to justify their acceptability and safety. One of the major problems faced by the *Ayurveda* physicians is the unavailability of unique quality control parameters for herbal medicines and their formulations. 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. These guidelines for the assessment of herbal medicines are intended to facilitate the work of regulatory authorities, scientific bodies and industry in the development, assessment and registration of such products. The advancement of analytical techniques will serve as a rapid and specific tool in the herbal research.

Thus the physic-chemical analysis of Ayurvedic Medicines (Final product) should be done by running high performance liquid chromatography (HPLC) or gas chromatography (GC) and

thin layer chromatography (TLC) methods, quantitative determinations by UV visible spectroscopy or combinations of these. HPLC and GC methods can be used for identification and purity testing, as well as the detection of single compounds for assay, is possible during one analysis.[19] LC and GC mass coupling are the also tools for determination but, they are highly sophisticated and expensive methods. Disintegration time, Loss on Drying, Total Ash, Acid Insoluble Ash, Acid Soluble Ash, Water Insoluble Ash, Water Soluble Ash, Water Soluble Extractive, Alcohol Soluble Extractive, Assay for Iron as Fe, Assay for Mercury as Hg, Assay for Copper as cu, Assay for Arsenic as As, Assay for Sulphur as S and Assay for other heavy metals for determination of proper amount of heavy metals in final product.

CONCLUSION

Consumption of a formulation which is not well purified may be harmful and may show toxic effects on the body. Such formulations may be ineffective or less effective in some cases whereas it may result in poisonous effect also. A great attention in this regard is necessary. It is stated that strong poisons can be best medicine when used in correct therapeutic dose, formulation and a good medicine can also effect adversely if not used properly for proper person in proper dose.[20] Consumption of such a formulation which is not well purified may be harmful and may show toxic effects on the body. The Drug can be useful only after removing these impurities. Otherwise it can be hazardous rather than beneficial. Therefore it is the necessary to standardize Ayurvedic Medicines for their quality evaluation. The present paper provides summary of Physicochemical analysis for testing formulations containing poisonous ingredients. The subject for herbal drug standardization is massively wide and deep. The assurance of the safety and efficacy of herbal drug requires monitoring of the quality of the product from collection through processing to the finished packaged product[21]. Thus for the quality evaluation of Ayurvedic medicines it is necessary to standardize Raw materials, in process standardization and final product standardization using sophisticated modern techniques of standardization.[22]

Thus we can conclude that various government agencies should follow a more universal approach to prepare Ayurvedic medicines by adopting the WHO guidelines and parameters for quality evaluation. This will strengthen the regulatory process and minimize quality breach. The safety and efficacy of herbal products are dependent upon the standardization of the herbal drugs.[23],[24] The quality of herbal drugs is the sum of all factors which contribute directly or indirectly to the safety, effectiveness and acceptability of the product.

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