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COMPENDIAL TESTING METHOD ON HERBAL CRUDE DRUG - A REVIEW

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ABSTRACT

In recent years there is a spurt in the interest regarding survival of Ayurvedic forms of medication. In the global perspective, there is a shift towards the use of medicine of herbal origin, as the dangers and the shortcoming of modern medicine have started getting more apparent, majority of Ayurvedic formulation are prepared from herbs. Herbal product has been enjoying renaissance among the customers throughout the world. However, one of the impediments in the acceptance of the Ayurvedic formulation is the lack of standard quality control profile. The quality of herbal medicine i.e. the profile of the constituents in the final product has implication in efficacy and safety. Plant material and herbal remedies derived from them represent substantial portion of global market and in this respect internationally recognized guidelines for their quality assessment and quality control are necessary. WHO has emphasized the need to ensure quality control of medicinal plant products by using modern technique and by applying suitable parameters and standards. In order to overcome certain inevitable shortcoming of the Pharmacopoeial monograph other quality control measures must be explored. Quality control has wide connotation and covers; many aspects of drug manufacture, distribution and sale is not restricted to final product analysis either regulatory or otherwise, while engaging in this task, it must be realized that some of the Quality control practices that work excellently either modern drug may not be appropriate with ASU drug.

Key words: herbal medicines, Quality control testing, crude drug.

INTRODUCTION

World Health Organization (WHO) has defined herbal medicines as finished labeled medicinal product that contain active ingredients, aerial or underground parts of the plant or other plant material or combinations.[1,]

In almost all the traditional system of medicine, the quality control aspect has been considered from its inspection of itself Rishis, Vaidyas and Hakims. However, in modern concept it require necessary changes in their approach by that way concrete method of quality control in terms development of modern methodologies. Thus today quality assurance is thrust area for the evaluation of traditional used medicinal plants and herbal formulation.

Hence the first important task is to evolve such parameter by which the presence of the entire ingredient can be identified, various chromatographic and Spectrophotometric methods and evaluation of physicochemical properties can be tried to evolve pattern for identifying the presence of different ingredient [2].

Current Regulations for Standardization of Crude Drugs

Internationally several pharmacopoeias have provided monographs stating parameter and standard of many herbs and some product made out of these herbs. Several pharmacopoeias like

- Pharmacopoeia Committee
- Chinese Herbal Pharmacopoeia

- United States Herbal Pharmacopoeia
- British Herbal Pharmacopoeia
- British Herbal Compendium
- Japanese Standards for Herbal Medicine
- The Ayurvedic Pharmacopoeia of India (API)

Lay down monograph for herbs and herbal products to maintain their quality in their respective nations. Government of India too has brought out Ayurvedic Pharmacopoeia India, which recommends basic quality parameters for eighty common Ayurvedic herbal drugs.

Standardization and Quality Control of Herbal Crude Drugs [3]

Accounting to WHO it is the process involving the physicochemical evaluation of crude drug covering the aspects, as selection and handling of crude material, safety, efficacy and stability assessment of finished product, documentation of safety and risk based on experience, provision of product information to consumer and product promotion.

- **Macro and Microscopic Examination:** For Identification of right variety and search of adulterants.
- **Foreign Organic Matter:** Remove of matter other than source plant to get the drug in pure form.
- **Ash Values:** It is criteria to judge the identity and purity of crude drug – Total ash, sulfated ash, water soluble ash and acid insoluble ash etc.
- **Moisture Content:** To check moisture content helps prevent degradation of product.
- **Extractive Values:** These are indicating the approximate measure of chemical constituents of crude drug.
- **Crude Fiber:** To determine excessive woody material Criteria for judging purity.
- **Qualitative Chemical Evaluation:** It covers identification and characterization of crude drug with respect to phytochemical Constituent.
- **Chromatographic Examination:** Include identification of crude drug based on use of major chemical constituent as marker.
- **Qualitative Chemical Evaluation:** Criteria to estimate amount the major class of constituents.
- **Volatile oils:** its cover the measurement of the volatile content of the plant.
- **Bitterness value:** The bitter properties of plant material are determined by comparing the threshold bitter concentration of an extract of the materials with that of a dilute solution of quinine hydrochloride R.
- **Haemolytic activity:** The haemolytic activity of plant materials, or a preparation containing saponins, is determined by comparison with that of a reference material, saponin R.

- **Foaming index:** The foaming ability of an aqueous decoction of plant materials and their extracts is measured in terms of a foaming index.
- **Pesticide residues:** it measures the pesticide residues in the plant.
- **Swelling index:** it measures the swelling property of the medicinal plant.
- **Arsenic and heavy metals:** Contamination of medicinal plant materials with arsenic and heavy metals can be attributed to many causes including environmental pollution and traces of pesticides.
- **Microorganisms:** Current practices of harvesting, handling and production may cause additional contamination and microbial growth.
- **Radioactive contamination :** A certain amount of exposure to ionizing radiation cannot be avoided since there are many sources, including radio nuclides occurring naturally in the ground and the atmosphere.
- **Toxicological Studies:** Pesticide residue, potentially toxic elements, and Microbial count approach to minimize their effect in final product.

Physical evaluation: [1]

Each monograph contains detailed botanical, macroscopic and microscopic descriptions of the physical characteristics of each plant that can be used to insure both identity and purity. Each description is accompanied by detailed illustrations and photographic images which provide visual documentation of accurately identified material.

Microscopic evaluation [2]

Full and accurate characterization of plant material requires a combination of physical and chemical tests. Microscopic analyses of plants are invaluable for assuring the identity of the material and as an initial screening test for impurities. Most manufacturers of herbal products lack the quality control personnel to accurately assess plant identity and purity microscopically. The Ayurvedic Herbal Pharmacopoeia (AHP) fully characterize herbal products against the literature and AHP. Verified trade mark authenticated materials to assure identity of test materials. Ideally, submitted materials should be in their whole or semi-whole (cut) form for microscopic assessment. However, much information can be discerned from microscopic evaluation of powders as well.

Chemical evaluation

A chemical method for evaluation covers the isolation, identification and purification. Chemical analysis of the drug is done to assess the potency of vegetable and animal source material in terms of their active principles. The chemical tests include colour reaction test, these tests help to determine the identity of the drug substance and possible adulteration.

Biological evaluation

Pharmacological activity of certain drugs has been applied to evaluate and standardize them. The assays on living animal and on their intact or isolated organs can indicate the strength of the drug or their preparations. All living organism are used, these assays are known as Biological assays or Bioassay [4].

Analytical Methods

Critical to compliance with any monograph standard is the need for appropriate analytical methods for determining identity, quality, and relative potency. There are a plethora of analytical methods available. However, it is often difficult to know which is the most appropriate to use. The primary goal of AHP is to provide multiple methods of identification and testing by which all aspects of the botanical can be appropriately assayed.

Chromatographic Characterization

Chromatography

Chromatography is the science which studies the separation of molecules based on differences in their structure and/or composition. In general, chromatography involves moving a preparation of the materials to be separated the "test preparation" over a stationary support. The molecules in the test preparation will have different interactions with the stationary support leading to separation of similar molecules. Test molecules which display tighter interactions with the support will tend to move more slowly through the support than those molecules with weaker interactions. In this way, different types of molecules can be separated from each other as they move over the support material. Chromatographic separations can be carried out using a variety of supports, including immobilized silica on glass plates (thin layer chromatography), very sensitive High Performance Thin Layer Chromatography (HPTLC), volatile gases (gas chromatography), paper (paper chromatography), and liquids which may incorporate hydrophilic, insoluble molecules (liquid chromatography).

Purity Determination

Each monograph includes standards of purity and other qualitative assessments which include when appropriate: foreign matter, ash, acid-insoluble ash, moisture content, loss of moisture on drying, and extractives.

High performance thin layer chromatography (HPTLC) is valuable quality assessment tool for the evaluation of botanical materials. It allows for the analysis of a broad number of compounds both efficiently and cost effectively. Additionally, numerous samples can be run in a single analysis thereby dramatically reducing analytical time. With HPTLC, the same analysis can be viewed using different wavelengths of light thereby providing a more

complete profile of the plant than is typically observed with more specific types of analyses [5].

Quantitative Analysis

Primary factors for considering a method as appropriate include accuracy of the findings, speed, basic ruggedness, applicability to a large segment of the manufacturing community, and avoidance of the use of toxic reagents and solvents. In an attempt to promote harmonization, primary consideration is given to those methods which are already accepted in official pharmacopoeias or by AOAC International. The validation process minimally includes: standard precision, linearity, sample precision using replicate samples, sample linearity, selectivity (co-elution, sensitivity to analyte degradation), retention times, and limits of detection. Other methods which may be of value to the industry may be included or cited in the monograph but are not required for compliance with the monograph.

WHO Guidelines for Quality Standardized Herbal formulations

Standardization and quality control parameters for herbal formulations are based on following fundamental parameters:

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 ethnomedical information and biological activity evaluations.

Quality Control of Crude Material

According to pharmaceutical manufacturers association of U.S. "quality is the sum of all the factors which contribute directly or indirectly to the safety, effectiveness and acceptability of the product" [3]. Standardization describes all measures taken during manufacturing process and quality control leads to reproducible quality of particular product. Standardization of botanicals offers many obstacles because synthetic drugs have well defined structure and other analytical parameters as well as reference standard for comparison also established assays and pharmacopoeias. Therefore, quality control is not problematic for synthetic drug [5]. There are several challenges as standardization of herbal product is considered like controversial identity of various plants, deliberated adulteration of plant material, problems in storage and transport, which should be considered [6]. One of the impediments in the acceptance of the herbal products worldwide is the lack of standard quality control profiles. Most of the herbal formulations, especially the classical formulations of traditional medicine, are polyherbal. In the United States, herbs are used either as dietary supplements,

with minimal standards of safety and efficacy, or as drugs, which require expensive and cumbersome testing procedures.

Concept of Validation

In order to control quality of herbal drugs in better way, we must amalgamate newer techniques and terms to maximum extent. USFDA defines validation as, "Validation is documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predefined specifications and quality attributes".

This concept of validation is getting well applied to manufacturing of synthetic drugs from long time back. But this concept is not that much deeply or methodically studied and applied for the manufacturing of herbal drugs. All international regulations like USFDA, MCC, MHRA, TGA etc. shows the applicability of validation to pharmaceutical manufacturing but no one regulation except WHO applies the validation concept to manufacturing of herbal drugs. WHO also emphasize on very little part of validation. Due to that reason the authors want to emphasize on the concept of validation and also the validation model for manufacturing of herbal drugs. There is simple and mostly used validation model for manufacturing of synthetic drugs.

Validation model for synthetic drugs

We propose how this model is applied to for manufacturing of herbal drugs and also the limitation of that validation model for synthetic drugs. Generally one can describe this model straightforward that means starting from input and ends to output. But in case of validation one has to go in reverse direction. First of all to identify and define which type of quality product required i.e. product has its own identity, strength, safety, purity and efficacy [7].

1. Identity - having specific shape, packing (strip or blister or alu-alu)

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2. Strength - having specific strength (500mg/tablet, strip of 10 tablets having 500mg/tablet etc.)
3. Safety - safe for both i.e. person who is engaged in manufacturing and the person who is going to take that tablet.
4. Purity - shows purity (99.9% pure)
5. Efficacy - it shows the desired therapeutic efficacy.
6. After deciding the required output, the processes and its parameter are defined, e.g. for manufacturing of tablet (Gutika),
7. Mixing - how much time is required for mixing?
8. Granulation - which type of granulation (Wet or Dry) for how much time?
9. Compression - how much pressure and for how much of time is required?
10. Packing - which type of packing (strip or blister or alu-alu)?

Validation Model for Manufacturing of Herbal drugs

There are lots of parameters which has to be considered while certifying the manufacturer: Type of Herbs

1. Environmental conditions
2. Time of collection etc.
3. Variation in composition

CONCLUSION

Because of gravity of the problem, profound knowledge of the important herbs found in India and widely used in Ayurvedic formulation along with new standardization techniques is of utmost importance. Incorporation of this will authenticate quality thereby reducing further problems. Quality is inspected at right starting point then it will eliminate all bottlenecks in quality control of herbal formulations to obtain better formulations. We wish to draw the attention of readers to the rapidly evolving standardization aspects of herbal drugs with some new ideas, so that this area could be expanded significantly.