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STANDARDIZATION OF MEDICINAL PLANT MATERIALS

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ABSTRACT
With the changing pattern of life style most of the diseases are now becoming lifestyle diseases. The world is witnessing an unprecedented growth in the usage of herbal product at national as well as international levels. These have necessitated development of modern and objective standards for evaluating the safety, quality and efficacy of these medicines. The current standards, parameters and protocols available to test the quality of herbal medicines were originally developed for allopathic drugs and can at best authenticate the identity plant materials (may be purity to some extent) not their safety and efficacy.
Herbal medicines are natural products and their phytoconstituents depending on time and region, processing and storage. Variations in the collection, processing or storage of an herb could impact its efficacy profile. Since prior knowledge regarding appropriate collection and usage of most medicinal plants exists in tradition, it can be used as a guide to quality standardization. The parameters of testing the quality of materials (dravya) in traditional medicines, such as rasa (taste), guna (properties), (potency), vipaka (post digestion effects) and karma (action) are very different from the western methods. These traditional parameters reflect not only the quality but also efficacy. Having said which, there are no direct written protocols available in traditional medicines either for collection or for testing the action. The methods of testing are lost today need revivification
KEYWORDS: Standardization, Traditional Medicine, efficacy, revivification

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INTRODUCTION

Medicinal plants, since times immemorial, have been used in virtually all cultures as a source of medicine. The widespread use of herbal remedies and healthcare preparations, as those described in ancient texts such as the Vedas and the Bible, and obtained from commonly used traditional herbs and medicinal plants, has been traced to the occurrence of natural products with medicinal properties. Herbal medicine is still the mainstay of about 75 - 80% of the world population, mainly in the developing countries, for primary health care. The recent years have witnessed resurgence of interest in herbal medicines as more and more people throughout world are turning to use medicinal plant products in healthcare system. The sales for herbal medicine products have plateaued to such an extent that these products have become available to consumers as positive healthcare just like vitamins. They are now found in supermarkets, pharmacies and numerous other main stream retail outlets as over-the-counter drug products. This is primarily because of the general belief that herbal drugs are without any side effects besides being cheap and locally available. According to the World Health Organization (WHO), the use of herbal remedies throughout the world exceeds that of the conventional drugs by two to three times[22]

The increased use of herbal medicines in developed countries is mainly due to the failure of modern medicine in providing effective treatment for chronic diseases and emergence of multi-drug resistant bacteria and parasites. These include various new diseases such as cancer, HIV/AIDS, diabetes, hepatitis, allergies and mental disorders. The adverse effects of chemical drugs, questioning of the approaches and assumptions of allopathic medicine, their increasing costs and greater public access to information on safety and efficacy of medicinal plants has also led to an increased interest in medicinal plants[3]

When patients use home remedies for acute, often self-limiting conditions, such as cold, sore throat, or bee

sting, it is often because professional care is not immediately available, too inconvenient, costly or time-consuming.

In rural areas, there are additional cultural factors that encourage the use of botanicals, such as the environment and culture, a "man earth relationship." People believe that where an area gives rise to a particular disease, it will also support plants that can be used to cure it. In India vast sections of the rural population have no assess to modern medicine. Hundred of primary health care centers which are intended to serve rural areas, lack staffs, diagnostic facilities, and adequate supplies of drugs. Thus rural population is heavily dependent on traditional medicinal systems.

With more and more no. of people switching once again towards the alternative system of medicine in order to avoid harmful side effect of synthetic drug, it is essential that they get superior quality and genuine medicines. Most herbal products on the market today have not been subjected to drug approval process to demonstrate their safety and effectiveness. Some of them contain mercury, lead, arsenic and corticosteroids and poisonous organic substances in harmful amount. Hepatic failure and even death following ingestion of herbal medicine have been reported. The majority of Ayurvedic formulation available on the market is spurious, adulterated or misbranded. Most commercially available preparation does not even conform to ancient Ayurvedic text. It is therefore essential to establish quality standards for their use as drugs and as raw material for preparation of other drug products. Without a quality control, there is no assurance that the herb contained in the bottle is the same as what is stated on the outside. Quality standards for some plants are available in various Herbal and Ayurvedic Pharmacopoeias but due to diversity and vast number of species of plants numerous plants have not been listed in the pharmacopoeia which devoid them of proper methodologies for standardization. Thus Standardization of a crude drug is an integral part of establishing its correct identity. Standardization of herbal drugs is gaining momentum in India and as a result, it is also proposed to include the safety parameters as per International norms. Standardization of medicinal plants means the approval of quality and identity of that medicinal plant which contain no adulteration or contamination that can reduce the efficiency of its medicinal capabilities[22]

History of Herbals

Medicinal plants used in traditional system of medicine since antiquity as mentioned in **Table 1**. i.e. the no. of drugs which were used in traditional systems[13]. History reveals that medicinal plants have traditionally served as man's most important weapon against pathogen. A large number of plants have been used in traditional medical practices for more then 3000 years such as in Chinese traditional medicine, Ayurveda, Unani medicine As early as 2000 B.C. the Chinese were using moulds to treat ulcers and Egyptians are known to have applied mouldy bread to open wounds in 1984[15]

There are about 10,000 plant species which are being used in Indian System of Medicines (ISM) / traditional medicines in Indian subcontinent. Out of these, 450-500 species are mostly used in over 85% of Ayurvedic, Unani and Siddha formulation and about 40 species are used in modern drugs[9]

Revival of Herbal medicines

An evolution of pharmaceutical industry arose around the early part of 20th century globally. With the progress in chemical techniques, crude drug came to be replaced by pure chemical drugs and the developed countries witnessed a decline in popularity of medicinal plant therapy. However, during the recent past, the pendulum has swung again and there is a resurgence of interest in study and use of medicinal plants. Now the medicinal plants as a whole occupy a stable position in modern medicine, since the pharmaceutical industry is showing special interest in using or synthesizing natural substances extracted from plants[21]. **Table 2** lists some of the plants which are used for their medicinal or insecticidal use[20] Further there has been an ever-increasing demand especially from developed countries for more and more drugs from plant sources. The revival of interest in plant derived drugs is mainly due to current widespread belief that "GREEN MEDICINE" is safe and more dependable than the costly synthetic drugs, many of which have adverse side effects[21]

Advantages of Herbal Medicine

Herbal medicine have long history of use and better patient tolerance as well as acceptance.

Medicinal plants have a renewable source, which is our only hope for sustainable supplies of cheaper medicines for the world growing population.

Availability of medicinal plants is not a problem especially in developing countries like India having rich agro-climatic, cultural and ethnic biodiversity.

The cultivation and processing of medicinal herbs and herbal products is environmental friendly.

Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.

Through out the world, herbal medicine has provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude

form and as a pure chemical upon which modern medicines are structured[22]

These medicinal plants are responsible for changes in socio-economic status as poor farmers cultivate medicinal plants viz . *Albizia lebbek Benth*.(siris), *Chlorophytum borivilianum* (safed musali), *Aloe barbadensis*.(Aloe vera), *Terminalia* arjuna (arjuna), *Withania somnifera* (asvagandha)[18] and various species which can be used are listed in **Table 3** which also shows that a single medicinal plant can be used foe multiple ailments[8]

Limitations of Herbal Medicines

The prominent limitations of herbal medicine can be summarized as follows

Ineffective in acute medical care

As may be observed, herbal medicines are not very effective to treat any acute illness, as most of the medicines are designed to work at molecular level of physiology, the drug takes its time to deliver the results.

Inadequate standardization and lack of quality specifications

This is the most often criticized aspect of herbal medicines. One important fact is that a herbal medicines. One important fact is that a herbal preparation is administered for its holistic value. Each herbal ingredient in the herbal preparation has an array of chemical constituents with complex molecular formulae. This each herbal preparation is a source of polypharmacy within itself. As results, standardization of herbal preparation or its ingredients become a highly complex issue.

Lack of scientific data

Literature on herbal medicines, lack of Lack of scientific data in support of the medicinal activity claimed and their safety and efficacy assumed. Hence there is a need to incorporate certain parameters of the pharmacological evaluation of moderns on modern lines[22]

Potentially serious drug interactions

Increasingly more patients are taking herbal medication either as health supplement or for treatment of ailments. many patients have already tried some form of OTC herbs before consulting a physician. Herbal medicine present a greater risk of adverse effects and interactions **(Table 4)** than any other complement medication therapy this is particularly true in elderly patients with chronic cardiovascular disease as many common herbs alter bleeding time (garlic, ginger, ginseng) and interact with conventional cardiac medications (digoxin, diuretics, anti-arrythmics)[4]

Why peoples switching once again towards herbal

Four approaches to the use of plants as medicine include

1. The magical/shamanic

Almost all non-modern societies recognise this kind of use. The practitioner is regarded as endowed with gifts or powers that allow him/her to use herbs in a way that is hidden from the average person, and the herbs are said to affect the spirit or soul of the person.

2. The energetic

This approach includes the major systems of Ayurveda, and Unani. Herbs are regarded as having actions in terms of their energies and affecting the energies of the body. The practitioner may have extensive training, and ideally be sensitive to energy, but need not have supernatural powers.

3. The functional dynamic

This approach was used by early physiomedical practitioners, whose doctrine forms the basis of contemporary practice in the UK. Herbs have a functional action, which is not necessarily linked to a physical compound, although often to a physiological function, but there is no explicit recourse to concepts involving energy.

4. The chemical

Modern practitioners - called Phytotherapists - attempt to explain herb actions in terms of their chemical constituents. It is generally assumed that the specific combination of secondary metabolites in the plant are responsible for the activity claimed or demonstrated, a concept called synergy[2]

So it can be said that the increased use of herbal medicines in developed countries is mainly due to failure of modern medicine in providing effective treatment for chronic disease and emergence of multi drug resistant bacteria and parasites. These include various new diseases such as cancer, diabetes, hepatitis, allergies, and mental disorders. The adverse effects of chemical drugs, questioning of approaches and assumptions of allopathic medicine, their increasing costs and greater public access to information on safety and efficacy of medicinal plants has lead to an increased interest in medicinal plants[3].**Table 5** lists some of plants which are used in Treatment of Cancer[16]

Why Make Herbal Remedies?

(For every ailment, there is a cure growing somewhere on earth)

Why go to the trouble of making herbal remedies when the drug store is a block away? In terms of history, this question has only been around for about 3 generations maybe 100 years or so. People in the past didn't have drug stores. And surprise, they didn't have headaches, indigestion, gas, or constipation either. One of the biggest problems with modern medicine is the overuse of antibiotics. We have used antibiotics to a point that we have found ourselves in an age of Super Diseases that are

resistant to every tool known to modern medicine. Antibiotics completely thwart that natural defense mechanism and render it much less effective over the long-term

So why aren't the big drug companies tripping over themselves trying to find an herbal combination that will cure cancer or AIDS? You guessed it - Money. Time and time again, It's all about money and our industrialized society, and the fact that plants can't be patented. No drug company in it's right mind is going to commit to millions of dollars in research for something that, as soon as the results are published, will be duplicated and marketed by every competitor on the planet - because plant materials can't be patented[7]

NEED OF STANDARDIZATION

In olden times, vaidyas used to treat patients on individual basis, and prepare drug according to the requirement of the patient. In almost all the traditional system of medicine, the quality control aspect has been considered from its inspection of itself Rishis, Vaidyas and Hakims. Unlike in olden times where traditional practitioners prepared and tested the qualities of herbal medicines, the problem faced today are these of economics of industrial scale production, shelf life and distribution to long distances. These have necessitated development of modern and objective standards for evaluating the safety, quality and efficacy of these medicines. People are also becoming aware of the potency and side effect. To gain public trust and to bring herbal product into mainstream of today health care system, the researchers, the manufacturers (**Table 6** lists the various manufacturers of herbal formulation[19]) and the regulatory agencies must apply rigorous scientific methodologies to ensure the quality and lot-to-lot consistency of the traditional herbal Products [22]

It is the cardinal responsibility of the regulatory authorities to ensure that the consumers get the medication, which guarantee Purity, safety, potency and efficacy. 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.[22] Due to complex nature and inherent variability of the constituents of plant based drugs (**Table 7** & **Table 8**), it is difficult to establish quality control parameter and modern analytical technique are expected to help in circumventing this problem[9].

Quality controls of synthetic drug offer no problems with very well defined parameters of analysis. In contrast, herbal products represent a number of unique problems when quality aspects are considered. These are because of the nature of the herbal ingredients present therein, which are complex mixtures of different secondary metabolites that can vary considerably depending on environmental and generic factors[22]

Furthermore, the constituents responsible for the claimed therapeutic effects are frequently unknown or only partly explained. These complex positions of quality aspects of herbal drugs are further complicated by the use of combination of herbal ingredients as are being used in traditional practice. It is not uncommon to have as many as five different herbal ingredients in one product. Thus batch to batch variation starts from the collection of raw material itself in the absence of any reference standard for identification. These variations multiply during storage and further processing.

The task of lying down standards for quality control of herbal crude and their formulation involves biological evaluation for a particular disease area, chemical profiling of the material and lying down specification for the finished product. Therefore, in case of herbal drugs and product, the word "Standardization" should encompass entire field of study from cultivation of medicinal plant to its clinical application.[22]

The poor quality of herbal medicines can be attributed to use of substandard raw medicinal plant materials. **(Table 9)** The factors that can affect the safety and quality of raw medicinal plant materials and finished product can be either intrinsic e.g. genetic or extrinsic such as environment and storage practices. Microbial or chemical contamination during processing can also compromise the safety and quality. Mistakes in proper identification of the plant species, accidental contamination or intentional adulteration by other species or plant parts can also lead to poor quality of end product. (Adulteration indicates the admission of impurities or removal of all part or valuable portion of drug or it may be addition of grade or spoiled with the genuine one. Many methods have been and are still used for the adulteration of crude drugs particularly in those stocks which are collected from wild sources in general adulteration occurs

- When a drug is scarce
- When the price of drug is normally high, though there may be no scarcity[15]

It is necessary to standardize the safety and quality assurance measures so as to ensure a steady, affordable and sustainable supply of medicinal plant materials of good quality. The pharmaceutical industry has shown interest in development of standardized plant

preparations with proven safety and efficacy. However, their focus has been on isolating newer active principles from plant unlike the rural communities that use fresh/dried plant material or their crude extracts. Moreover it is generally believed that standardization of plant material is not required when used by rural communities for primary health care, but regardless of whether the medicinal plant is to be used by local communities or by industry, a systemic approach is required for the validation of efficacy and safety of medicinal plants[22]

To ensure safety and quality of the medicinal plants it is necessary to focus on all aspects of medicinal plant research from ethno - pharmacology, utilization, isolation and identification of active constituents to efficacy evaluation, safety, formulation and clinical evaluation. Quality control of the medicinal plants starts right at the source of the plant material. The phytochemical composition of the plant material and the resulting quality can vary due to several factors including a number of environmental factors such as geographical location, soil quality, temperature and rainfall etc. taxonomy, the time of collection, method of collection, cultivation, harvesting, drying and storage conditions, preparation and processing methods can also affect composition. Contamination by microbes, chemical agents such as pesticides and heavy metals as well as by insects and animals during any of these stages can also lead to poor quality of the finished products. Standardization of all these factors is necessary to meet the current standards of quality, safety and efficacy[3]

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 [22]

ROLE OF W.H.O. IN HERBAL MEDICINE

Traditional medicine has been defined by WHO as "Referring to health practices, approaches, knowledge, and beliefs incorporating plants animals and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat diagnose and prevent illness to maintain well being[14]

WHO developed guidelines for the assessment of herbal medicine and same were ratified by the 6th international conference of DRA held at Ottawa

WHO has also provided guidelines for clinical research of traditional medicines which consider both efficacy and safety and is done for Good Clinical Practices. In addition to evaluate safety and efficacy of traditional medicine there may be a number of different objectives

Some of objectives specific to assessment of traditional medicine through clinical research are to

- Evaluation of traditional medicines in its own theoretical framework
- Evaluate traditional medicines in theoretical framework of conventional medicine
- Compare the efficacy of different traditional practices within a system of traditional medicine[11]

WHO Guidelines for Quality Standardized Herbal Formulations

a. Quality control of crude drugs material, plant preparations and finished products.

b. Stability assessment and shelf life.

c. Safety assessment; documentation of safety based on experience or toxicological studies.

d. Assessment of efficacy by ethnomedical 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). The standardization of crude drug materials includes the following steps:

1. **Authentication** (Stage of collection, parts of the plant collected, regional status, botanical identity like phytomorphology, microscopical and histological analysis, taxonomical identity, etc.)
2. **Foreign matter** (herbs collected should be free from soil, insect parts or animal excreta, etc.)
3. **Organoleptic evaluation** (sensory characters – taste, appearance, odor, feel of the drug, etc.)
4. **Tissues of diagnostic importance present in the drug powder**.
5. **Ash values and extractive values**.
6. **Volatile matter**
7. **Moisture content determination**
8. **Chromatographic and spectroscopic evaluation**. TLC, HPTLC, HPLC methods will provide qualitative and semi quantitative information about the main active constituents present in the crude drug as chemical

markers in the TLC fingerprint evaluation of herbals (FEH).

9. **Determination of heavy metals** – e.g. cadmium, lead, arsenic, etc.

10. **Pesticide residue** – WHO and FAO (Food and Agricultural Organization) set limits of pesticides, which are usually present in the herbs. These pesticides are mixed with the herbs during the time of cultivation. Mainly pesticides like DDT, BHC, toxaphene, aldrin cause serious side-effects in human beings if the crude drugs are mixed with these agents.

11. **Microbial contamination** – usually medicinal plants containing bacteria and molds are coming from soil and atmosphere. Analysis of the limits of E. coli and molds clearly throws light towards the harvesting and production practices**(Table 10)**. The substance known as afflatoxins will produce serious side-effects if consumed along with the crude drugs. Afflatoxins should be completely removed or should not be present.

12. **Radioactive contamination** – Microbial growth in herbals are usually avoided by irradiation. This process may sterilize the plant material but the radioactivity hazard should be taken into account. The radioactivity of the plant samples should be checked accordingly to the guidelines of International Atomic Energy (IAE) in Vienna and that of WHO.

The stability parameters for the herbal formulations which includes physical parameters, chemical parameters, and microbiological parameters.

Physical parameters include color, appearance, odor, clarity, viscosity, moisture content, pH, disintegration time, friability, hardness, flow ability, flocculation, sedimentation, settling rate and ash values.

Chemical parameters includes limit tests, extractive values, chemical assays, etc.

Chromatographic analysis of herbals can be done using TLC, HPLC, HPTLC and GC, UV, Fluorimetry, GC-MS, etc.

Microbiological parameters include total viable content, total mold count, total enterobacterial and their count. Limiters can be utilized as a quantitative or semi quantitative tool to ascertain and control the amount of impurities like the reagents used during abstraction of various herbs, impurities coming directly from the manufacturing vessels, impurities from the solvents, etc.

Chemical decomposition of substances present in the formulation also produces several toxic or impure compounds during storage in undesirable conditions. Contaminants may come directly from the atmosphere also. This include mainly dust, sulfur dioxide, H_2S, CO_2, Arsenic, moisture, etc[23]

WHO simultaneously has taken job to develop monographs for herbs and traditional medicines

A typical monograph should contain

- Definition
- Synonyms
- Selected vernacular names
- Description
- Organoleptic properties
- Microscopic characters
- Powdered pt. Materials
- Geographical distribution
- General identity test
- Purity test microbiology
- Total ash
- Acid insoluble ash
- Water soluble extractive
- Alcohol soluble extractive
- Pesticide residue
- Heavy metals
- Radioactive residues
- Other purity test
- Chemical assays
- Major chemicals
- Dosage form
- Medicinal usage
- Uses described in pharmacopoeias
- Uses described in TM's
- Pharmacology
- Contraindications
- Warning
- Precautions
- Adverse reactions
- Posology [12]

STANDARDIZATION AND QUALITY CONTROL OF HERBAL CRUDE DRUGS

Accounting to WHO it is the process involving the physicochemical evaluation 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.[22]

Several approaches have been proposed to reach a significant level of reliability of the phytochemical diagnostics for the herb. These include many approaches as[17]

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 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 phytochemicals 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 .

Toxicological Studies: (Pesticide residue, potentially toxic elements, and Microbial count approach to minimize their effect in final product.

Physical evaluation:

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 that provide visual documentation of accurately identified material.

Microscopic evaluation

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.

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 color 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.

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.

Chromatographic Characterization

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.

Quantitative Analysis

When applicable, the most appropriate quantitative analytical method with accompanying chromatograms shall be provided. The primary goal of the method(s) is to provide validated methods to be used for the quantization of the compound(s) most correlated with pharmacological activity or qualitative markers as determined by the primary pharmacological literature, constituent declaration in product labeling, and a survey of experts. The method(s) will be selected from the primary analytical literature by a Methods Selection Committee with priority given to compendial methods when available. In this context, validation consists minimally of a two-lab validation using the same procedures, samples, and reference standards.[22]

EXAMPLES-

Pharmacognostic Evaluation of Leaves of *Mitracarpus scaber* Zucc (Rubiaceae)

Purpose -It assist in standardization of quality, purity and sample identification. Various parameters which has been calculated are listed in **Table 11** & **Table 12**

So any crude drug which is claimed to be *Mitracarpus scaber* but whose characters significantly deviate from the accepted standard above would then be rejected as either contaminated, adulterated or downright fake [1]

Pharmacognostic Evaluation of Leaves of *Gisekia pharnacioides* (Molluginaceae)

Various parameters which has been calculated are listed in **Table 13** & **Table 14**

So any crude drug which is claimed to be *Gisekia pharnacioides* but whose characters significantly deviate from the accepted standard above would then be rejected

as either contaminated, adulterated or downright fake The pharmacognostic constants, the diagnostic microscopic features and numerical reported could be useful for compilation of a suitable monograph for its proper identification [10]

CONCLUSION

With the tremendous increase in the global use of medicinal plants, several concerns regarding the safety and quality of herbal medicines have also been observed. hence it has become necessary to standardize the quality and safety assurance measures so as to ensure supply of medicinal plants of good quality. Though the pharmaceutical industry has been focusing on standardization of plant material when manufacturing herbal drugs, it is generally believed that standardization is not required when used by the rural community for their primary health care. However irrespective of whether the plant is being used by the industry or the rural community standardization is being required

The difference comes when using isolated active constituents that are required by the pharmaceutical industry for manufacturing herbal drugs whereas rural communities may use standardized extracts. The decision on whether to collect plants from wild or to cultivate it depend on the feasibility of approach for that particular species. After proper botanical identification, WHO guidelines should be followed for collecting plant materials in term of proper season and climatic conditions, correct plant part practices that are non destructive and would provide contamination from soil, toxic weeds or microbes. Post collection, appropriate processing and storage conditions are required to reduce drying time, detoxification to reduce side effects and to enhance therapeutic value of the plant material and to improve its shelf life. Phytochemical standardization for identification of the plant material can be carried out by obtaining chemical fingerprint through chromatographic technique or through bioassay or DNA fingerprinting. Chromatographic and spectroscopic techniques have proved very useful in isolation and proper identification of active constituents in the plant extracts. Hence standardization involve the quality control of various factors affecting the therapeutic activity of plant right from selection of plant species to formulation of herbal drugs so as to minimize batch to batch variation and meet standard of quality, safety and efficacy

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Table 1 - No. of drugs mentioned in traditional systems

S.N	Year	Type	Drugs
1	2000 BC	Rigveda	67
2	2000 BC	Yajurveda	81
3	1600-1100 BC	Atharvaveda	290
4	900 BC	Charak Samhita	341
5	600 BC	Sushruta Samhita	395
6	1550 AD	Bhava Mishra In His Treatise	470

Table 2 - Medicinal/insecticidal plants of desert reason in Rajasthan

S.No	Plant species	Utilization resources
1	*Acacia nilotica* (deshi babool)	Anti - diabetic
2	*Asparagus racemosa* (satavari)	Rejuvenator
3	*Calotropis procera* (aak)	Larvicidal, anti-malarial, analgesic, and anti pyretic
4	*Cucumis sativas* (khira)	Insecticidal
5	*Ocimum americanum* (ram tulsi)	Mosquito repellant
6	*Salvadora oleoids* (kharo jhal)	Flowers in prevention of heat stroke
7	*Evolus alsinoides* (shankhpushpi)	Brain tonic
8	*Azadirachta indica* (neem)	Mosquito repellant
9	*Solanum nigrum* (makoii)	Larvicidal

Table 3- Important species of medicinal plants

Vernacular name	Scientific name	Number of formulations in which it was included	Number of ailments treated
Tulsi	*Ocimum sanctum* L.	16	15
Kali- mirch	*Piper nigrum* L.	14	12
Haldi	*Cucurma domestica Valeton*	13	12
Sarson	*Brassica campestris*	10	10
Muli	*Raphanus sativus* L.	13	9
Bel	*Aegle marmelos* (L.)	11	9
Pyaz	*Allium cepa* L.	9	9
Pudina	*Mentha longifolia* L.	9	9
Awala	*Phyllanthus emblica* L.	9	9
Adrak	*Zingiber officinale*	10	7
Neebu	*Citrus spp.*	7	7
Badam	*Terminilia catappa* L.	8	6
Neem	*Azadirachta indica*	7	6
Lahsun	*Allium sativum* L.	6	6
Aam	*Mangifera indica* L.	6	5
Saunf	*Foeniculum vulgare*	5	5
Haida	*Termenalia chebula*.	5	5
Anar	*Punicum granatum* L.	5	5
Amrood	*Psidium guajava* L.	5	5
Ritha	*Sapindus muskorosii*	4	4
Methi	*Trigonella foenumgraceum* L.	4	4
Kela	*Musa* sp.	4	4
Karela	*Momordica charantia* L.	4	4
Doob	*Cynodon dactylon* L.	4	4
Arandi	*Ricinus communis* L.	4	4

Table 4 - Different herbs their evidences and their potensial problems

Herb	Uses	Evidence	Conventional drug	Potential problem
Echinacea	Prevention & treatment of common cold	Lack of properly designed trials, data inconclusive	Steroids, methotrexate, ketoconazole	Hepatotoxicity
Evening primrose oil	Pre-menstrual syndrome	2 best trials failed to show benefits	Anti - convulsant	Lowered seizure threshold
Gingko leaf	Dementia, tinnitus	Superior to placebo	Warfarin, aspirin	Altered bleeding time
Valerian root	Insomnia	Inconclusive data	Barbiturates	Additive-effects
Feverfew z leaf	Migarine Prophylaxis	Superior to placebo	Warfarin, NSAIDs	NSAIDs inhibit feverfew. Altered bleeding time
Garlic	Hypercholes trolemia	Small short time benefits on lipid and anti platelet properties	Warfarin, aspirin	Altered bleeding time
Ginger root	Nausea & vomiting	Promising data, but more rigorous trials needed	Warfarin, aspirin	Altered bleeding time

Tab.5 - Some of Important Medicinal Plants Used In Treatment of Cancer

PLANT NAME / FAMILY	DRUGS	TREATMENT
Catharanthus roseus L (Apocyanaceae)	Vinblastine and vincristine	Hodgkins, lymphosarcomas
Podophyllum emodi wall. (berberidaceae)	Podophyllotaxin	Testicular cancer, small cell lung cancer and lymphomas
Taxus brevifolius (taxaceae)	Paclitaxel, taxotere	Ovarian cancer, lung cancer and malignant melanoma
Mappia foetida miers.	Comptothecin, irenoteccan and topotecan	Lung, ovarian and cervical cancer

Table 6 - Manufacturers of herbal formulation

S.NO.	Name of the company
1	Ansar Drug Laboratories, Surat
2	Avis laboratories, Kanpur
3	Allen Laboratories, Kolkatta
4	Dabur India Limited, Ghaziabad
5	Herbal Pvt. Limited, Patna
6	Hamdard (Wakf) Laboratories, Delhi
7	Zandu Pharmaceutical Works Ltd., Bombay
8	Charak Pharmaceuticals, Bombay
9	Baidyanath Ayurveda Bhawan, Jhansi
10	The Himalya Drug Co.,Banglore

Table 7 - Different plants sold under the name of ajmoda

S.NO.	Species	Volatile oil	Important constituents
1	*Apium graveolens* (celery)	1-2%	Limonene(85%), pentyl benzene, 3-n butyl phthalide & other phthalides
2	*A.leptophyllum*	1-2%	Monoterpenes, coumarins
3	*Trachspermum roxberghianum*	4-5%	Limonene (l5%),cadinener(24%), cycloavandulala/acid (l5-25%), seselin (l2-l5%)
4	*T.ammi*	2-5%	p-cymene, terpinene, thymol

Table 8 - Different plants sold under the name of Kala Zeera & Safed Zeeera

Species	Volatile oil	Important constituents
KALA ZEERA		
Carum carvi	2.5-4%	d-limonene, d-carvone
Bunium periscum	4-12%	p-cymene, terpinene, cuminaldehyde, p-mentha 1,3dienals
B .cylindricum	1-2%	Myristicin, elemenes
Nigella sativa		Carvone, limonene, p-cymene, thymol, nigellone
SAFED ZEERA		
Cumin cyminum	1.5-3%	p-cymene, cuminaldehyde, p-mentha-1,3 dienals

Table 9 - Some Common Medicinal Plants And Their Adulterants

S.no	Botanical name and family	Common name (s)	Adultrant (s)
1	*Atropa acuminata* Royle ex Lindley	Deadly night shade- angur shala	Leaves of *solanum nigrum* and other species of *solanum* and datura as adulterants
2.	*Azadirachta indica A.juss Melia azadirachta* Linn. meliaceae	Neem, margosa, nim, neem	The leaves of *melia azedarach* (often used as substitute)
3	*Cassia angustifolia* Vahl. (caeselpiniaceae)	Senna leaves, Indian senna	Often confused with leaves of *Cassia acutifolia, C.obovata*
4	*Datura stramonium* Linn (Solanaceae) .	Thorn apple, Sada datura	Leaves of *xanthium italicum, chenopodium hybridum* and some other species are adulterated with it
5	*Datura metel* Linn. (Solanaceae)	White datura, safed datura	Leaves of other species of datura
6	*Digitalis purpurea* Linn.(Scrophulariaceae)	Foxglove, digitalis	*Digitalis lanata, digitalis lutea, inula conyza*
7	*Mentha piperita* Linn. (Labiateae)	Peppermint, pudina	Genuine species are widely adulterated with species having less % of menthol particularly with *M. virdis, M.arvensis*
8 .	*Momordica charantia* Linn (cucurbitaceae)	Bittergourd , karela	*Momordica balsamina, M..dioica*

Table 10- Limits for Microbial Contamination

Microorganism	Finished product	Raw materials
E. coli	10^1	10^4
Salmonella	-	-
Total aerobic bacteria	10^5	-
Enterobacteria	10^3	-

Table 11 - Numerical data of leaves of *Mitracarpus scaber*

Parameter	Mean (%w/w)
Moisture content	13.6500 ± 0.156
Total ash	13.3167± 0.2565
Acid - insoluble ash	06.1667± 0.1351
Water - soluble ash	02.1667 ± 0.0630
Water soluble extractive	00.3440 ± 0.0017

Table 12 - Quantitative leaf microscopy of *Mitracarpus scaber*

Parameter	Range	Mean
Palisade ratio	6.00-8.00	6.85 ± 0.3841
Stomatal number-Upper surface	8.00-10.00	8.80 ±0.1864
Stomatal number- Lower surface	5.00-9.00	6.95 ± 0.2348
Stomatal index- Upper surface	17.02-23.26	20.2785 ± 0.4150
Stomatal number- Lower surface	13.95- 17.65	16.0275 ± 0.2617
Vein islet number	3.00 - 4.50	3.35 ± 0.2915
Vein termination number	2.75-3.00	2.85 ± 0.0612

Table 13 Quantitative leaf microscopy of *Gisekia pharnacioides* (Molluginaceae)

Parameter	Range	Mean
Palisade ratio	24-32	28.0
Stomatal number	36-48	41.0
Stomatal index	09-13	10.0
Vein islet number	09-14	11.5
Vein termination number	11-14	12.3

Table 14 Numerical data of leaves of *G. pharnacieoides*

Parameter	Mean (%w/w)
Moisture content	11.20 ± 2.0
Ash Value	5.50± 0.1
Acid - insoluble ash	2.00 ± 0.4
Alcohol-extractive value	6.60 ± 0.5
Water - extractive value	32.84 ± 2.0

Table 15 Major Traditional Sectors of Pharmaceutical Companies

S.N	Traditional sector pharma	Modern sector pharmas	Standardization of phytomedicine (formulation)
1	Himalya	Ranbaxy	Chromatography technique
2	Zandu	Lupin	Thin layer chromatography
3	Dabur	Allembic	U.V. spectrophotometer
4	Hamdard		High performance lipid chromatography (HPLC)
5	Maharishi		Nuclear magnetic resonance spectroscopy (NMR)