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Indispensability of herbal drug standardization

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Abstract
The world is witnessing unprecedented growth in the usage of herbal products. India is the mother hub for natural herbs based science. One of the major problems faced by the herbal industry is the unavailability of rigid quality control profiles for herbal materials and their formulations. Traditional medicines, an age-old heritage inherited from years of experience, are bound to contain some valuable elements but inevitably they also contain some ingredients which are no longer useful. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicine.

Keywords: Standardisation, raw material, in-process control, sophisticated techniques

Introduction
From times immemorial, herbal drugs have been used as the medicines for treating various kinds of diseases. Medicinal herbs have played a key role in World health. In spite of the great advances noted in modern medicines in recent decades, plants still make and predominant contribution to health care. Natural products have been our single most successful medicinal source. Plants can be compared with the factories because of its capability to produce various secondary metabolites.

"The Greatest thing about herbal drug is that its Treatments always yield side benefits, not side effects."
Herbals are traditionally considered harmless and increasingly being consumed by people without prescription [1]. However, pure form of herbal drugs has to be consumed. There are certain factors influencing phytochemical profile of medicinal plants such as seasonal changes, Geographical factors, genetic variants [2], etc., Therefore, quality of raw drugs used in manufacturing as the finished Ayurvedic formulations are seen with a suspicion by the common people. Hence the evaluation of quality of any herbal preparation is inevitable requirement of industry and other Ayurvedic organisations.
The major obstacle in the wider acceptability of Ayurveda and its products is the lack of proper standardisation techniques. WHO guidelines are to be strictly followed for the assessment of the safety, efficacy and quality of herbal medicines is of prime importance [3].
We are in the urge of transforming Ayurveda into a dynamic, scientifically validated and evidence based which takes its roots from rich knowledge base of oral tradition and scriptures.
The Allopathic practitioners themselves have lost confidence in the use of it. Since most of the people are looking for natural cures to diseases, a new branch of Allopathy is emerging, the natural Allopathy. The medicines used there under are made from natural ingredients and are safe to be used by one and all.
Some profit making companies are adulterating Ayurvedic formulations by using the allied species or by skipping one/ other drug present in the general composition. For instance, Nilavembu Kashayam has mentioned by the Ayurvedic Pharmacopeia of India Says that it includes 9 various plant materials out of which *Andrographis paniculata* is the key ingredient. Profit minded industries started producing the Kashayam by using only two to three local ingredients available. Because of this, the effect produced by the genuine formulation is reduced or hampered in one or the other way. All these consequences will be nullified only when the rules and regulations are becoming mandatory for the authentication and standardisation of raw materials used in the formulation.

Unexplored Queries of Herbal Formulations
Following are the questions pertaining to Herbal formulations which were unanswered so far.
1. The analysis and the standardisation of finished products.
2. Safety and side effects of the formulation.

3. Correct doses and duration of treatment.
4. Mode of Action.

These questions become more compounded in the absence of any standards for raw and finished material. Lack of in-process quality control techniques makes it tedious to maintain the consistency and quality of the formulation. Therefore, there is an immediate need to develop standard protocol for the following.

1. Standardisation of raw material.
2. Assessment of in-process quality control techniques.
3. Standardisation of finished products.
4. Safety studies in animals.
5. Effective dose studies & Clinical trials.
6. Pharmacokinetic studies.

Limitations of Modern Medicines [4]

- Drugs taken against diabetes, neoplastic diseases, GI disorders, neuro degenerative disorders are to be taken for the life time. Apart from the adverse effects they cause, prolonged treatments imply heavy economic burden on patients.
- Rather treating and curing the diseases, they are primarily useful for alleviating morbidity resulting from disease conditions.
- Modern medicines predominantly focus on personalised medicines rather than the block buster drugs.
- Due to the economical reasons and poor returns on investments, many diseases of the poor are not targeted by the R&D department of large Pharma Companies.

Need and Necessity for the Herbal Drug Standardisation

- To prove that the medicine is safe and effective.
- Vegetable drugs are invariably inconsistent in composition. The composition of plant depends on age of the plant, season of the harvest, method of drying, etc[5].
- It serves as the tool to standardise the functional remedies of ingredients that are used in formulation.
- Standardisation is one of the prime factors to understand the uniform inactive principle.
- To encounter the adulterations done during the formulation[6]. Various adulterants are as follows,

i) Substitution with sub standard commercial varieties.
ii) Substitution with superficially similar inferior drugs.
iii) Substitution with artificially manufactured substances.
iv) Substitution with exhausted drugs.
v) Presence of vegetative matter from the same plant.

Quality Assessment as per WHO Guidelines [5]

- The botanical definition including genus, species and authority should be given to ensure the correct identification of a plant.
- A definition and description of the part of the plant from which the medicine is made should be provided together with an indication of whether fresh, dried or traditionally processed material is used.
- Manufacturing procedure and formula including the amount of excipients should be described in detail.
- The finished product should comply with general requirements for particular dosage forms.

General Protocol for the Quality Control of Raw Material [7-9]:

Raw materials used in the formulation are subjected to the standard quality control tests in order to ensure the quality of the finished product. The general protocol for the raw material standardisation can be designed in the following way.

Authenticity

The medicinal herbs can be identified by detailed taxonomical studies so that it can be distinguished easily from its allied species.

Foreign Matter

The plant parts other than those, which constitute the drug, are considered foreign matter. The drug should be free from foreign matter as well as extraneous matter like soil, dust, sand, etc.

Organoleptic Evaluation

Evaluation parameters which can be identified through the sensory organs such as taste, odour, fracture, etc. are inclusive under organoleptic evaluation.

Microscopical Examination

Adulteration in the raw material can be identified by the help of this method. It includes quantitative microscopy like lycopodium spore method, leaf constants, linear measurements, etc.

Volatile Matter

Mostly the volatile matter present in the raw material can be estimated by Steam distillation.

Ash Values

Purity of the raw material can be analysed by determining the various ash values like total ash, water soluble ash and acid insoluble ash.

Extractive Values

In order to find the amount of soluble constituents present, one may adopt the determination of extractive value. Water soluble extractive, ether soluble extractive and alcohol soluble extractive are the various types.

Chromatography

Most widely accepted method which in used both in the qualitative as well as the quantitative aspects. High performance thin layer chromatography, Liquid Column Mass spectroscopy, etc. are most commonly employed.

Pesticide Residue

In the present status, addition of pesticides to the crops has become unavoidable. Hence, pesticide residues should be determined.

Heavy Metal Determination

Heavy metal determination is one of important analysis in order to find out the presence of heavy metals. It should be within the specified limits.

Microbial Contamination

Microbes such as bacteria and moulds are likely to be present in the raw material. It should be tested and verified whether they are in the specified limits.

Radiation Contamination

This is to be tested as per the WHO guidelines.

In Process Control [5, 10]

1. For Extracts / Liquid Formulations:

a) Solvent and solvent blend composition.
b) Ratio of crude drugs to solvent.
c) Temperature.
d) Extraction time.
e) Method of collection of extract.
f) Method of concentration
g) Light sensitivity during extraction
h) Storage conditions, precautions, etc.

2. Solid Dosage Forms:

a) Particle size diameter
b) Order for blending
c) Time of blending
d) Granulating agent, binding agent and their concentration.
e) Drying time and temperature
f) Moisture content
g) Tablet hardness, friability, thickness, disintegration, weight, etc.
h) Spray rate
i) Coat and core ratio

3. Semi-Solids:

a) Solvent blend composition
b) Extraction process controls like temperature, time.
c) Concentration
d) Viscosity and other rheological parameter, etc.

Standardisation of Finished Products [5, 11, 12]

Although the raw materials used in the formulation were standardised, it becomes mandatory to check the quality of the final product. Following parameters are to be adopted in order to standardise an Ayurvedic formulation as per Ayurvedic Pharmacopoeia of India

- Organoleptic.
- Physical characteristics like viscosity, particle size, specific gravity, specific rotation, refractive index, etc..,
- Chemical characteristics that include chemical tests for identification and assay procedures.
- Biological activity (Efficacy and toxicity)
- Microbiological examination.
- Storage.
- Package and labeling.

Conclusion

WHO 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 assessment should reflect scientific knowledge gathered in the field. Such assessment could be the basis for future classification of herbal medicine in different parts of the world.

The effective regulation and control of herbal medicines moving in international; commerce also requires close liaison between national institutions that are able to keep under regular review of all aspects of production and use of herbal medicines, as well as to conduct or sponsor evaluative studies of their efficacy, toxicity, safety, acceptability, cost and relative value compared with other drugs used in modern medicine [5, 13].

Selling the medicinal item as a value based product is the great craze in the current scenario. For example, Neem sticks were used way long by our ancestors. But now it is sold in packets as value added products with an attractive label. Hence, it is our prime duty to prove the efficacy and the power of Ayurvedic drugs to the society in the way in which they will be accepted by all.

India can emerge as the major country and play the lead role in production of standardized therapeutically effective Ayurvedic formulation. Our mother nation needs to explore the medicinally important plants. This can be achieved only by the Sophisticated and modern methods of standardization techniques.

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