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STANDARDIZATION OF HERBAL DRUG: NEEDS, CHALLENGES AND SOLUTIONS

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ABSTRACT

We live in 21 century where everyone has become health conscious. A new fashion of eating a safe, quality product originated from natural sources are adopted and is in trend and this trend in people is increasing day by day. Even the pharmaceutical company cannot lack behind in providing the above requirements of people. The ultimate goal of pharma company is to produce and provide safe and effective quality of drug product in order to fulfil the demand of patient safety and efficacy. Hence in order to assure that their product is a quality product the company has to standardize the product. Also to minimize the side effect caused by the allopathy medicine, many companies are drifting their path to the herbal medicines. As the herbal medicine are natural in origin, there is minimum chances of side- effects, contamination and adulteration of products. It act as a boon for the manufacturing company as it has a easy availability with low cost of raw material. Hence it's a way of minimum cost with maximum production and reduce hassle.

KEYWORDS: Standardization, Herbal Drug.

INTRODUCTION

Herbal drugs are the drugs that are originated from the natural source. Herbal drugs are the drugs that are obtained from plants. The concept of Ayurveda was appeared and developed between 2500 and 500 B.C. Use of parts of plant such as root, shoot, stem, flower were used as a medicine. Their juice, churna, lepa were directly applied on the wound. But as the time

progress, need for urge in demand for standardization increased, leading to the standardize herbal drug product with safety and quality. Majority of the companies are focused on the standardization of the product as a parameter towards the safety and efficacy of the product. Many regulatory bodies such as WHO (World Health Organization) have establish the guidelines for the standardization of the herbal medicine.

NEEDS FOR STANDARDIZATION

- To help to produce the quality - based product drugs based on their active ingrediants .
- To determine the in-vivo parameter.
- To depict the acceptability in the modern system of medicine.
- To determine the quality and purity of the herbal drug.
- Assessment of quality of drugs by the physical, chemical, morphological, biological and analytical methods.

GUIDELINES AS PER WHO FOR HERBAL DRUG STANDARDIZATION

1. Botanical evaluation- refers to the drug identity which includes the sensory characters, foreign organic matters, microscopical, histological, biochemical evaluation and quantitative measurements.
2. Physicochemical characters- includes the physical and chemical characters like the extractive value, volatile oil, moisture content, alkaloid assay.
3. Pharmacological parameters include bitterness value, swelling index, foaming index.
4. Toxicity details includes pesticides, heavy metal.
5. Microbial contamination.
6. Radioactive contamination.

STANDARDIZATION OF HERBAL DRUGS

i. Organoleptic evaluation

evaluation which is physically examined i.e. the physical characteristics like colour, taste, size, shape are examined.

ii. Microscopic studies

-it includes the study under microscope. In order to observe the parts of crude drug in detail, T.S(transverse section), L.S. (lateral section) of crude drug are taken and studied under compound and simple microscope, if possible, Scanning Electron Microscope (SEM).

iii. Chemical evaluation

some crude drugs are identified after performing the chemical test. Depending upon the chemical constituent present crude drug are identified qualitatively. Qualitative methods include HPTLC (High Performance Thin Layer Chromatography), DNA fingerprinting. Whereas quantitative methods includes HPLC (High Performance Liquid Chromatography), GLC (Gas Liquid Chromatography).

iv. Physical evaluation- this includes the

a) Ash value

its used to measure the total amount of material produce after complete incineration of drug material at the lowest temperature in order to remove all the carbons. Total ash usually consist of carbonates, phosphates, silicates. According to IP and USP- 675 (plus or minus25 degree Celsius).

BP -600(plus or minus 25 degree Celsius),

WHO – 500-600 degree Celsius.

b) Acid insoluble ash

ash insoluble in HCL residue obtained after extracting the total ash with HCL, gives the idea of earthy matter. IP method 25 ml 2M HCL solution. USP method- 25ml 3N HCL solution, BP method – 15 ml water and 10ml HCL.

c) Water insoluble ash

content which is soluble in water, good indicator of previous extraction of water soluble salts in the drug or amount of inorganic matter.

d) Swelling index

it’s the volume taken up by swelling of 1 gram of plant material under the specified conditions.

e) Foaming index

it is the ability of the aqueous decoction of plant which contain saponins that cause a persistent foam when an aqueous decoction is shaken. Foaming ability is measured in terms of foaming index – Formula = 1000/a, where a – volume in ml of the decoction used for preparing the dilution in tube where foaming to the height of 1 cm is observed.

f) Determination of Arsenic, Lead, Cadmium

increase in the traces of arsenic may lead to the adverse effect on human as well as environmental pollution, hence a limit test for arsenic, cadmium, lead is performed. Lead and Cadmium is determine by the Atomic Emission Spectrometry.

g) Alfatoxins

naturally occurring mycotoxin produced by Aspergillus flavus and Aspergillus parasiticus, Aflatoxin are determined by using the standard aflatoxin B1, B2, G1, G2 mixtures.

IP method – NMT 2ug/kg of aflatoxin B1 and total aflatoxin 4ug/kg.

USP method- NMT 5ppb of aflatoxin B1 and total aflatoxin 20ppb.

h) Microbial assay

microbes are present everywhere. But by the cup-plate method, zig-zag method and other microbial count method one can determine the count of microbes in a specific region.

CHALLENGES IN STANDARDIZATION OF HERBAL DRUGS

- Impurities or contamination

Impurities are found in herbal drug, as its naturally obtained. Pesticides, heavy metals, microbial impurities are found in the herbal drug. Hence the detection of the impurities like foreign matter detection are conducted. The pesticide level should be within the acceptable range. Sample and reagents, GC-MS apparatus can be used for the determining the pesticides levels.

- Heavy metals

Presences of toxic metals and its increased amount is harmful for human leading to the toxicities and adverse effects. It can range to mild symptom like nausea to the serious effect like death. Limit test is carried out for arsenic, mercury, lead, cadmium. If its within the range the test complies with the I.P.

- Pesticides

Pesticides are used to get rid from the prey like rodents, birds, fungus. Hence fungicide, rodenticide, herbicide are used to get rid of it. But due to increase in the amount of the pesticide it leads to the mild side effect to severe condition like carcinogencity specially in case of DDT.

- False identification of the plants

This occurs when 2 herbs look alike or have a similar morphological characteristics. Sometime due to the common names or vernacular names, it creates a confusion among the vendors.

- Improper cultivation and no appropriate physical needs for growth of plants

If there is no proper cultivation of the plant it leads to the decrease in the active phytoconstituent of the plant yielding the inferior quality and poor standardization. Also care should be taken that the proper growth of plant should be done in the proper environment conditions like proper rain, adequate amount of sunlight, height, suitable temperature. As these factors determine the phytoconstituents quality.

SOLUTIONS

Here are some solutions that can provide an aid in the improvement in the quality of the herbal drugs-

Follow and practice the guidelines given by the international and national agencies like-

- Good Agricultural and Collection Practices (GACP) –

✓ Selection of medicinal plant

Species of botanical plant cultivated should be same as specified in the pharmacopoeia or respected authorities of country. If there is a new botanical plant species then first it should be identified and then documented.

✓ Botanical identity

Botanical identity includes the biological name of the plant, which is accepted and followed worldwide. biological name /botanical identity includes the name, genus. species, order of the plant. In case of propagated, collected and grown in specific region, records should be kept. For example – Holy basil is known as tulsi, tulas whereas the biological name is Ocimum sanctum.

✓ Cultivation

This requires proper management and care, the condition and duration of cultivation required vary depending upon the quality of the plant material required. If there is no scientific data of cultivation then the traditional practice should be followed. for example tea should always be cultivated on the hill tops at the altitude of 1000-2000 meters.

✓ Site selection

It's a vital aspect of selection while considering the plant product yield. Its observe that same plant species, cultivated at different site produce different quality product. hazardous chemicals, contamination risk should be avoided. If the land used for cultivation of plant or crops then application of plant protection should be evaluated.

✓ Ecological environment and social impact

Plant cultivation affect the surrounding flora & fauna of environment. Also, If there is non – indigenious plant species, then it should be monitored from time to time.

If there is medicinal drug cultivation on large scale, then the local communities should be directly benefited. for example cultivation of saffron may be the aid for the unemployment people.

✓ Climate

For cultivation of plant, climate of the surrounding should be considered, adequate rainfall proper amount of sunlight, appropriate temperature, altitude, which affect the overall quality of herbal drug. for example coffee prefers tropical climate.

✓ Soil

It contains organic & inorganic. It also consist of macro and micro nutrients and trace elements which provide an acid in plant development. For example coffee prefer rich soil for growth.

✓ Harvest

Harvest of medicinal plant should be done during the optimal season to ensure the production of medicinal plant material & finish product. Time of the harvest depends on the part of the plant used. During harvesting ensure that no foreign matter, weeds are mixed with harvested medicinal plant. Cutting device, harvesters should be kept clean & adjusted to reduce damage & contamination from soil.

✓ Personnel

Growers and producers should have adequate knowledge of medicinal plant. Proper hygiene should be followed as well as practiced at all stages of cultivation. Only properly trained personnel, wearing protective clothing (gloves, helmet, gloves, mask).

- Good Collection Practices

➢ Permission to collect

Its practiced in some countries, that prior to collection, permission from the government authorities or local body should be taken. If any medicinal plant is intended for export, then the phytosanitary certificates, Convential on International Trade in Endangered Species of wild fauna and flora (CITES) permits (for export and import), (CITES) certificates (for re-export) must be obtained.

➢ Technical planning

Prior to the initiate the cultivation of the targeted drug, few things should be considered i.e. the taxonomical, morphological characteristics should be studied. A good team which is expert in the cultivation, collection, harvesting of the plant should be assembled. Devices, fertilizers should be arranged. Maintenance and protection of the sustainable targeted species must be ensured.

➢ Selection of medicinal plants

When medicinal plant is cultivated, documents and pharmacopoeia should be considered first. If there are no documents or no mention of the drug in the pharmacopoeia, then the herbal plant should be identified and documented.

➢ Collection

Medicinal plant should be collected during the appropriate season or period. Best time of the collection should be determined according to the quality and quantity of biologically active constituents. Precaution should be taken that, raw material collected should not come in direct contact with the soil. After the collection, raw material should be subjected to the preliminary processing. If one or more herbal drugs are collected, cross contamination of the product should be prevented, by mixing the herbal drugs.

➢ Personnel

Daily training of the personnel should be conducted. The personnel should have a profound knowledge about the local and vernacular names and botanical names of the plant. Personnel should be protected from the toxic and dermatitis causing plants, poisonous animals and disease carrying insects.

- WHO guideline for drug storage

- Storage facilities of medicinal plant should be well aerated, dry and protected from light, if necessary, air conditioner and humidity equipment should be installed. floor should be neat and tidy. Wall should be painted with epoxy paint.
- Medicinal plants should be stored in the shelves away from one another and at a specific distance from the wall.
- Inspection of the storage room should be done after a time interval.
- Medicinal plant should be packed in the clean, dry boxes. Wooden boxes and paper bags should not be used for storage of drug.
- Fresh plant material should be stored ideally at 2-8 degree celsius, or less than this temperature if possible

CONCLUSION

Someone has rightly said "Precaution is better than cure." Standardization is very vital aspect while considering the patient life. In order to get a better quality of drugs one must follow the guidelines given by the regulatory bodies of national and international agencies. Standardization is a critical topic even in today's era. A lot of research must be done in order to gain more knowledge and also gaining access to the advancement in it. Care should be taken that the drugs that are cultivated comply with the national and international authorities. Standardization of the drug assures the safe way for the formulation intended for the human use.

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