ISSN 2347-2375

UNIQUE JOURNAL OF AYURVEDIC AND HERBAL MEDICINES

Available online: www.ujconline.net

Review Article

STORAGE, PACKAGING AND LABELING CONCEPT WITH PERSPECTIVE OF RAW HERBS AND THEIR FORMULATION

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Received 12-06-2015; Revised 09-07-2015; Accepted 07-08-2015

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ABSTRACT

The standardization of herbs are important factors but Raw material storage place, its condition, packing material and their labeling in terms of post production plays an important aspect when drug enters into health sector. The assessment of quality, safety and efficacy of medicinal plant can be established by regulating preservation technique. While labeling is necessary for safety use of herbal formulation by people when they bought it. Various guidelines are provided for selecting herb but very few guidelines are provided for storage preservation and labeling of herbal formulation.

Keywords: Packaging, Herbal drug, Storage facility, Storage material, Labeling.

INTRODUCTION

Indian medicinal system is the 3000 years oldest system of medication use in India[1]. Many traditional formulations have herbal drug/ plant as its core ingredient. Storage of medicine or raw material was an ancient idea for preservation of drug or things, practiced by many country. Acharya charaka has mention the concept of collection and preservation of raw material in Charak samhita[2]. e.g. roots should be collected in grishma and Shishir rutu (summer season), Bark, Stem, Latex, Gums oleoresins should be collected in Sharad rutu (between late monsoon -early winter). Various material has been used to store drug e.g. fermented syrup *Aasava arishtha* had been stored in earthen pot. This is example of preservation used in earlier era. But as a world is advancing the newer concept are coming forward. Lots of technologies are there which can help us to preserve herbs or make them available for all over the year. Hence storing drug for future use preserve them from foreign body contamination and after processing use them in formulations now become easy. Once the final formulation ready it should be accompanied with proper labeling is necessary. Though traditional formulations are available in market but very few formulations are with proper information with them. OTC sell of lots of traditional formulation is tremendous but people should know what exactly they are taking. and this knowledge we get from label, hence the current article deals with storage area, storage of raw material and content of labeling.

Storage

India is tropical country, where various range of medicinal plant are available in rainy season but this season is not present all over the year. Some medicinal plant has life of few days to few months or season wise so if one wish to use them afterwards they have to stored it. e.g. *Cassia tora* is a plant used in dermal infection[3] has been used to many herbal formulation available in market (*Visora oil, Mahamarichiyadi tailam*.) But if we closely watch this herbal plant it is available only during rainy season. So if one has to use it; they must collected it in rainy season and store it for future use. Another e.g. *Hibiscus rosasinensis* commonly known as shoe flower is used in many herbal hair oil product[4]. Mainly leaf and flowers are used to color the oil as well as hair, its available all over the year so one wants to use it can directly use without storing it. While storing this herbal plant following point should be considered.

1. Storage of raw herbs.
2. Storage material in which the herbs are kept.
3. Proper labeling.

Proper storage of raw herb[7]

Herbs after collecting fresh from field or from wholesaler/ retailer should be authentified first. The personnel should have adequate training in appropriate fields such as pharmaceutical technology, taxonomy botany, phytochemistry, pharmacognosy, hygiene, microbiology and related subject such as traditional use of herbal medicines. after arrival at the

processing faculty, the herbal material should promptly unloaded and unpacked. During this process the herbal material should not come in contact with soil. It should not be exposed directly to the sun. it should protect from rain and microbiological contamination.

- Identification should be done with naked eyes
- Cleansing of collected part with fresh water if necessary
- Washing of crude drug
  Crude drug part like stem, bark, root, leaves may be contaminated by soil hence the dust particle should be removed by high pressure air blower after it should passed through clean water once and if require twice. Washing dry herbal material with water is generally inappropriate, when it is necessary to clean them, an air duster or air shower should be employed.
- Drying of crude drug[7]

Crude drug if contain volatile oil should be shed dried or kept in shed, try to avoid it passing repeatedly through high pressure air blower as it could be lead to reduction of percentage of volatile oil. The method of drying herb depend on the active ingredient e.g. essential oil and the type of the plant part collected e.g. root, leaf, flower. drying by direct exposure to sunlight, is possible, but drying on the ground should be avoided. Sterilize raw drug by treating it with ethylene oxide to remove microbes.

Consistent quality for herbal formulation can only be assured if the starting raw herbal plant materials are good in quality. The specification for herbal plant, herbal formulation should be ensuring safety and efficacy. Raw herbal plant should have following information:

The family and botanical name of the plant used according to the binomial system (genus, species, verity and authority. i.e. the references to the originator of the classification, e.g. Linnaeus.) it may also be appropriate to add the vernacular name and the therapeutic use in the country or region of the origin of the plant. Details of the source of the plant e.g. region from where its collected whether its cultivate or collected from wild, method of cultivation, dates and condition of harvesting, collection procedures, collection areas, use of pesticides if any then type and quantity of pesticides. Which part of the plants used e.g. whole and reduced. for dried plant material, the drying system should be specified. A description of the plant material macroscopic and microscopic examination. Suitable identity test should be conducted for starting material. A benchmark sample should be kept for future use [7].

Proper labeling on stored material

Each lot of processed and cleaned herb should be stored with proper labeling, including following details

- Name of herb
- Date of arrival, consignment number
- Name of supplier
- Geographical location of collection
- Time of collection
- Batch no
- Part stored(root, stem, bark, leaf, flowers, rhizomes
- Inspection status (tested/ rejected/ approved)
- Taste report, number and date
- Expiry date

The authentic sample should be set as Reference/ Bench mark of each collected drug. The reference sample should be kept in museum with detail information. Use herb in first come first serve basis. Organoleptic taste should be done before further use, it should be free from fungi, pests, insects, micro organism, heavy material, pesticides, drug should be assessed for heavy metals. Once the primary level was passed then we can go for quantitative tests like total ash value, moisture content, water soluble, alcohol soluble etc.

Testing raw herbal material[5]

Storing and preservation are necessary for future use of herb in formulation. The assessment of quality, safety and efficacy of formulation in different disease are depending upon storing and preservation condition of herb. When herbal drug is collected various factor such as place of collection, time of collection, botanical age of collected plant, ecological factors etc. has impact on chemical constitution of drug. Hence after collection the storage and testing of raw material is another concern subject. Testing of raw material should be done as per API/ or concern guidelines.

Sr. No.	Test parameters for collected herbal raw material
1.	Data of collected plant material (place and date of collection), part of plants, botanical description and adulteration and substitution if any reported in literature.
2.	Foreign matter (> 2%)
3.	Organoleptic character (color, odor, taste, texture)
4.	Macroscopic and microscopic characters, powder microscopy
5.	Loss on drying at 105ºC/ moisture content
6.	pH value (10%aqueous extract)
7.	Total ash
8.	Acid insoluble ash
9.	Water soluble extractives
10.	Alcohol soluble extractives
11.	Volatile oil percentage (for oil percentage bearing plants, generally plants to compositae and labiatae family)
12.	TLC/ HPTLC/ GC/ HPLC/ LC-MS(as per requirement) Assay for active constituents (total tannins/ total alkaloids/ resins etc. or individuals

	constituents)
13.	Test for heavy/ toxic metals, lead, cadmium, mercury, arsenic
14.	Pesticide residue, organo chlorine pesticides, organophosphorus pesticides, pyrethroids
15.	Microbial contamination, total viable aerobic count, enterobacteraceae, total fungal count
16.	Test for specific pathogens, E. coli, salmonella spp, staphylococcus aureus, Pseudomonas aeruginosa
17.	Aflatoxins(B_1 B_2, G_1, G_2)
18.	Shelf life

If the herbal material for processing does not comply with its quality specification, rejected herb stored separately and disposed accordingly.

Store house[5]

Storage area should be well organized and tidy. Special attention should be paid to cleanliness and good maintenance. Any accidental spillage should be cleaned up immediately using methods that minimized the risk of contamination. Different herbal material should be stored in separate areas. To protect the store material, and reduce the risk of pest attacks, the duration of storage of any herbal material in unpacked form should be kept to minimum. Incoming fresh herbal material should be processed, unless specified otherwise, as soon as possible.

If appropriate, they should be stored between 2 ^{0}C and 8 ^{0}C, where as frozen materials should be stored below – 18 ^{0}C. Avoid Direct exposure to light, air or microbial organism effect on active component of herb which leads to lower the therapeutic efficacy of drug; but if the herb are stored in bulk to reduce the risk of mould formation or fermentation it is advisable to store them in aerated rooms or container using natural or mechanical aeration and ventilation. The room should be rodent free. Hence raw material should kept with proper storage with appropriate packaging material. Raw drug may be stored under conditions that prevent contamination and deterioration. Any variation organoleptic or phytochemical readings are indication of poor quality of herbs in terms of therapeutic activity.

There should be adequate space for in-house quality control testing. Approved and rejected herb should be stored with proper arrangement. All equipment used while processing should be made up of SS 404 material. All herbs should be washed clean, dry and orderly placed with controlled temperature, humidity in closed room. Temperature should be kept at cool and dry place in between 8ºC to 25ºC, protected from moisturizing, freezing, light and excessive heat to prevent decomposition[5].

Storage material

The drug storage techniques are to be followed with most care as the potency of raw drug has to be retained until we utilize it in the formulation. for this our classical also narrates the fact of proper storage of raw material . As per Acharya shushruta the material used for drug storage are said as:

"Plot mrutbhandam phalaka shanku vinyasta bheshjam prashstayam dishi shuchou bheshjagaram mishyate" [10]

The raw drug required for the preparation of medicines are to be stored in cloth, mud pots, drugs hanged in cloths/ gunny bags or specially designed hangers to the roof of the store house or to the nails (sanku) fixed in the walls. East or north direction of the storehouse is preferred for storing the drugs.

Herbal material even when stored in fiber drums, bags or boxes should be stored off the floor and suitably spaced to permit cleaning and inspection. The storage of plants, extracts, tinctures and others preparation may require special condition of humidity and temperature or protection from light. To facilitate cleaning and avoid cross contamination, adequate precautions should be taken during the sampling, weighing, mixing and processing of medicinal plants. Non wooden equipment should be used unless tradition demands wooden material. Where it is necessary use traditional equipment such as wooden implements, clay pot, pallets, hoppers, etc. When such equipment is used, it is advisable that it does not come into direct contact with chemicals or contaminated material. If the use of wooden equipments is unavoidable, special consideration must be given to its cleaning as wooden materials may retain odors, be easily discolored and easily contaminated. Earthen pot play major role for packaging purpose but due to their fragile in nature they are abandoned their place has been taken by metal pot which sometime interact with kept formulation due to chemical reaction. It get contaminated same for umber color bottle are good, interactive but fragile in nature. They had to kept in dark places.

Material for specific packaging and storage of raw herbs:

- Stem, heartwood, bark - Gunny bags and woven sacks
- Creepers, leaves - woven sacks with ld liner, high gauge HMHD bags, woven sacks with LD liner, High Gauge polyethylene bags.
- Fruits and rhizomes - High gauge HMHD bags, woven sacks with LD liner, Wooden boxes.
- Flower, anthers, stigma, petals, seed - Corrugated box with polypropylene woven sacks, HDPE containers, Fiber board's liner.
- Herbal extracts and compounds - Air tight HDPE containers, corrugated box with polyethylene woven sacks and fiber board's drums with polyethylene bags

separate store for different categories of medicinal and aromatic plants e.g. fresh herb, dry herb, volatile oil, poisonous herb parts as defined under drug and cosmetics act 1940 schedule. Guidelines for storehouse under GMP1.1(F), 1.1.(F)(A) proper ventilation, free from dampness, adequate space should be there for different kind of material. Fresh herb, Dry herb, Plant extract should be stored separately.[7]

Labeling on final product

Though traditional formulation are always claimed to be therapeutically proven from many years as they written in manuscript. But now its need of time that we should

standardize them to prove their bioavailability and efficacy. After selecting storing and preserving the herb it undergoes for formulation production then the product launch in market for public use. As its deal with health of people it should be presented with proper information in the form of label.

The formulation should be properly label as per guideline provide by GMP. Each description might not possible everywhere but the formulation contains necessary information. The herbal formulations available in market are either don't have proper labeling or lack of labeling.

Label on the container should have following points:

- Composition the structure of formulation whether it had hard capsule, tablet, gel. Herbal drug information along with scientific name, % of drug used in formulation.
- Color of formulation
- Dosage
- Manufacturing, license no, batch number of formulation.

Each formulation should be provided with product inlet about information of formulation

The specific requirement on the content and format labeling for human prescription drug are as follows:

A. Description

It should contain proprietary and established name. so that correct information is known by the patients. Type of dosage form and route of administration should be mention so that it provide guidelines to patient as well as avoid confusion, while intake qualitative and quantitative ingredient information should be given about each and every ingredient used while preparing drug. Along with their (Pharmacological and therapeutic use) scientific name and structural formula should be written.

B. Clinical Pharmacology

It should consist the concise factual summary of the clinical pharmacology and action of the drug in human.

C. Indication and Usages

The indication for treatment/ prevention/ diagnosis of disease, manifestation of disease, symptomatic relief as adjacent therapy.

D. Contraindication

This section should be describe those situation in which drug should not be used.

E. Warning

Section should describe serious reaction and potential safety hazards limitation in use imposed by them.

F. Precautions

1. Information regarding any special care to be taken by patient or by practitioner for safe and effective use of the drug.
2. Information for patients e.g. precaution concern with driving or working on heavy machinery. Uses of other substance that may have harmful additive effect.
3. Drug - Drug interaction
4. Carcinogenesis, mutagenesis, impairment of fertility.
5. Pregnancy including teratogenecity(Classification ABCDX) and non teratogenenic effects.
6. Impact on labor and delivery.
7. Nursing mother.
8. Pediatric use if it's not suitable for pediatric use then it should be supported by adequate clinical data.

G. Adverse reaction.

An undesirable effect reasonably associated with the use of the drug that may occur as part of pharmacological action of the drug or may be unpredictable in its occurrence.

H. Drug abuse and Dependence

If the drug is controlled by the drug enforcement administration, the schedule in which it is controlled should be stated. If appropriate for the drug involve, types of abuse and relevant realities should be stated here. Characteristic effect of dependence and quantity of the drug leading to tolerance and dependence.

I. Over dosages

This part should desire the signs, symptoms and laboratory findings of acute over dosages and general principal of treatment.

J. Dosages and Administration

This section should state the recommended usual dose, dose range and if appropriate, an upper limit which beyond which safety and effectiveness have been established.

DISCUSSION

Ayurveda is an ancient science where formulations are made with herbal drug. to have good efficacy of formulation raw material storage and packaging condition plays most important role. Certain drugs are available as per season, so we have to restore them for future use. Raw herbs are collected from field has contaminated with soil. They undergo for cleaning drying and before utilizing in formulation. Quality testing e.g. test should be perform to assess the total ash value, total foreign matter, extractive values etc. So after their testing they should be stored in proper manner for future use. Once the formulation developed it has to be enter in market with proper labeling along with product information inlet. Out of 20% herb base formulation provide proper information about the medicine including manufacturing date, active composition, excipient in proper quantity, dosage, manufacturing license number, batch number, mfg date, expiry date, storing condition, this information is sufficient but as herbal drug are more sold out as OTC medication they should be accompanied with proper herbal formulation information leaflet as described above for spreading knowledge about preparation.

CONCLUSION

Most of Ayurvedic medication has raw herbs as its core ingredient the safety, efficacy and quality of Ayurvedic medicines are depend upon the way they are stored. API has provide a guidelines on preservation of herb in order to retain the active constituent of herb. When herbs are stored in proper condition their active constitution are preserve properly hence they shows good efficacy in therapy. by proper labeling the handling of drug become more safe and informative. In this way, safety, efficacy and quality of the ayurvedic medicines shall be maintained and would be useful for providing market for herbal industry.

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Source of support: Nil, Conflict of interest: None Declared