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A REVIEW ON GOOD STORAGE PRACTICES OF RAW DRUGS: CLASSICAL AND CONTEMPORARY

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ABSTRACT

Ayurvedic Pharmaceutical Science, the *Bhaisajya Kalpana* has a long history since Vedic period. With time and new researches in the field of Ayurveda this pharmaceutical science has also progressed with its own significance. Herbal drugs have been increasingly been used world-wide during last few decades as evidenced by rapidly growing global and national markets of herbal drugs. According to WHO estimates, the present demand for medicinal plants would reach from billion to trillion US $ year by year. With the increasing use of herbal medicine its marketing and safety has become a major part for the authorities and the industry. The safety, efficacy and quality of Ayurvedic herbal drugs should be achieved by Good Storage Practices guided by API, WHO along with classical texts. This could accelerate the global acceptance of Ayurvedic Pharmaceutics. Good Storage Practices improve the quality, efficacy safety of the medicines so as to achieve attention of global market and to provide better health to human beings.

Keywords: Herbal Raw Drugs, Storage, classical and contemporary*, API, WHO*.

INTRODUCTION

Raw drug storage practice is very important as it plays an important role in safety, efficacy and quality of the finished products. Herbal medicine has been used therapeutically all around the world, being an important aspect of various traditional medicine system. Around 119 plants derive pharmaceutical medicines; about 74% are used in modern medicine too. So WHO has taken steps in assessment of quality, safety and efficacy of medicinal plants thus storage, packing and handling of herbs for various Ayurvedic dosage forms is an important aspect[1].

Proper storage of crude materials is very necessary in pharmaceutics as this leads to quality medicine. Without proper storage conditions of either raw drugs or finished products medicine can lose its potency and thus efficacy will be lost. So manufacturing units, pharmaceutical importers, contractors and wholesalers, and community or hospital pharmacies must comply with the guideline suggested by WHO. Here we are discussing about the details of raw drug storage techniques both classical and contemporary.

Classical version:

Collected drugs should be stored in *Bhaishajagara. Bhesajagara* is a place which will be unaffected by the external atmospheric conditions like smoke, rain, wind, moisture etc., the place should be convenient for all the seasons.[2]

Collected drugs should be stored in suitable pots and the pots should be kept in such store rooms which the gages on east or north. Should be closed from all the sides but having ventilations from one side where always auspicious ceremonies are performed like offering of flower garlands and Bali karmas which should well protected from reach of fire, water humidity, smoke sand rats or any other quadrupeds.

These drugs should be covered with lids and should be kept on the loop or swing.

Potency and actions are enhanced by the excellence of *Desa* (place) *Kala* (season) *Guna* (property) and *Bhajana* (container).[3]

The raw drugs required for the preparation of medicines are to be stored in cloth, mud pots, drugs hanged in clothes 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 store house is preferred for storing drugs[4].

Contemporary:

Guidelines for good storage practice (raw material)[5]. This includes

A. Storage premises and facilities such as storage areas, storage conditions
B. Storage requirements such as documentation, labelling and containers
C. Receipt of incoming materials,
D. Stock rotation of raw drugs and control,
E. Control of obsolete and outdated materials.
F. Sterilization and storage temperature particulars of of raw herbs
G. Testing the quality of raw herbs
H. Materials for specific packing and storage of raw herbs.

A. Storage Premises Facilities:

1. Precaution must be taken to prevent unauthorized persons from entering storage areas.
2. Storage area should be sufficient capacity to allow the orderly storage of the various categories of materials like fresh herbs, dry herbs and plant extracts/concentrates.
3. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. The floor and suitably spaced to permit cleaning and inspection.
4. Storage should be clean and free from accumulated waste and vermin. A written sanitation programme should be available indicating frequency of cleaning and the methods to be used to clean then premises and storage areas. There should be a written programme for pest control. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.
5. Receiving and dispatching bays should protect materials and products from the weather. Reception areas should be designed and equipped to allow containers of incoming materials and pharmaceutical products to be cleaned, if necessary, before storage.
6. Where quarantine status is ensured by the storage in separate areas should be clearly marked and their access restricted to authorized personnel.
7. Highly active and radioactive materials, narcotics and hazardous, sensitive and dangerous materials and pharmaceutical products, as well as substances presenting special risks of abuse, fire or explosion should be stored in a dedicated area with appropriate additional safety and measures.
8. There should be adequate space in the store house for Under test, Approved and Rejected herbs with arrangements and equipment's to allow washing cleaning drying and orderly placement of stored herbs with controlled temperature and humidity. The store house for storage of herbs, handling of herbs and drying space etc., should be as per GMP.

9. Materials and pharmaceutical products should be stored in conditions which as sure that their quality is maintained, and stock should be appropriately rotated. The "first expired /first out" (FEFO) principal should be followed.
10. Storage conditions for the materials and products should be in compliance with the labelling, which is based on the results of stability testing.
11. Recorded temperature data should be available for review.
12. Equipment used for monitoring should also be calibrated at defined intervals.

B. Storage Requirements

1. Documentation Written instruction and records should be available which document all activities in the storage area.
2. Records should be kept for each delivery. They should include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, assigned batch number and the expiry date. Such records should be retained for a period equal to the shelf life of the incoming materials.
3. All containers should be clearly labelled.

C. Receipt of incoming materials and pharmaceutical products

On receipt, each incoming delivery should be checked against the relevant purchase order and each container physically verified eg., by the label description, batch number, type of material and quantity.

D. Stock Rotation and control

Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.

E. Control of obsolete and outdated materials

Damaged containers or outdated materials should not be used and quality controller should monitor this to prevent the issue of the outdated materials.

F. Sterilization and storage temperature particulars of raw herbs

Sterilization of raw herbs which needs to be stored may be done by any of the below mentioned methods as applicable: Dry heat sterilization, Steam sterilisation, Sterilization by radiation like infrared radiation, UV rays, Gamma rays, Alpha radiations and beta radiations, Chemical methods like gaseous sterilization like ethylene oxide etc.,

Temperature for storage of raw herbal drugs

All the raw herbal drugs may be stored at a cool place between 8^{o}-25^{0}, raw herbs must be protected from moisture, freezing, light and excessive heat for preventing decomposition.

G. Testing the quality of raw herbs

- Authentication: Taxonomical study and Botanical identity may be established
- Foreign Matter: Herbs should be entirely free from soil, stones, dust, insects and other animal contamination.
- Organoleptic Evaluation: It includes the macroscopic appearance of drug, its odour, taste, sound feel of touch, colour.
- Microscopic Examination: It gives information regarding type of stomata, vessel thickening which is helpful for identification of species.
- Volatile matter: Volatile oil in menthol, Osmium etc., is determined by steam distillation of plant. It plays an important role for quality for quality of raw herbs.
- Ash Value: The presence of ash in the medicinal plant is determined as Total ash, Acid insoluble ash etc., A high acid insoluble indicates contamination with earthy material.
- Extractive Values: It also indicates regarding quality of raw herbs.
- Chromatographic profile and Marker component: Thin layer chromatography and High performance liquid chromatography (HPTLC) provides information regarding the active alkaloids of the drugs.
- Pharmacological Evaluation: Bitterness value, Haemolytic activity, Foaming index etc.,

- Toxicological pesticides residues: Pesticides are helpful to reduce the presence of insects, fungi, and moulds in raw herbs. Medicinal plants are to be taken for longer periods so pesticides residue limit may be established for safety.

- Testing of Raw Herbs:

Testing of raw herbs maybe conducted for Macroscopic examination, Microscopic examination identity, purity, and strength, TLC, constituents etc.,

Table 1: Testing of raw herbs may be conducted as per guidelines of WHO and CCRAS.[6]

S.No	Test parameters for raw plant materials as CCRAS
1.	Passport data of plant material (place and date of collection), part of plant, botanical description and adulteration (if any) reported in literature, substitution if any reported in literature.
2.	Foreign matter(not more than 2%)
3.	Organoleptic character (colour ,odour, taste and texture etc.,)
4	Macroscopic and microscopic characters powder microscopy
5.	Loss on drying at $10^{5\,o}$ C / 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 berating plants generally plants belonging to composite and labiate families)
12	TLC/HPTLC/GC/HPLC/LC-MS (as per requirements)
13	Assay for active constituents (total tannins/total alkaloids/resin etc., or individual constituents)
14	Test for heavy toxic metals lead cadmium mercury, arsenic
15.	Pesticide residue, oregano chlorine pesticides, organophosphorus pesticides, pyrethroids
16	Microbial contamination, total viable aerobic count Enterobacteriaceae, total fungal count
17	Test for specific pathogens, Escherichia coli, Salmonella spp. Staphylococcus aureus, Pseudomonas aeruginosa
18	Aflatoxins (B1,B2,G1,G2)
19.	Shelf life

- Microbial contamination: The presence of microbes, moulds, aflatoxins in plant material may be tested.

Removing of microbes from raw herbs

Generally the limits for bacterial and mould contamination for internal use shell be considered as same as for food stuffs. Considerable quantities of drugs are sterilized by special equipment's by treatment with ethylene oxide. Sterilization is the process in which there is complete destruction of all bacterial life including their spores but in disinfection, there is destruction of bacteria but not their spores. A product is said to be sterile when it is free from all living micro organisms and passes the sterility test.

Table 2: Permissible limits of Microbial load and pathogens as per WHO/API.[7]

S.No.	Microbial load	For contamination In crude plant materials	For plant materials that have been pre-treated	For other plant materials for internal use
1.	Total viable aerobic count		$<10^{7cfug-1}$	$<10^{5cfug-1}$
2	E.coli	10^{4g-1}	10^{2g-1}	10^{g-1}
3	Total yeast and mould count	10^{3g-1}	10^{4g-1}	10^{3g-1}
4	Total Enterobacteriaceae		10^{4g-1}	10^{3g-1}

5	Salmonellae		None	None
6	S.aureus	Absent	Absent	Absent
7	Pseudomonas aeruginosa	Absent	Absent	Absent
8	Coliforms	Absent	Absent	Absent

Determination of heavy metals in plants materials show permissible limit by WHO.

Table 3: Permissible limits of Heavy metals (National Sanitation Draft Proposal)[8]

Heavy metal	Raw Dietary Supplements	Finished Dietary Supplements
Mercury		0.02mg/day
Cadmium	0.3 ppm	0.006 mg/day
Lead	10 ppm	0.02 mg/day
Arsenic	5 ppm	0.01 mg/day
Chromium	2 ppm	0.02 mg/day

Table 4: Permissible limit heavy metal cosmetic herbal products (Herbal Cosmetic Health Canada)[9]

Heavy Metal	Permissible Limit
Mercury	1 ppm
Cadmium	0.30 ppm
Lead	10 ppm
Arsenic	3 ppm

Table 5: Permissible limit as per API[10]

Heavy metal	Permissible limit
Mercury	1 ppm
Cadmium	0.3 ppm
Lead	10 ppm
Arsenic	3 ppm

- Radioactive contamination: The presence of radioactive particles may also be tested.

H. Materials for specific packing and storage of raw herbs:

Table 6: The following materials are used for packing raw drugs[11].

Sl. No	Category	Packing Material
1.	Woody in nature like stem, Hard wood, bark etc.,	Gunny bags and woven sacks
2.	Soft in nature like creeper, leaves etc.,	High gauge HMHD bags, Woven sacks with LD liner, High gauge polyethylene bags
3.	Fleshy in nature like fruits, rhizomes etc.,	High gauge HMHD bags , woven sacks with LD liner, wooden boxes.
4.	Flowers, anthers, stigma, petals, seeds etc.,	Corrugated box with polypropylene woven sacks, HDPE containers, Faber boards drums
5.	Volatile contents	Air tight HDPE containers, Airtight HDPE Carboys, cardboard box with polyethylene liners
6.	Herbal extracts and compounds	Air tight HDPE containers, Corrugated box with polyethylene woven sacks and fibre boards drums with polyethylene bags.

*HMHD (High molecular weight high density polyethylene) *LD (Low density) *HDPE (High density polyethylene)

For proper storage of raw herbal materials to follow the guidelines of API, WHO and classical texts are proven the best methods.

Do's: Follow the API, WHO guidelines not ignoring classical texts in the order mentioned below.

- Identification by naked eyes
- Cleaning of herbs
- Washing of crude drugs
- Drying crude drugs
- Removing of microbes from raw herbs
- Proper packing for storage

Don'ts;

- Improper storing.
- Using inappropriate packing materials.
- Mixing of under tested approved and rejected lots of raw drugs.
- Ignoring First in first out, Shelf life and long storage.
- Abnormal weather situations.

CONCLUSION

- Good Storage Practices protects the quality and confidence in the field of Ayurvedic Pharmaceutics.
- As a part of Globalisation of Ayurvedic System, it strengthens the Evidence based Ayurveda.
- It boosts up the Ayurvedic Pharmaceutic Industry towards Global market.
- Governing Drug and Cosmetic Act 1945 in storage and packing wings enhances Safety, Efficacy, and Quality of the Ayurvedic drugs.

REFERENCES

1. W.H.O. guidelines for assessing quality of herbal Medicines with reference to contaminants and residues; 2007. P. no, 7, 9 W.H.O Traditional Medicine Strategy; 2002-2005.
2. Susrutha Suthrasthana 38/81
3. Charaka Samhita KALPASTHANA 1/11
4. Susrutha Suthrasthana 36/17
5. Quality Control & Standardization of Ayurvedic Medicines by Dr.Devendrajoshi and Dr.Geeta Joshi, p.no92-103, Chukambha Ayurvedic Pratishthan 2011, Varanasi.
6. Laboratory guide for the analysis of Ayurveda and Siddha formulations by CCRAS; 2010 (Annexure -2, p.152, Annexure-3 p. 153, Annexure-5 p.153) ref table 21, p.134.
7. ibid
8. W.H.O. Guidelines for assessing quality of Herbal Medicines with reference to contaminants and residues. Annexure 3: 2007.P.24
9. Health Canada, Draft Guidance on Heavy metal impurities in cosmetics, section 4.
10. A.P.I PART 2 VOL 3 (Formulations) p. 149
11. ibid.

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