



QUALITY & QUANTITY ISSUES/PROBLEMS & PACKAGING OF HERBAL DRUGS IN INDIA

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ABSTRACT

The quality control must start with raw materials. At present, the big markets of medicinal plants are in Delhi, Amritsar and Mumbai. Here, the raw or crude drugs are sold in the traditional manner. There is no cleaning, grading or selection of the medicinal plants. The buyer has no yardstick to judge the genuineness of the plants and their quality. There are no indications about the shelf life. There is no proper packing or labelling. Therefore it is imperative that quality control

process is stressed upon. Pharmaceutical packaging is one market across the globe which is advancing at constant pace. It is expected that market will grow to worth \$78.79 Billion by 2018. Packaging is a key for sale, safety and success. Like other packaged goods, pharmaceuticals packaging need to be in such a manner that it will provide speedy packaging, protection, identification, product quality, patient comfort, display and needs of security. Advancement in research of pharmaceuticals development had always being dependent on the packaging technology. Maintaining integrity of pharmaceuticals during storage, shipment, and delivery is assured by quality of packaging available. This article reviewing current pharmaceutical packaging trends and predicting the packaging outcomes in future in India.

KEYWORDS: Medicinal plants, shelf life, Pharmaceutical packaging, quality of packaging.

INTRODUCTION

In India, the single most important factor which is standing in the way of extensive acceptance of medicinal plants is non-availability or shortfall of standards to check or test the quality by modern instrumentation methods. A serious thought should be given to this aspect.

A survey done revealed that due to increasing demand of Ayurvedic medicines & raw materials, the traders as well as Ayurvedic manufacturers are using substandard medicinal plant material. During the survey of the traders it was found that manufacturers are using substandard raw material for making Ayurvedic medicines. There appears to be no strict rules, policies, or any checks by the government in this regard. Ayurvedic industries are manufacturing huge quantity of medicines to meet the increasing market demand without considering the quality. Most of the people involved in the trade are substituting costly Safed musli (*Chlorophytum borivillianum*), Baibidang (*Embelia ribes*), Kali haldi (*Curcuma caesia*), Satawar (*Asparagus racemosus*) etc. with other similar type of medicinal plants of inferior quality. Due to lack of correct identification, similar looking plants are collected from the field site along with the genuine medicinal plant by mistake. But many times similar looking (inferior) cheap alternatives are intentionally mixed along with some quantity of genuine plant. This may be due to non-availability of the genuine medicinal plant in the large quantity. Generally the soil gets adherent to the medicinal plant or its useful part at the time of collection from the field, there by contaminating the medicinal plant. Due to lack of proper post collection care, the collected medicinal plants lose their pharmaceutical efficacy. After collection from the field, the medicinal plants are sold in local markets or, 'mandi' or to middle man sooner or later. The collected plants are kept in direct sun/rains; in sub-standard go downs, having dust, fungus, termites and rats etc. which adversely affect the medicinal properties. It was also observed that the adulterers not only mix plants of similar species of cheap and inferior quality but some rotten or substandard materials also which can be procured at very cheap rates, like safed musli being adulterated with lesser priced *Asparagus*, rotten aonla powder in triphala, and so on. The safety and quality of raw medicinal plant materials and finished products depend both on intrinsic (genetic) and extrinsic (environment, collection methods, cultivation, harvest, post-harvest care, transport and storage practices) factors. Inadvertent contamination by microbial or chemical agents during any of the production stages can also lead to deterioration of quality and affects the safety. Medicinal plants collected from the wild may be contaminated by other similar looking species or plant parts because of wrong identification, accidental contamination or intentional adulteration, all of which may have undesirable consequences. The quality control must start with raw materials. At present, the big markets of medicinal plants are in Khari Baoli in Delhi, Amritsar and Mumbai. Here, the raw or crude drugs are sold in the traditional manner. There is no cleaning, grading or selection of the medicinal plants. The buyer has no yardstick to judge the genuineness of the plants and their quality. There are no indications about the shelf

life. There is no proper packing or labelling. Therefore it is imperative that quality control process is stressed upon. First of all, the crude drugs of standard quality need to be identified and preserved as the reference standard and an excellent herbarium having authentic reference samples needs to be established. This centre should have the crude drug samples (processed medicinal plants), herbarium specimen, chemical finger print profiles, anatomical slides, supporting literatures-and a collection of living plants. It should provide easy access to all the groups including traders, medical practitioners, plant chemists, Traditional Medicine students, academics, regulators as well as the pharmaceutical industry. User services also should be made available. This repository should then become the official certification centre for raw materials, so that the industry can get the certified raw materials from the centre. Perhaps, some regional branches of this centre could also be started. The centre could generate some income by way of charging fee for the authentication work of the crude samples. Perhaps some of the existing institutes working on medicinal plants could be developed into official certification centers. In addition to the crude drug samples, it is also necessary to have reference samples of standard marker compounds. A repository of such marker compounds can be developed at the Official Certification Centres. One important aspect is the issue of quantity. As pointed out earlier, about 80% of the medicinal plants grow in wild and the rest 20% is cultivated. Much damage to the medicinal plants is being done in the collection stage itself as the sector is not well organized with unskilled workers/ collector. Due to this the vital parts are getting damaged and they are being disposed off as they don't find a place in the trade sector. As a result of this, the quantity required for the trade decreases thus seriously affecting the demand and supply chain. Sometimes the quantity required in the market is not readily available thus adding to the already existing pressure of supply as per the requirement.

Value addition of Medicinal Plants

To assess the extent of value addition of medicinal plants, in many regions, village level collectors of MAPs, members of local community, traders and wholesalers were contacted. It is quite disappointing to note that the information obtained revealed that no attempt of value addition has been done so far to maintain or improve the quality of the plants before the material reaches the industry. Value addition of the medicinal plants is very much essential for commercial exploitation as well as the medicinal value of the raw drugs. Even authenticated plant material may not be of desired quality, strength and standards of the consumer / industry requirements. Such material is liable to be rejected or accepted at very

low price causing not only economic loss to the cultivators or collectors of the medicinal plants but also entails doubtful efficacy or curtails the potency of the raw drug in the alleviation of the human suffering. The focus should be on horticulture, food processing, oil-seeds, cotton, sugar, cereals, spices and floriculture and on the forest based industries like Sal, herb, olive, bran and amla processing industries. The potential for the growth of agro and forest based industries should be identified in each district. This should be done considering the climatic and the soil conditions. The bio-diversity of the forests should be mapped by the systematic classification of the rare flora and fauna in India. In India this is an area of lacunae as there are certain gaps which need to be fulfilled in order to achieve value addition of medicinal plants. Direct value addition is not achieved because of the following reasons.

- Collection doesn't take place in specific season.
- Poor harvesting and processing of plant material.
- Improper grading and sorting.
- Improper cleaning, packaging and storage.
- Indirect value addition is also not achieved due to presence of moisture, foreign matter, ash content, extractives, pesticide residue and microorganism.

Value addition of the medicinal plants can be achieved directly by improving the quality of the cultivated or collected plant material and indirectly by quality assurance of the plant material or the semi-processing of the material to a value added product.

I. Direct Value Addition

Collection in the proper seasons

Seasonal variation in the concentration of secondary metabolites present in the plant and which are of medicinal importance is found to be a common phenomenon and consequently the efficacy or the potency of the raw drugs may not be the same all-round the year or at different stages of plant growth. This fact need to be very much considered and the collection of the material should be made in the appropriate season. Medicinal plant materials should be collected during the appropriate season or time period to ensure the best possible quality of both raw materials and finished products. It is well known that the quantitative concentration of biologically active constituents varies with the stage of plant growth and development. This also applies to non-targeted toxic or poisonous indigenous plant ingredients. The best time for collection (quality peak season or time of day) should be determined according to the

quality and quantity of biologically active constituents rather than the total vegetative yield of the targeted medicinal plant parts.

• **Harvesting and processing of the plant material**

A few guidelines followed, as given in the annexure for the harvesting and processing of the different parts of the plant material would increase the shelf life and help in the value addition of medicinal plants instead of indiscriminate and non judicious harvesting. At the time of harvesting, collection practices should ensure the long-term survival of wild flora and their associated habitats. First, the density of the target species at the collection site(s) should be determined and it should be ensured that species which are rare or scarce are not to be collected. To encourage the regeneration of source of medicinal plant materials, a sound demographic structure of the flora has to be ensured. Management plans should refer to the species and the plant parts (roots, leaves, fruits, etc.) to be collected and should specify collection levels and collection practices. It should also specify collection levels and collection practices. It is incumbent on the government or environmental authority to ensure that buyers of collected plant material preserve it with maximum caution. While collecting the material, ecologically non-destructive systems of collection alone should be employed and they vary widely from species to species. For example, when collecting roots of trees and bushes, the main roots should not be cut or dug up, and severing the taproot of trees and bushes should be avoided. Some of the lateral roots should be identified and collected. When collecting species whose bark is the primary material to be used, the tree should not be girdled or completely stripped of its bark; long strips of bark should be cut along one side of the tree for collection. If more than one part of medicinal plant is to be collected, the different plant species or plant materials should be gathered separately and transported in separate containers. Cross-contamination should be avoided at all times. Collecting implements, such as machetes, shears, saws and mechanical tools, should be kept clean and maintained in proper condition. Those parts that come into direct contact with the collected medicinal plant materials should be free from excess oil and other contamination. After collection, the raw medicinal plant materials may be subjected to appropriate preliminary processing, including elimination of undesirable materials and contaminants, washing (to remove excess soil), sorting and cutting. The collected medicinal plant materials should be protected from insects, rodents, birds, other pests, from livestock and domestic animals. If the collection site is located at some distance from processing units, it may be necessary to air or sun-dry the raw medicinal plant materials prior to transport.

• Grading and sorting

Instead of assorted material, which may include infested, immature and other kinds of unacceptable material, sorting and grading will be a means of value addition and market potential. In the course of collection, efforts should be made to remove parts of the plant that are not required and foreign matter, in particular toxic weeds. Decomposed medicinal plant materials should be discarded.

• Cleaning

Any soil, stones, sand, dust and other foreign inorganic matter must be removed before medicinal plant materials are cut or ground for testing. In general, the collected raw medicinal plant materials should not come into direct contact with the soil. In the case of underground parts of plants (such as the roots), any adherent soil should be removed from the plants immediately after collection. Collected material should be placed in clean baskets, mesh bags, other well aerated containers or drop cloths that are free from foreign matter, including plant remnants of previous collecting activities.

• Packaging

The container and its closure must not interact physically or chemically in any way that would alter its quality. A *well-closed container* must protect the contents from extraneous matter or from loss of the material under normal conditions of handling, shipment or storage. Different categories of the plant material need different packaging practices to prevent spoilage and also to maintain the quality.

• Storage

Medicinal plant materials must be stored under specified conditions in order to avoid contamination and deterioration. Avoid formation of moulds, which may produce aflatoxins. Materials that need to be stored at temperatures other than room temperature should be stored at low temperatures to avoid decomposition of phyto constituents or deterioration of quality. Low humidity may be maintained using a desiccant in the container if necessary. Medicinal plant materials requiring protection from light should be kept in a light resistant container or the container may be placed inside a suitable light-resistant (opaque) covering. Information on proper storage practices of medicinal plants is rather sketchy and has not received due attention from experts till date. As is in the case of other plant materials exposure to air, moisture, light, dust, etc. cause deterioration in the keeping quality of medicinal plant raw drugs. However this can be minimized by proper cleaning, packing and storage. Lack of

proper infrastructure is one of the major bottlenecks to the growth of this sector. Apart from the core infrastructure, some industry specific infrastructure facilities which include setting up of sector specific industrial parks like an agroindustrial park or herbal villages should be created. Developing other infrastructure facilities including setting up of cold storage facilities at the district level, developing cold chains in the rural areas that would link warehouses to cold storage facilities for perishable horticulture and food products as well as forest produces and facilities to sort out, dry up and pack the agro based products etc.

II. Indirect Value Addition: Testing for the Physico-chemical standards (Moisture, Foreign matter, Ash Content, Extractives).

• **Moisture**

An excess of water in medicinal plant materials will encourage microbial growth and also causes deterioration following hydrolysis. This is especially important for materials that absorb moisture or deteriorate quickly in the presence of water. The test for *loss on drying* can be carried out either by heating to 100-105 °C or in desiccators over phosphorus pent oxide for a specified period of time.

• **Foreign matter**

Medicinal plants should not be collected in or near areas where high levels of pesticides or other possible contaminants are used or found, such as roadsides, drainage ditches, mine tailings, garbage dumps and industrial facilities which may produce toxic emissions. Apart from this, the collection of medicinal plants in and around active pastures, including river banks and downstream from pastures, should not be done in order to avoid microbial contamination from animal waste. Macroscopic examination can conveniently be employed for determining the presence of foreign matter in whole or cut plant materials. However, microscopy is indispensable for powdered materials.

• **Ash Content**

Ignition of medicinal plant material yields total ash constituting both physiological (from the plant tissue) and non-physiological (extraneous matter adhering to the plant) ash. Acid insoluble ash represents sand and siliceous earth.

• **Extractives**

It is the amount of soluble constituents (active or otherwise) extracted using solvents like alcohol and water from a given amount of medicinal plant material.

• Pesticide residues

Medicinal plant materials are liable to contain pesticide residues, which accumulate from agricultural practices such as spraying and treatment of soils and fumigation during storage. Since many medicinal preparations of plant origin have to be taken over long periods of time, the intake of residues from medicinal plants should not be more than 1% of the total intake from all the sources including food and drinking water.

• Micro organisms

While a large range of bacteria and fungi form the naturally occurring micro flora of herbs, aerobic spore forming bacteria frequently predominate, current practices of harvesting, handling and production may cause additional contamination and microbial growth.

Problems

- It was observed that there is a market linkage right from the village level to the export market. However, at the village level the plant collector gets a paltry sum as compared to the price the product is getting at the national / international market. Actually the plant collector at the village level gets paid around 15-20% of the final product price. Thus the poor people are getting exploited at the village level.
- From the local haat, there are middlemen who buy the produce from the collectors/farmers and sell them to the markets at Raipur and Dhamtari. These middlemen get a good sum of money for the plant materials. Thus they are the real benefactors.
- When the traders were contacted to discuss about the problems of the medicinal plant industry, they expressed that lack of cooperation from the government and lack of definite government policy to enable easy trade are mainly responsible for the problems of the industry.
- The traders expressed the opinion that the government should finalise the policy and take a positive stand on issues pertaining to medicinal plant trade. Now since there is nothing organised and medicinal plants has not been recognised as a sector, outside traders are taking advantage of many states as a herbal state.
- Corruption is rampant which enables outsiders to buy their way into the medicinal plants business in the states.

- As the process of submitting tender for the medicinal plants and its products is tedious, only big players are able to take advantage.
- Communication gap between the government and the departments, especially the forest department is worsening the situation.
- Absence of trade unions results in poor understanding and cooperation among the traders in the states.
- Proper buying and selling is hampered due to the lack of funds. There is no finance or subsidy in the medicinal plants business as it is not being encouraged by the government. The banks in the state are noncooperative in extending loans. Even if they offer loans, they are collecting high rates of interest. The small amounts of loans being extended by the banks are insufficient to meet the cost of production.

There are problems in transportation facilities. There is no provision of forest pass for the transportation of goods. Obtaining a permit is a big problem. The interstate transportation takes much of paper work and sometimes there is non availability of transportation on time. Proper packaging of the material to preserve the quality of the material is not being done and the medicinal plants are exposed to direct sun/rains, in sub-standard go-downs, having dust, fungus, termites, rats, etc. which adversely affect the medicinal properties. There is absence of proper storage facilities due to which the quality of the produce deteriorates and ultimately there is poor pricing for the products.

Packaging issues

Dry extracts usually being very hygroscopic, should therefore be ground and mixed under such conditions which exclude moisture to the extent possible. Intermediate and end products must also be stored under dry conditions. Annealing or sealing of the products in suitable moisture proof, tight synthetic foils have proved to be a suitable method for this. But nothing as such is done in this manner at any of the levels in the market linkages. The general requirements of packaging materials are the following (Kraisintu,1997).

- Economical or low cost
- Impermeable as glass or metal or of acceptable permeability to moisture, gases, volatile solvents etc.

- Non-reactive and inert with no exchange or interaction with the contents
- Easy to manufacture in a wide range of shapes, preferably by a number of manufacturing processes.
- Easy to decorate and /or print by a range of processes
- Good production line efficiency-performance, with the minimum of rejects or wastage.

Effective as a pack (container and closure), i.e., easy to open and close after use if it is a multi dose preparation; or open if single dose. It should meet special requirements such as good quality with child resistance and tamper evidence, etc. Easy to produce and maintain Preferably readily available both in terms of source of supply for raw materials and as a converted item component from several suppliers.

Eco- friendly Able to optimize use of space when stacked or during transportation. The common types of packaging materials currently available are given below (Kraisintu, 1997).

•**Glass:** It can be found as several variants such as treated soda glass, soda glass and non parenteral.

•**Metals:** A variety of metals including tin plate (tin coated mild steel) tin free steel, aluminium, and alloys of aluminium are widely used in packaging, being found as rigid containers, collapsible containers, aluminium foils, metalised coatings etc.

•**Plastics:** There are five economical materials for rigid type of containers i.e., those based on polyethylene (PE), polypropylene (PP), Polystyrene (PS), PVC and polyester.

•**Elastomeric materials:** Elastomers can be found as a wide range of basic materials (i.e., natural rubber, synthetic polyisoprene, neoprene, nitril, butyl, including bromo-and chlorobutyl, ethylene propylene diene modified (EPDM), acid silicone elastomers.

However, the primary survey findings revealed that none of the required practices are followed and none of the acceptable material were followed while packaging the medicinal plants and / or their derivatives. When the physical examination was done in primary (hatts), secondary and wholesale trade centers everything was found to be just opposite. The only containers which were seen around were gunny sacks. On detailed discussion with the whole sale trade centres, it was ascertained that they come in this form only from the secondary

market, indicating poor packaging of the products. Surprisingly, even the traders also did not have any reservations regarding the poor quality of packaging. During the course of discussions with the traders, they said that they didn't have any issues pertaining to packaging as the only packaging methods used was in gunny bags. Probably, the exporters might be re-doing the packaging at their end lest they might lose their clientele.

Establishment of Quality Standards for raw MAPs material

The regional MAPs authority will prepare quality standard schedule with respect to various parts of the MAPs including leaves, stem, flower, fruit, seed, root/rhizome/ tuber and bark. The Standard will include freedom from insect damage/infestation, diseases due to fungi, bacteria and viruses, freedom from weeds, extraneous plant material, weed seeds, germination of seeds (in some cases viability of seeds is destroyed to prevent them from illegal germination and propagation) etc. Quality Standards should also include Colour, Flavour, Fragrance and Chemical & Physical Properties.

Justification

- Maintain the quality of MAPs produce from India.
- To fetch optimal possible price.
- To build and maintain the reputation of Indian MAPs in domestic and overseas market.
- Assistance in overall certification of MAPs material from the States.

Establishment of Herbal Drugs Quality Control Schedule

This schedule of standards is aimed at maintenance of quality of herbal drugs. It will mainly aim at (a) composition of the drug in terms of plant material and quantity per unit drug (gm/ml or tablet), (b) absence of heavy metals (Cadmium Lead, Arsenic, Mercury etc.), (c) Absence or presence of coloring material, (d) Absence or presence of binding material in tablets, (e) Declaration that drug has been prepared according to WHO parameters and/ Ayurvedic pharmacopoeia recognized in India.

Justification

- Maintenance of Quality of herbal drugs from the States.
- Establish lasting reputation of herbal drugs from the States.
- Build public confidence in herbal drugs from states.

Standardization of Packing of MAPs and herbal drugs

The MAPs and/or the drugs made from herbal need to be transported from one place to another. Subsequently, they either need to be processed for storage and/or for drug manufacture or formulation. The packing of MAPs material and drug manufacture is governed by availability, shape and size of storage place as well as consumer requirement and preference on the size of packing. Hence packing has to be defined in terms of size, container and display on the shelf and in advertisement(s).

Justification

- Good packing ensures transportation of goods in fresh, proper and desirable condition.
- Satisfies the consumer with container size, usable quantity commensurate with cost of the product.
- Optimal packing is cost effective and fully usable at household level.
- Optimal Packing avoids wastage of packing material to save the cost of packing.
- Optimal packing in terms of usage of environment friendly packing material checks damage to environment.

Packing and Containers

Different types of Medicinal & Aromatic plants and AYUSH drugs are packed using different material like metals (aluminum), glass, plastic, Styrofoam, paper etc. Emphasis needs to be placed on the point that, packing material should be as far as possible is biodegradable and/or amenable for recycling in the interests of environment protection and conservation.

Justification

- Environment protection
- Natural resource conservation
- Child safety
- Recycling of used packing material
- Cost saving to all the concerned parties.

CONCLUSIONS

The following facts about herbal drugs sector in India.

- The sector has traditionally occupied an important position in the sociocultural, spiritual and general health arena of rural and tribal population in India. In recent years, due to growing recognition of natural products and processes in sustaining human, animal and environmental health, the economic as well as environmental importance of the medicinal plant resources has increased tremendously.
- The World Health Organisation (WHO) estimated that 80% of the population of developing countries relies on traditional medicines, mostly plant drugs, for their primary health care needs. Also modern pharmacopoeia contains at least 25% drugs derived from plants and many others which are synthetic analogues built on prototype compounds isolated from plants.
- The growing importance of herbal remedies in the developed countries has attracted global attention. Medicinal plants being natural, non-narcotic, having no side-effects and being effective in the treatment of ailments like cerebral malaria, cardiac diseases, hepatitis, arthritis, jaundice, mental disorder, premature aging, general immunity, stress related diseases, diarrhoea, etc.
- At present 90% collection of medicinal plants is from wild forests, generating about 40 million mandays of employment. Current practices of harvesting are unsustainable and responsible for depletion of our resource base. Marketing of medicinal plants is inefficient, imperfect, informal, secretive, and opportunistic. As a result, the raw-material supply situation is shaky, unsustainable and exploitative.
- Medicinal plants are collected without paying attention to the stage of maturity, dried haphazardly and stored for long periods under unsuitable conditions and hence they deteriorate in quality. As the price paid to the persons engaged in herb gathering tend to be very low they often "mine" i.e up root the plants as their main objective is only to earn income for themselves and not pick the herbs with discretion and help their growth.
- Several medicinal plants have been assessed as endangered, vulnerable and threatened due to over harvesting or unskilful harvesting in the wild. Habitat destruction in the form of deforestation is an added danger. Since rural communities still depend on herbal medicines, so much so that it is the only source of health care available to them some times. Unmindful deforestation deprives them of the only available remedies for ill health.

- There is a growing demand for natural product based medicines, health products, pharmaceuticals, food supplements, cosmetics etc. in the national and international markets. For meeting this increasing demand, cultivated material is infinitely useful and appropriate for various purposes.
- The control of quality of the raw materials, finished products and of processes is an absolute necessity if one has to produce goods for world market. The quality requirements for medicinal plant preparations are stringent in terms of active principles and toxic materials. Quality has to be built into the whole process beginning from the collection/cultivation of herbs to the final product reaching the consumer. Standard preparations need to be developed to improve quality, efficacy and effectiveness of the traditional drugs.

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