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Medicinal Plants: Cultivation to Value Addition: Problems and Issues.

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ABSTRACT

Natural products (crude drugs, extracts and pure compounds) have been derived from higher plants, microbes and animals. The medicinal preparations are based upon these raw materials. The journey of raw materials from its origin to finished product goes like: Cultivator- Collector- FDC- Pharmacy- Retailer- User. The pharmaceutical research has received much attention and has been recognized as complex and multidisciplinary activity. On a global scale alone USA and Japan contributes over 50 % new drugs. It is estimated that India contributes to Rs. 100 million out of about 2500 million markets of pharma based industries. This comes to merely 1 %, the figure that does not seem to be considerably significant. The state of Gujarat has approximately some 900 pharmaceutical units that contribute very little to this 1 % global share of India, in spite of it being bestowed with variations in topographical features, rainfall pattern and diversified agro climatic and agro ecological zones. The total number of medicinal plant lore comes to 18,000 species in India (MoEF, 2010). Gujarat too has rich medicinal plant diversity with 1500 species routinely used by different pharmaceutical companies. The advancements and scientific inputs are not sufficient to combat the problem of quality assurance, continuous supply for the ever increasing demands of medicinal plants. The problems arises at several stages of the journey from non-availability of planting material, conventional methods for agricultural packaging practices, cultivation as per GAP norms and the most prominent problem of lacunae in getting technically skilled man power. Further the issues like adulteration and substitution of drugs, manipulations in quality control parameters do affect the theme of "Co-operative management" and "Combination of Techno- Economy" in spite of tremendous advances made in field of herbal technology. There are still a large number of issues like market potential, marketing channels, buy back guarantee for which suitable drugs filtered under GMP and GAP rules is not available or if available is not reaching to required persons. The present compilation highlights all such problems and issues from source raw material to finished product available in market.

INTRODUCTION

Background- Need for Good Agricultural Practices

India has a rich tradition of plant based health care systems contained in its classical texts like Charak Samhita and Sushruta Samhita. In recognition of the diversity of health care practices, the Government of India have recognized Ayurveda, Yoga & Naturopathy, Siddha, Unnani and Homoeopathy as the alternative systems of medicine under the National Health Policy.

Department of Ayurveda, Yoga and Naturopathy, Siddha, Unnani and Homoeopathy (AYUSH) in the Ministry of Health and Family Welfare has the responsibility for quality assurance and standardization of the production processes of Ayurveda, Siddha and Unnani (ASU) medicines and disseminate the guidelines for production of raw material used in ASU medicines.

To ensure and enhance the quality of ASU medicines, the Government of India have notified Good Manufacturing Practices under Schedule 'T' of the Drugs and Cosmetics Act 1940. These guidelines for Good Agricultural Practices seek to lay down standards for production of raw material that goes in to the making of the ASU medicines and standardize the production processes from farm to factory ^[1-10].

Scope

- This document is designed to play a facilitator role and shall be recommended to all stake holders.
- In the current form, these GAPs are essentially meant for and applicable to commercial scale of farming.

Soil and climatic conditions:

- The grower should identify the best possible environment where the plant can express its full potential in terms of both quality and quantity during its entire growth period (germination, growth and maturity). Meteorological data collated for preceding three years should be taken into account while judging the suitability of the site.
- In general sites designated with high-degree stress factors (salinity, acidity and toxicity), water logging conditions, industrial wastes and affluent.
- The sites in proximity to grave yards, crematoria or having a traceable history of such usage.
- A well-drained fertile soil with optimum level of water holding capacity and productivity status should be used for medicinal plants cultivation.
- In soils with low fertility levels use of soil amendments as per the specific site and requirement of species are to be followed. The latest soil test report on physico-chemical parameters and nutrient profile should be obtained to decide the nature and quantity of soil amendments required.
- The site must be in proximity to a reliable source of irrigation water.
- The quality of irrigation water should have been adequately understood and classified in the context of both soil type and the target crop in terms of total salt concentration, Sodium absorption ratio, Bicarbonate and Boron concentration etc.
- When the end-product is required to conform to standards of residual contaminants, the irrigation water must be analyzed for heavy metals and residual pesticides also.
- When shade-loving crop is planned for, availability of shade across the field should be ascertained. Provision for artificial shading should be examined in the light of crop economics.

Seeds and propagation material

The seed/planting material should be accompanied with the following information

- Name as per pharmacopoeias nomenclature and trade name
- Botanical name
- Cultivar/ Selection / Phenotype/ Chemotype/ Genotype
- Projected quality of crop in terms of physico-chemical analysis/ marker based analysis – on the basis of earlier data/ reports

Precautions

- Seed

- Stem cutting
- Root cutting

Crop management for cultivation

- Field preparation
- Sowing and transplanting
- Manures and fertilizers
- Irrigation
- Weeding and intercultural operations
- Crop protection

Harvest and post-harvest management:

- Harvesting
- Primary processing
- Packaging, storage and transportation:

Documentation

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 and strength and not conforming to the physicochemical parameters or the concentration of the active constituents or marker compounds as per the pharmacopoeial standards or 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 the potency of the raw drug in the alleviation of the human suffering. 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.

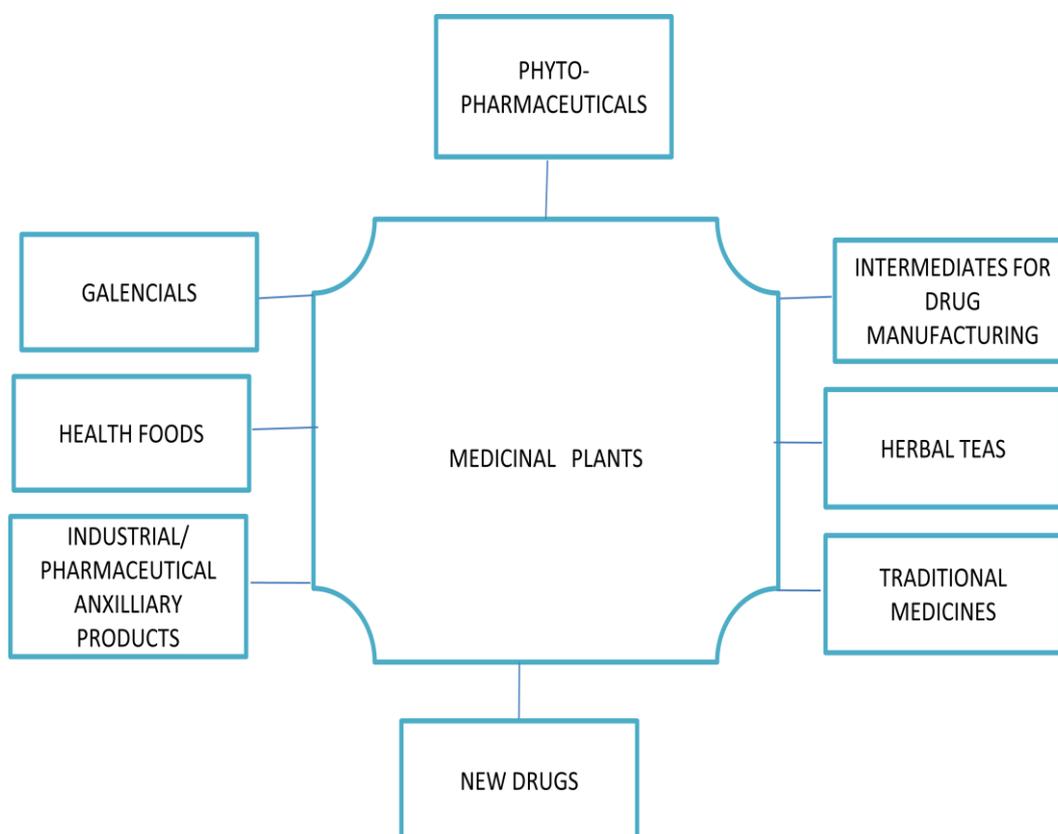


Figure 1: Industrial Uses of Medicinal Plants

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 need to be very much considered and the collection of the material should be made in the appropriate season as per the guidelines given in the annexure -1.

Harvesting and processing of the plant material (Annexure I)

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 nonjudicious harvesting.

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.

Cleaning

Any soil, stones, sand, dust and other foreign inorganic matter must be removed before medicinal plant materials are cut or ground for testing.

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.

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.

General Tips on storage of raw drugs

1. Enough and right space –dry and free from dampness or humidity.
2. Prevention of rodents, insects and birds etc.
3. Separate area for different categories of raw drugs e.g. hygroscopic, volatile materials etc.
4. Storage space should allow free movement of people and equipments.
5. Separate sections for “approved”, “rejected” and “untested” raw drugs.
6. Separation of physically similar looking raw drugs so that identity do not get mixed up.
7. Labeling raw drugs as per the following format:
 - Part (seed, bark, leaf etc)
 - Part (seed, bark, leaf etc)
 - Date of arrival and consignment no
 - Time of collection
 - Geographical region of collection
 - Name of the supplier

- Inspection report (approved, rejected and untested)
 - Test report no and date
 - Best use before date (stage for retesting)
8. Name of the raw drug Keep authenticated samples as “reference standards” for each drug in stores.
 9. Use raw drugs on a first in first out basis (FIFO).
 10. Place packed raw drugs on wooden or plastic pallets. Keep one raw drug in one pallet.
 11. Use appropriate packing material for storing raw drugs.

Always avoid

1. Storing in open spaces
2. Storing on the surface directly
3. Storing alike raw drugs in close vicinity.
4. Using inappropriate packing material.
5. Storing the material for long time.
6. Keeping the material exposed to heat and moisture.
7. Storing inadequately processed materials.

Macroscopic and Microscopic examination

Medicinal plant materials are categorized according to sensory, macroscopic and microscopic characteristics. Visual inspection provides the simplest and quickest means to establish identity, purity and possibly, quality. Macroscopic identity of medicinal plant materials is based on shape, size, color, surface characteristics, texture, fracture and appearance of the cut surface. However, since these characteristics are judged subjectively and substitutes or adulterants may closely resemble the genuine material, it is often necessary to substantiate the findings by microscopy or physico chemical analysis. Microscopic inspection of medicinal plant materials is indispensable for the identification of broken or powdered materials.

Indirect Value Addition

Quality testing for purity and strength

Testing for the Physico-chemical standards (Moisture, FOM, 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^o C or in a desiccator over phosphorus pentoxide for a specified period of time.

Foreign Matter

Medicinal plant materials should be entirely free from visible signs of contamination by moulds or insects, and other animal contamination, including animal excreta. 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.

Foreign matter consists of any or all of the following:

- Parts of the medicinal plant material or materials other than those named with the limits specified for the plant material concerned;
- Any organism, part or product of an organism, other than that named in the specification and description of the plant material concerned;
- Mineral admixtures not adhering to the medicinal plant materials, such as soil, stones sand and dust.

For some medicinal plant materials where the foreign matter may closely resemble the material itself, it may be necessary to take a pooled sample of the plant material and apply a critical test, either

chemical, physical or by microscopy. The proportion of foreign matter is calculated from the sum of portions that fail to respond to the test.

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 silicious earth.

Extractives

It is the amount of soluble constituents (active or otherwise) extracted with solvents like alcohol and water from a given amount of medicinal plant material. It is employed for materials for which as yet no suitable chemical or biological assay exists. Pharmacopoeial standards of some raw drugs native to Andhra Pradesh.

- Thin layer chromatography (TLC) identity test for the active / marker compounds.
- Quantitative assay of the active/marker compounds

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 are 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.

Microorganisms

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. The determination of *Escherichia coli* and moulds may indicate the quality of production and harvesting practices.

Certification of the quality.

Semi-processing of the medicinal plants to value added products

Powder

Thoroughly cleaned and dried plant material is powdered in a pulveriser and sieved to obtain a homogenous powder of the desired particle size.

Tablets / capsules

The homogenous powder is mixed with a suitable binding agent and compressed to a tablet or filled into a capsule of desired dosage.

Extracts

The dried and clean plant material free from foreign organic matter substitutes or adulterants is powdered and extracted with a suitable solvent like pure ethyl alcohol or methyl alcohol or solvents diluted with water in a percolator for cold extraction or in a Soxhlet extractor under reflux for hot extraction. The extracts are distilled under reduced pressure at low temperatures to remove the solvent and the concentrated extracts are spray dried. These extracts can be also standardised to a required strength of the active/marker compounds. This simple or semi-processing of the medicinal plant material adds to the value may fold.

CONSTRAINTS TO THE DEVELOPMENT OF TRADE

Cultivation of medicinal plants faces a number of problems, partly due to the typically small scale of operation. These include the following:

- The majority of farmers have small land holdings;
- Shortage of labour in rural high altitude areas;
- Long period between crop growing and harvesting;
- Bureaucratic difficulties in obtaining permits for cultivating restricted species;
- Lack of technology and difficulties in cultivating medicinal plants (particularly in high altitude areas);
- Even if cultivation technologies are developed, problems with packaging, storage, transportation and quality control persist and are neglected;
- Experiences as well as the needs of farmers are often not included in the research activities of the laboratories;
- The link between research institutes and industry is weak;
- The lack of planting material and the poor quality of planting material; and
- Prices are too low to make cultivation attractive.
- Poor harvesting (indiscriminate) and post-harvest treatment practices;
- Lack of research on development of high-yielding varieties, domestication, etc.;
- Inefficient processing techniques leading to low yields and poor quality products;
- Poor quality control procedures;
- Lack of research and development on product and process development;
- Difficulties in marketing;
- Lack of local markets for primary processed products;
- Lack of access to latest technological and market information;
- Lack of knowledge of their supply capabilities;
- Limited knowledge of plant properties;
- Intellectual property rights

AREAS FOR IMPROVEMENT

Establish a critical mass of cultivable land in order to guarantee larger consistent supply. Reduce the number of intermediaries involved in the distribution and marketing chain and increase the negotiating power of the producers and collectors. Improvements are needed in the areas of post collection handling, value addition and product presentation. Research and development on the chemical composition and the effect of poor practices on the active ingredients of the selected species. Country authorities to develop effective strategies to support improved cultivation, quality controls systems, provision of high quality planting materials, and then encouragement of investments in new technologies. Undertake a more in-depth global overview of the demand and supply of medicinal plants, herbal products and herbal drugs in order to clarify market issues, and consider more effective solutions. Developing countries should aim to cultivate their resources in a sustainable manner and enter markets at the early stages of the value chain by first supplying developed country manufacturers with unprocessed raw materials. Identify products which would be most amenable to sustainable commercial development and industrial processing in the supplying countries. Value-addition through processing, and improved marketing of the medicinal plants. It is also important that the benefits of the expanded interest in medicinal plants be more equitably shared. Value-addition through processing, and improved marketing of the medicinal plants. It is also important that the benefits of the expanded interest in medicinal plants be more equitably shared.

CONCLUSIONS

Continued loss of habitat in the future due to deforestation and development can be expected to remain a threat to many medicinal and aromatic species in both developing and industrialized countries. In tropical areas such as Amazonia and West Africa, changing land use from logging, ranching, mining, and agriculture have been identified as responsible for changes in forest composition and structure, frequently creating environments unfavorable to growing native medicinal and aromatic species and posing detrimental effects on traditional healthcare. Such destruction in natural ecosystems and the resultant losses in medicinal and aromatic species will surely increase pressure for preservation and cultivation of endangered flora. Shortages of available plant material for collection in the natural environment of

medicinal and aromatic plants can be expected to lead to increased costs for plant material until cultivation systems are in place. Estimates suggest the number of plant species used for medicinal purposes, most of which are collected in the wild, is more than 52,000 [12,13,14].

Some key features of the trade in medicinal plants are highlighted by this review:

- Pressure on the natural resource is increasing for the plants which are in greatest demand.
- The increasing market for the plant materials that are used in health and medical products.
- International trade in medicinal plants is expanding.
- Regulation is increasing.
- There is a lack of detailed, accurate, information available.

ANNEXURE – I

General Guidelines for harvesting and processing of Medicinal Plants

- Collect only mature parts.
- Do not collect the herbs from Roadsides, Sea Shores, Anthills, near Sewerage etc.
- Start drying process immediately after collection.
- Ensure complete drying before packing and storage.
- Dry aromatic herbs, delicate fruits etc. in shade.
- Store the herbs in properly constructed stores to minimize losses on storage.

Guidelines for collection of different parts of the medicinal plants:

I. Underground Parts & Whole Plants:

- Collect the whole plants after seed shedding.
- Collect underground parts when the mother plant is fully mature.
- Dry fleshy parts before packing and storing. Cut large parts into smaller pieces.

II. Bark and Stem

- Do not harvest from immature Plants.
- Collect from the Branches instead of Main Trunk.
- Strip the bark longitudinally & not all over the circumference of Trunk/Branches.
- Cut into small pieces to facilitate complete drying.
- Harvest only mature branches or stem.

III. Leaves Flowers, Fruits, Seeds and Floral Parts etc.:

- Harvest only mature parts.
- Do not collect from unhealthy plants.
- Do not collect parts manifested with insects, fungi etc.
- Dry flowers and floral parts in shade. Fleshy flowers may be dried in Sun.
- Rotten and diseased fruits should be segregated from rest of the supply.

IV. Gums, Oils, Resins, Galls etc.:

- Make vertical incisions only on some portions of the tree.

Do not collect the gums or resins from a tree continuously.

Collect the gum/resin in the right season.

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