AJH
eISSN- 0976-724X

THE ASIAN JOURNAL OF HORTICULTURE
Volume **11** | Issue 1 | June, 2016 | 233-237
Visit us -*www.researchjournal.co.in*

A REVIEW

DOI : 10.15740/HAS/TAJH/11.1/233-237

Article history :
Received : 06.02.2016
Accepted : 28.05.2016

Quality standards in medicinal plants

■ **J.D. NIRMALATHA AND G.R. SULEKHA[1]**

Members of the Research Forum

Associated Authors:
[1]Department of Plantation Crops and Spices, College of Agriculture, VELLAYANI (T.N.) INDIA

ABSTRACT : Interest in traditional systems of medicines has increased substantially in both developing and developed countries. A major lacuna in traditional medicine is the lack of drug standardization information and quality control. Most of the ayurvedic medicines are in the form of crude extracts which are mixture of several ingredients and the active principles when analyzed failed to provide the desired effect. So quality standards is utmost important in medicinal plants. It is, therefore, essential to establish internationally recognized guidelines for assessing their quality. In spite of having in depth traditional knowledge, plant biodiversity, suitable agro ecological situations and vast scientific man power, India has not achieved the level of growth what China has achieved, in the global drug market. China has pharmacologically validated and improved many additional herbal medicines and eventually integrated them in formal health care system. Considering these facts, it is high time that we should give enough attention for maintaining the quality standards in the whole process beginning from the selection of propagation material to the final product reaching the consumer, by choosing the right plant with correct botanical identity, growing in original ecological situation, meeting the requirements of good collection practices, good agricultural practices, good laboratory practices and good manufacturing practices, harvesting at the right time, drying and storage at controlled conditions, absence of pesticide, aflatoxin, and heavy metal contamination, absence of bacteria and fungal contamination, the required per cent of active ingredients, packing, labelling and proper documentation. If all the above mentioned procedures are strictly adhered, India can no doubt become an important player in the international drug market in the immediate future.

KEY WORDS : Medicinal plants, Ayurveda, Unani, Siddha

HOW TO CITE THIS ARTICLE : Nirmalatha, J.D. and Sulekha, G.R. (2016). Quality standards in medicinal plants. *Asian J. Hort.*, **11**(1) : 233-237, **DOI : 10.15740/HAS/TAJH/11.1/233-237.**

Author for correspondence :
J.D. NIRMALATHA
Department of Plantation Crops and Spices, College of Agriculture, VELLAYANI (T.N.) INDIA

This is the base for which a survey was done for quality herbal products. About 2000 native plant species are curative and 1300 are known for their aroma and flavour. The Indian system of medicine *viz*., Ayurveda, Unani and Siddha are gaining much interest in the country and world wide. The international market of medicinal plants is over US $ 60 billion per year which is growing at the rate of 7 per cent. Around 8000 sp. of plants are used by different systems of medicines in India. The Ayurveda system uses about 1769, Siddha 1121, Homeopathy 482, Folk 4671 and Unani 751 medicinal plants (Skaria *et al.*, 2003). In International market, the single most factors which is standing in the way of wider acceptance of drugs based on medicinal plants is non availability or inadequacy of standards to check or test the quality by modern analytical methods. A series of thought needs to be given to this aspect. No system of medicine can achieve any degree of credibility and mass acceptance unless some degree of quality control or assurance is maintained. In fact, this lack of regulation governing the identity and quality of herbs in the international trade has enabled substitutes, adulterated as well as take plants to penetrate the international market, thus giving a bad name to the particular system

of medicine (Rawat and Uniyal, 2003).

Quality standards in medicinal plants can be maintained by (Anonymous, 1996) :

Good collection practices (GCP)
Good agricultural practice (GAP)
Good laboratory practices (GLP)
Good manufacturing practices (GMP)
Good collection practices (GCP)

Factors affecting quality during collection :

– Age of plant
– Influence of geographical regions
– Climatic conditions
– Source of collection
– Influence of temperature
– Influence of light
– Influence of water stress.

Collection practices should ensure the long term survival of wild population and their associated habitats. Management plants for collection should provide a frame work for setting sustainable harvest levels and describe appropriate collection practices that are suitable for each medicinal plant species and plant part used such as roots, leaves, fruits etc. Prior permission is needed from government authorities and land owners for collecting plants from wild. National legislation such national "red" list should be consulted and respected. The species that are rare or scarce should not be collected. Medicinal plant materials should be collected during the appropriate season or time period to ensure best possible quality of both source materials and finished products. The species or botanical variety selected for collection should be the same as that specified in the national pharmacopoeia. In the case of newly introduced medicinal plants, the species or botanical variety selected for collection should be identified and documented as the source material.

The best time for collection should be determined according to the quality and quantity of biologically active constituents rather than the total vegetative yield. Only ecologically non destructive systems of collection should be followed. Collected plant materials should be cleaned and placed in clean baskets, mesh bags, other well-aerated container, free from foreign matter. After collection the raw material may be subjected to appropriate preliminary processing to eliminate undesirable materials and contaminants. If the collection site is located some distance away from processing units it may be necessary to air or sun dry the raw materials prior to transport.

Good agricultural practices (GAP) :

– Selection of medicinal plants. The species or botanical variety selected for cultivation should be the same as the specified in national pharmacopoeia.

– Botanical Identity: The scientific name, genus, sub species, variety, author, family of each medicinal plant under cultivation should be verified and recorded.

– Seeds and other propagation material: Seeds and other propagation materials should be specified and suppliers of seeds and other propagation materials should provide all necessary information relating to identity, quality and performance of their products. Seeds and other propagation materials used for organic production should be certified as being organically derived.

– Site selection: Medicinal plant materials derived from the same species can show significant differences in quality when cultivated at different sites. Contamination as a result of pollution of the soil, air or water by hazardous chemicals should be avoided. The impact of past land uses on the cultivation site, including the planting of previous crops and any application of plant protection products should be evaluated.

– Cultivation: Cultivation of medicinal plants requires intensive care and management. The conditions and duration of cultivation requirement vary depending on the quality of medicinal plant materials required. If no scientific published or documented cultivation data are available, traditional methods of cultivation should be followed or else a method should be developed through research. Conservation agriculture (CA) technique should be followed where build up of organic matters and conservation of soil humidity is essential.

Irrigation :

Irrigation and drainage should be controlled and carried out in accordance with the needs of the individual medicinal plant species during its various stages of growth.

Organic production:

Emphasis should be given for the organic production of medicinal plants. Use of easily degradable pesticides / botanicals / biocontrol agents / microbial, control measures is necessary. "The medicinal plants should be to cured and not to cause a disease." (Skaria *et al*., 2003)

Harvest:

Medicinal plant should be harvested during the optimal season or time period to ensure production of medicinal plant materials and finished herbal products of the best possible quality. The time of harvest depends on plant part used. The best time for harvest (quality peak season / time of the day) should be determined according to the quality and quantity of biologically active constituents rather than the total vegetative yield of the targeted medicinal plants. During harvest care should be taken to assure that no foreign matter weeds or toxic plants are mixed with the harvested plant material. Medicinal plants should be harvested under the best possible conditions avoiding dew, rain or high humidity. If harvesting occurs in wet conditions the harvested material should be transported immediately to an indoor facility to expedite drying, so as to prevent microbial fermentation or mould growth.

Good manufacturing practice (GMP) :

It is a pre-requisite to a pharmaceutical manufacturer. It covers a wide variety of issues including quality management, documentation and audit procedures.

Inspection (GAP) and sorting :

The inspection may include visual inspection for cross-contamination by untargeted medicinal plants and or plant parts, visual inspection for foreign matter, organoleptic evaluation such as appearances, damage, size, colour, odour, and possibly taste.

Primary processing :

Harvested or collected raw medicinal plant materials should be promptly unloaded and unpacked upon arrival at the processing facility. Prior to processing, the medicinal plant materials should be protected from rain, moisture and any other conditions that might cause deterioration. Medicinal plant materials should be exposed to direct sunlight only when there is a specific need for this mode of drying. Plant materials that are to be used in the fresh stage should be harvested / collected and delivered as quickly as possible to the processing facility in order to prevent microbial fermentation and thermal degradation. They should be stored under refrigeration in jars, in sand boxes or using enzymytic or other appropriate conservation and transported to the end user in the most expeditious manner possible.

Drying:

Medicinal plants can be dried in a number of ways, in the open-air, placed in thin layer on drying frames, wire screened rooms, in drying ovens or by solar dryers. The temperature and humidity should be controlled to avoid damage to the active chemical constituents. (Sabina Kop, 2001).Buildings used in the processing of harvested crops must be clean, thoroughly aerated and should not be used for the housing of livestock.

Packaging :

After repeated control and eventually elimination of low quality materials and any foreign bodies, the product should be preferably packed in new clean and dry sacks, bags or chests. Reusable packaging materials should be cleaned and dried perfectly. The label must be clear, permanently fixed and be made of non-toxic material. Information must conform with the European union and national labeling regulations.

Storage and transport :

Packed dry materials and essential oils should be stored in a dry, well aerated building. Fresh products (except basil) should be stored between 1^0C and 5^0C while frozen products should be stored below -18^0C. As a protection against pests, birds, rodents and domestic animals, the window and door openings should be protected (eg) wire netting. Organic products should be stored separately. In case of bulk delivery, it is important to ensure that the transportation conditions are dry. Further more it is highly advisable to use aerated containers to reduce the risk of mould (Anonymous, 1996).

Documentation:

All plant materials and processing steps, including the location of cultivation, have to be documented. All growers should maintain field records showing previous cropping and used input. It is essential to document the type, quantity and date of harvest of the crop as well as the chemicals and other substance (eg. fertilizers, pesticides, herbicides and growth regulators etc.) used during the production.

Quality guarantee :

Consultation between producers and buyers of medicinal plants with regards to quality questions (eg) active principles and other characteristic ingredients,

optical and sensoric properties, limited germ numbers, plant protection chemical residue and heavy metals must be based on internationally recognized or national specifications and should be laid down in written form (Anonymous, 2002).

Good laboratory practices (GLP) :

To standardize or to evaluate a crude drug means to identify and to determine its quality and purity. The identification of a crude drug can be established by actual collection of the drug from a plant that has been positively identified. The evaluation or standardization of a crude drug involves a number of methods that may be classified as

- Organoleptic
- Pharmacognostic method
- Phytochemical

Organoleptic methods:

Organoleptic refers to evaluation by means of the macroscopic appearance of the drug, its odour, taste and the feel of the drug to touch. For example the three common tulasi *Ocimum gratissismum, Ocimum basilicum* and *Ocimum sanctum* can be very easily differentiated by looking into size, colour of the leaves and also by odour (Harborne, 1973).

Pharmacognostic method:

Pharmacognosy is an applied science which deals with botanical, physico-chemical and economical features of the crude drugs (Varro and James, 1981). In a large number of cases botanically different plant now come to be used for same drug in different places and some times even in the same locality. A different plant, more easily and cheaply available is used in place of or even in addition to correct plant. The variants and substitutes are some time different species of the same genus or they may belong to different families or even to different classes. For example the morphological features of root of *Catharanthus roseus* and of *Prospis julifera* are similar. Hence, the roots of *Catharanthus roseus* which are used for curing cancer is adulterated with roots of *Prosopis julifera* which do not cure cancer. Similarly roots of *Asparagus racemosus* a well established galactagogue is adulterated with roots of *Asparagus adscendens, A. curillus,* in North Indian Market (Kishore *et al*., 1980). Another, factor which commonly produces confusion is the inconsistency in the use of vernacular names of the plants. This will affect the export of end products. Hence a systematic determination of pharmocognostical characters such as

– Anatomical studies of the fresh root, stem and leaf, physico-chemical characters such as ash value, loss of weight on drying, residue on ignition and extractive values will be very much useful in the correct identification and standardization of the crude drug (Gopala Krishnan, 2003).

Phytochemical method :

A high grade of quality in a drug is of primary importance and efforts should be made to obtain and maintain this high quality in plant drug. Hence, qualitative and quantitative estimation of the phytochemical constituents such as TLC and HPLC techniques can be employed for the isolation of a particular phytochemical. Using modern spectroscopic techniques such as UV, IR the new compounds can be characterized and their structure is determined (Goldstein *et al*.,1974).

Pesticide residues generally accumulate from agricultural practices of spraying. Since many medicinal preparations of plant origin are taken over long periods of time, limits for pesticide residues should be established following recommendation of WHO. Microbial Contamination limit in medicinal plant materials

Different limits are set according to the use of the material and material itself

For contamination of "Crude" plant material intended for further processing the limits adopted from the provisional guide lines are given below.

Escherichia coli- Maximum 10^4 per g.

Mould propagules –maximum 10^5 per g

For plant materials that have been pretreated with boiling water as used for herbal teas and infusion.-aerobic bacteria — maximum 10^7 per g

Yeasts and moulds - maximum 10^4per g

For other plant materials for internal use

Aerobic bacteria -maximum 10^5 per g

Yeasts and moulds - maximum 10^2 per g

Other enterobacteria - maximum 10^3 per g (Gupta, 2003)

Conclusion :

Plant materials are used throughout by both developed and developing countries as home remedies as drug products and raw materials for the pharmaceutical industry and represent a substantial of

the global model drug market. It is, therefore, essential to establish internationally recognized guidelines for assessing their quality. The World Health Assembly in its various resolutions (1978, 87, 89) has emphasized the need to ensure the quality of medicinal plant products by using modern control techniques and applying suitable standards. In spite of having in depth traditional knowledge, plant biodiversity, suitable agro ecological situations and vast scientific man power, India has not achieved the level of growth what China has achieved, in the global drug market. China has pharmacologically validated and improved many additional herbal medicines and eventually integrated them in formal health care system. Considering these facts, it is high time that we should give enough attention for maintaining the quality standards in the whole process beginning from the selection of propagation material to the final product reaching the consumer and of all the above mentioned procedures are strictly adhered, India can no doubt become important player in the international drug market in the immediate future.

REFERENCES

Anonymous (1996.).Good manufacturing practices: Supplementary guidelines for manufacture of herbal medicinal products. 1996. In: WHO Export Committee on specifications for pharmaceutical preparations 37th report. Geneva WHO 2003 (WHO technical report series No.908).

Anonymous (1996). WHO Export committee on specifications on pharmaceutical reparations. Thirty fourth report, Geneva WHO 1996. (WHO technical report series No.863

Anonymous (2002). Quality control methods for medicinal plant materials. *World Health Organization*, Geneva. A.I.T.B.S. Publishers, Delhi. p.115

Chandra, S.V. (1980). Toxic metals in the environment R&D Bulletin. Lucknow, India.p.62

Goldstein, A., Arnow, L. and Kalman, S.N. (1974). *Principles of drug action. The basis for pharmacology*, 2nd Ed. John Wiley and Sons, New York . p.836

Gupta, A.K. (2003). *Quality standards of Indian medicinal plants.* Vol. I, ICMR. New Delhi. 262 p.

Gupta, A.K. (2003). *Quality standards of Indian medicinal plants,* vol II, ICMR. New Delhi. 301 p.

Harborne, J.B. (1973). *Phytochemical methods,* 2nd Ed Chapman Hall, New York, p. 225.

Kishore, P., Panday, P.N. and Panday, S.N. (1980.). A note on galactogue activity of *Asparagus racemosus* in the lactating goats. *Indian J. Res. Ayur. Sidha,* **I** : 409-416.

Mathus, K. (1978). *The Alkaloid.,* **6** : 1-30.

Rawat, R.B.S. and Uniyal, R.C. (2003). Quality control and standardization in herbal products. International herbal export 2003 seminar 4-6 July, Chennai, p.31.

Sabina Kop (2001). Guidelines on production, processing, labeling and marketing of organically produced food. Rome, Joint FAO / WHO food standards program, 2001.

Skaria, B.P., Samuel Mathew and Mathew, Gracy (2003). Constraints and strategies for the development of medicinal and aromatic crops in India. National seminar on new perspectives in spices, medicinal and aromatic plants, 27-29 Nov. 2003, Goa.

Varro, E. and James, Roberts (1981). *Pharmacognosy*. 8th Ed., Lea and Febiger, Philadelphia. 250 p.