



Review Article

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QUALITY ASSURANCE IN PHARMACEUTICS: AN AYURVEDIC PERSPECTIVE

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ABSTRACT

Among the padachatushtaya, medicine is given the next importance after doctor and while highlighting its significance Acharya Charaka has said that doctor equipped with medicine is capable of restoring the health of the individual by removing the fear of disease. In saying this they meant that, the medicine should be of good quality and having maximum potency. ISO 9000 defines quality assurance as "A part of quality management focused on providing confidence that quality requirements will be fulfilled" and is different from quality control. The same has been highlighted in our ancient classics thousands years back. Acharyas mentions about the different parameters to be followed right from collection of raw drug, to processing and storage of final product. WHO have given certain guidelines to ensure the safety and efficacy of the medicine along with its quality control parameters. Following the ancient classics with a touch of scientific reasoning may help in solving the mystery and bringing back the glory of Ayurveda. The drugs used in Ayurveda fall under three categories viz herbal, mineral and animal origin. The collection of drugs include different steps like place, time, method of collection etc. processing techniques include various procedures carried out on the drug, where as storage techniques include different methods of preservation. All these steps involved not only ensure the high potency of medicine but also has a great impact on the preservation and conservation of the environment, thus providing an unending supply for our future demands.

Key words: Quality Assurance, Pharmaceutics, Ayurveda

INTRODUCTION

In the era of globalization and commercialization, the popularity of Ayurvedic medicines is seen vastly among the health seekers. The challenge lies in providing safe and efficacious medicines to the society not only to restore the health of an individual but also to generate faith among the masses. Here medicine plays a pivotal role and hence among Chatushpada (four pillars) it is given next importance to doctor¹. While highlighting its significance, Acharya Charaka has said that doctor equipped with medicine is capable of restoring the health of the individual by removing the fear of disease. In saying this scholars meant that the medicine should be of good quality and having maximum potency. ISO 9000 defines quality assurance as "A part of quality management focused on providing confidence that quality requirements will be fulfilled" and is different from quality control². The same has been highlighted in our ancient classics thousands years back. Acharyas mentions about the different parameters to be followed right from collection of raw drug, to processing and storage of final product thus fulfilling the qualities of superior medicine. WHO have given certain guidelines to ensure the safety and efficacy of the medicine, like GMP, GAP, GLP etc along with its quality control parameters. Following the ancient classics with a touch of scientific reasoning may help in solving the mystery and bringing back the glory of Ayurveda.

QUALITIES OF MEDICINE

Bahukalpaam bahugunam sampannam yogyamaushadham |
A H 1/26

While saying about the qualities it is said that the medicine should be rich in quality, available in abundance and should be multipurpose in utility and applicability³.

Yogadapi visham tikshnam uttamam bhashajam bhavet
Bhashajam cha api duryuktam tikshnam sampadyate visham |
Cha Sa su 1/126

Visha (poison) when properly administered acts like a superior medicine and medicine when not properly administered acts as a poison⁴

IMPORTANCE OF MEDICINE

Yatha visham yatha shastram yatha agni shani yatha
tathaushadham avidnyatam vidnyatam amrutam yatha |
Cha Sa su 1/124

Improperly understood drug acts like a poison, weapon or fire and same when properly understood acts like an amruta (elixir)⁵

Tadeva yukta bhashajam yad aarogyaya kalpate |
Cha Sa su 1/134

Doctor equipped with medicine can restore health by removing the fear of disease⁶

ISO 9000 defines quality assurance as "A part of quality management focused on providing confidence that quality requirements will be fulfilled"

According to WHO guidelines the following parameters should be fulfilled to ensure good quality of the drug⁷

- Quality control of crude drugs material, plant preparations and finished products.
- Stability assessment and shelf life.
- Safety assessment; documentation of safety based on experience or toxicological studies.

- Assessment of efficacy by ethno medical information and biological activity evaluations.

According to Ayurveda the quality assurance can be evaluated in following steps

- Raw drugs of herbal, mineral and plant origin
- Different procedures carried out during the process
- Different storage techniques adopted for final product

RAW DRUGS

Raw drugs can be classified as Pranjia (animal origin), Khanija (mineral), Vanaspatija (herbal)

Animal drugs

Animal products like blood, hair, nails, milk, urine and feces should be collected of matured animals and after the food is digested.⁸

Mineral drugs

For mineral drugs the grahya and agrahya lakshanas (selection criteria) should be followed which can be related to streaks, cleavage, hardness, fracture etc. eg Copper has hardness 3 where as Diamond has a hardness of 10 on Mohs scale, Tenacity of Mica is elastic where as that of Gold & Silver is malleable. Place of collection should be followed for ex Abhraka (mica) should be collected from north direction and at the depth of 56 cm from the ground level. Period of collection should be taken into consideration for eg Mandura (iron oxide) which is 100 yrs old is considered as best. For certain formulations some specific rules are mentioned eg Tamra(Copper) for Abharsundara rasa (Rasayoga Sagar) should be Nepalaja variety (available from Nepal), for Kasisadi Taila (Gadaniagraha), Kasisa (Ferrous sulphate) should be collected from KutchGujrat.

Herbal drugs

For herbal drugs the following factors should be considered viz growth, protection, nourishment, collection, preservation & storage.

1. Growth: the four important factors required to be considered for growth are season, place, water and seed while growing a plant. When all these four factors are appropriate the plant will have proper growth.
2. Protection: the plants should always be protected from natural calamities like rain, strong wind and insects.
3. Nourishment: the plant should be nourished with proper fertilizers. In Vruksha Ayurved and Agnipurana different fertilizers are mentioned⁹ Eg – for Matulunga (*Citrus medica*), faeces of horse, boar, Vidanga (*Embllica ribes*) and Kinva (yeast) with horse urine should be used to get good fruits, for Kadamba (*Anthocephalus indicus*) & Nagakeshara (*Mesua ferra*) to get good flowers dadhi mastu (whey), sura (alcoholic preparation), kanji, sesame etc. should be added as fertilizers. Watering of plants should be morning and evening in summer season, in winter for alternate days and in rainy season at night if the land dries.
4. Collection: For collection of drug the different stages of the growth of plants imparts certain qualities to the drug. The following are the examples of drugs which should be used at different stages.
 - a) Wet and dry drugs:¹⁰ The following drugs should always be used in wet form eg. in Kutaja (*Holerina antdysentrica*) the conesin, an active constituent is present in wet drug but absent in dry. In Vasa (*Adathoda vasica*) the volatile oil present, has kapha srava property which is absent in dry. In Ashwagandha (*Withania somniferra*) the wet tuber has peculiar odour of horse urine which is absent in dry.

Others drugs like Nagavalli (betal leaf), Tulasi (*Ocimum sanctum*), Kadali kanda etc should always be used in wet form.

- b) Nava and Purana(New & Old):¹¹ certain drugs should be kept for a duration and then used. For eg grains should be used after 1 yr as it becomes light for digestion where as new is abhishyandhi(Astanga Hrudaya). Old Jaggery (1-2 yrs) is hrudya and pathya whereas new is increases Kapha and reduces appetite. New honey increases obesity where as old (after 1 year) is grahi, lekhaana and reduces obesity.
 - c) Pakwa and Ama(Ripe & Raw):¹² the properties of the drug change from raw to ripe. Eg in raw Kapitha is kanthaghna and doshala and ripe subsides hiccups and vomiting & poison. Raw Bilwa (*Aegle marmalos*) is sangrahi, guru, deepana whereas ripe is tridoshaghna. Ripe Udumbara (*Ficus glomerata*) is pittaghna, madhura shramashoshajit whereas raw is astringent, deepana and rochana.
 - d) Desha bheda (Place of availability):¹³ The place from where the drugs are collected also influences their qualities. In general the drugs with hot potency should be collected from Vindya place where as drugs with cold potency are collected from Himalayan region. The drugs can also be collected from forests and other area where it is cultivated but they should never be collected from uneven surface, burial ground, temple area.
 - e) Types, colour & size:¹⁴ According to the type, the drug will have following properties, eg Ashok (*Saraca ashoka*) white variety is best for all formulations where as red variety improves the voice (Meghadoot), black variety of Datura (*Datura alba*) is best among its four varieties. Aragwadha (*Cassia fistula*), small variety is tikta, katu, ushna whereas as big variety is madhura and sheeta. Cardamom small variety will harmful for the foetus whereas big variety is beneficial.
 - f) Part of plant used: Certain parts of the plant have maximum potency and hence only those parts should be used in the formulation. The same has been mentioned in Sharangdhara Samhita, Shaligram Nighantu and also modern texts of pharmacognosy. Eg Chitraka (*Plumbago zeelaynica*) root should be used, Surana() tuber is used, Vasa (*Adathoda vasika*), Nimba (*Azardiracta indica*), Talisa (*Abies webbiana*) leaves, Dhataki (*Woodfordia fruticosa*) flowers, Triphala fruits, Khadira (*Acacia catechu*), Beejaka (*Pterocarpus marsupium*) heartwood should be used as they contain the maximum potency of the drug.
 - g) Time/season: The season also plays an important role in collection of drugs. Generally Sharada rutu (Autumn) is considered best for collection of all drugs, whereas Vaman & Virechan drugs should be collected in Vasanta rutu (Spring season). Some drugs should be collected during a specific time period to ensure maximum potency eg Amalaki in Magha/Phalgun (January/February) according to Charaka Chikitsastana, Apamarga (*Achyranthus aspera*) on Sunday according to Vrunda, Trivruta (*Operculina turpethum*) in Pushya nakshatra according to Shodal Nighantu, Dhatura in morning and Digitalis in evening and Surana should be 2 yr old for Kaishora Guggulu according to Rasayogasagar
5. Preservation: Drying of the drugs in shadow or sunlight helps in gaining the maximum potency eg Datura leaves dried in sunlight had less percentage of alkaloids compared to those dried in shade. In Tea, tannin is converted to tannic

acid which is less harmful after drying. Drugs like Shilajatu (*Euphorbia royalina*), Hingu (*Asafoedita*), Ahiphena (opium) should be in their natural wet form to maintain its potency.

6. Storage: for storing the containers should be wooden, glass, metal, tusks, horn etc and should be selected according to the drug being stored.

IN PROCESS PROCEDURES

The qualities of the drug/formulation can be altered by carrying out certain sanskaras (procedures). The following factors are responsible for the same viz Fire (heat), water, time, Shodhana (purification) and Marana (incineration).

1. Fire (Heat): It is very important for carrying out different procedures like melting, drying, frying, boiling etc. It can be used in two ways a) direct and b) indirect.
 - a) Direct heat can be used in two ways, one way is for eg Loha shodhana (iron purification), the fire of Khadira (*Acacia catechu*), Vibhitaki (*Terminalia chebula*), Jambu etc is used as the chemical present in them help in easy disintegration of iron sheets. The other way of using fire is for attaining proper paka of certain formulations like Sneha¹⁵ (oil/ghee), Avaleha (confectionaries), Parpati, Kupipakwa etc. The intensity and duration of fire helps in proper paka of these formulations. Also different putas and the type of fuel such as cowdung, husk, wood etc used varies depending upon the drug being processed. Fire can also be used through medium like Kshara (alkalis), Lavana (salts) etc in preparation of Hartala bhasma.
 - b) Indirect heat: indirect heat can be used in two ways, one is the heat from sun is used for preparing various formulations like eg Kasisadi taila prepared in sunrays, trituration in Arkamurti Rasa (Bhaishajya Ratnavali), drying for Grahani Kapata Rasa (Bhaishajya Ratnavali), Putana in Tarunagni Rasa. The other is after preparing the medicine heat is given through dhanyarashi(heap of grains), chullika garbha (fire place), bhugarbha (pit in earth) for certain duration to attain maximum potency eg Arshakuthar rasa should be kept in Bhallataka tree, Panchamutrasava in chullyagra(near fireplace) etc.
2. Water: It is important for carrying out different procedures like washing, cleaning, processing different preparations etc. Qualities of water from different sources and in different season are mentioned which should be selected according to the procedure. Eg in Sharada rutu(Autumn) water from all sources is considered as best (Nirdosha), similarly water from Jangala desha is laghu compared to Aanupa desha. Qualities of sanskarita jala are also mentioned. Eg boiled and cooled water is good for Murcha (unconsciousness), Daha (burning sensation), Shrama (tiredness), Bhrama (giddiness) whereas warm water is destroys Kapha, fat and undigested food.
3. Time: It includes the time period required during preparation and processing of medicine eg formulation containing Lavana and Kshara should not be prepared in rainy season.
4. Shodhana (purification): Different shodhana procedures are mentioned in the classical texts such as Bhavana (trituration), Swedana (fomentation), Bharjana (frying), Nimmajana (dipping), Dhavana (washing), Pachana (digestion), Nirvapa (quenching) etc. They are selected depending upon the drug undergoing shodhana process eg Bhavana for Tutha (Copper sulphate), Nirvapa for Abhraka. Shodhana media should be selected depending on the disease in which it will be used. Eg Hingula is given ginger

juice bhavana when used in Tribhuvana keerti rasa and lemon juice bhavana in Laghumalini vasanta rasa.

5. Marana: After shodhana the metal /mineral is subjected to Marana (incineration) to make it readily absorbable. After bhasma preparation it has to pass through certain tests i.e bhasma pareeksha to make it fit for internal administration. These tests reveal about the physical nature and chemical stability of bhasma thus avoiding untoward side effects.

FINAL PRODUCT¹⁶

Certain rules should be followed while storing a finished product. Bheshajagaar reference in (Charaka Kalpasthana) is almost similar to the requirements as per GMP. The finished product should be stored away from water, light and air. Vessels made from different material are mentioned for storing different formulations such as gold, silver, copper, mud, glass, wood, tusks etc. Eg Kumari asava is stored in stone or mud vessels according to Sharangadhara Samhita, Mahajwarankusha in container made of tusks (Rasa Ratna Sammucchaya), Kushmandaavalehya in mud container (Rasayogasagar) and Balamruganka rasa in gold container (Rasayogasagar).

DISCUSSION

Quality of a drug is of utmost importance to assure a good quality formulation. Ayurveda mentions about different parameters for herbal, mineral and animal origin drugs which assure its good quality. Some of these parameters can be explained with the help of modern techniques but some still remain unexplained. Following these parameters right from raw drug collection to making of final product can bring about a tremendous change in the potency of the medicine and also ensue about its safety. It also mentions about the part of drug having maximum potency thus helping in unnecessary wastage of the whole plant. The various fertilizers mentioned may help to reduce the percentage of pesticide residue and heavy metal content in the drug thus making it safe for internal use.

CONCLUSION

Ensuring good quality of drug will assure a good quality formulation. It is necessary to explore the concepts of Ayurveda for a better quality medicine. The parameters mentioned need to be evaluated with a scientific approach. There remains further scope of research with physical, chemical and biological evaluation of the drug for the benefit of mankind.

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