



RECENT ADVANCES IN QUALITY CONTROL METHODS OF AYURVEDIC FORMULATIONS

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ABSTRACT

Quality control is an integral part of medicine to ensure the quality of medicament. Various multi-disciplinary and bio-analytical approaches such as development of Standard Operative Procedure, preliminary Phytochemical evaluation, physicochemical evaluation, chromatographic evaluation, safety and efficacy evaluation have been employed for the standardization of various Ayurvedic formulations. One of the important factors hindering the globalization of Ayurvedic drugs and therapies is the lack of standardization. To achieve the reproducibility, efficacy and safety of the product standardized protocol of quality control is very essential. In ayurvedic system identification of the genuine raw drugs is done on the basis of their morphology and rasa panchaka. In addition the recent advancements like DNA finger printing, identification of biomarker compound also add for authentication and discrimination of genuine raw drugs. Various protocols containing the parameters to assess various dosage forms help in standardization of the formulations. An overview covering various techniques employed in extraction and characterization of herbal medicines as well as Nano medicines standardization is also reported. Advancements of instruments help to reduce the manpower and the advancements of quality control techniques assist to identify the adulteration and compound present in the formulation.

This paper aims to highlight the recent advancement methods adopted for standardization.

KEYWORDS: Quality control, Formulations, Advancements, Standardization

INTRODUCTION

Today, Ayurveda is an officially recognized system of medicine in India. Globally, the World Health Organization (WHO) recognizes it as a Traditional Medicine. Quality control is an integral part of medicine to ensure the quality of medicament. One of the important factors hindering the globalization of Ayurvedic drugs and therapies is the lack of standardization because most of the ingredients are in adulterated form. To avoid adulteration from raw drug to formulation need of proper quality control techniques is necessary. The basic principle of Ayurveda is the same as devised by our Acharyas only the way of presentation has changed owing to the advent of modern technology. The quality of the product should be ensured. In addition, the recent advancements like DNA finger printing, identification of biomarker compound also add for authentication and discrimination of genuine raw drugs. Also the newer era of instrumentation technique will help to avoid the man power and helps for the large scale production of Medications. So ayurvedic formulations need various protocols containing the parameters to assess various dosage forms help in standardization of the formulations.

Quality Control

The quality control technique has to be known before commencement of production. Quality control is an integral part of medicine to ensure the quality of medicament. Quality has to be maintained right from the collection and until the final

production. Standardization is a numerical value or specific property that quantifies the purity, quality and safety of a drug and formulated medicine. WHO has declared and focused on method of evaluation of medicinal plants and drugs using modern quality control methods to assure the standards of ayurvedic medicines.

Guidelines for Quality Control of formulation

The guidelines that need to be followed while analyzing the quality of the formulations are:

- Quality control of crude drugs material, plant preparations and finished products
- Stability assessment and shelf life assessment.
- Safety assessment; documentation of safety based on experience or toxicological studies
- Assessment of efficacy by pharmacological Information's and biological activity evaluations

Area of Interest

Ayurvedic compound formulations are broadly classified under Rasaushadhi and Kastaushadhi

In Case of Rasaushadhi:

Rasoushadhis are mainly based on minerals (compound state) and metals (elemental state). These are in used in less dosage, are tasteless, Quick in absorption and effective, also they have infinite shelf-life with wide range of therapeutic efficacy,

Effective on dreadful chronic and incurable diseases; also, it can be stored and transported easily. Generally claimed, that these are metals detoxified during the highly complex manufacturing process described in Ayurveda especially Rasa shastra text. But still in an era of developing Herbo metallic preparations proper validation and standardization is of utmost importance.

There are the products of mineral material like Shuddha dravya, Bhasmas, Sindura, Pottali, Parpati, Druti, Drava, Satwa and Kharaliya rasayana. Innumerable formulations of Rasoushadhis are derived with these combinations.

Highlight on the Concept of Bhasma along with its recent advancements:

- Herbs were widely used for medicinal purposes from the ancient past. Gradually minerals were also identified and incorporated for medicinal purposes. For making fine powder heating, quenching in various liquids, grinding and filtering through cloth were adopted. Later along with these techniques, many other specialized processing techniques like Shodhana (purification), Marana (incineration/calcinations), Samskara (specialized processing techniques specially used for mercury) etc were also developed. With the advent of processing techniques of Rasa Shastra, use of metals and minerals came frequent in therapeutics.
- For the production of Bhasmas, Shodhana and Marana, these two -fold procedures are the important steps (including some intermediary procedures in respect of particular materials like Dhanyabhraka for Abhraka and jarana for lead, tin and zinc).

There are many testing parameters, through which product can be judged, Like

1. Physical:

- Rekha purnatwa (indicative of fineness)
- Varitaratwa (lightness)
- Nishchandratwa (free from metallic luster),

2. Chemical:

- Apunarbhavatwa and (complete conversion into non reversible compound)
- Nirutthatwa (absence of free metal in bhasmas)
- Niswadu, Dadhi / Amla parikshaas for Tamra or Tamra containing metals (indicative of absence of free metallic radicals in the bhasmas),

Also the Colour of various Bhasmas i.e.

- Swarna - Champaka Varna (reddish yellow colour),
- Rajata and Tamra - Krishna Varna (black),
- Vanga – Sweta Varna (white) etc.
- Kamsya – Dhusara.
- Naga – Kapot Varna.
- Teekshna loha – Pakwa Jambu phala Varna.
- Abhraka – Istika Varna (brick red colour).

These testing parameters are essentially followed for the determination of Bhasmas on process as well as on product level.

While Uses of modern tools and recent techniques for testing bhasmas:

Ancient time period of tests are time tested and perfect but these essentially based only on naked eye observation and experience. They have limited sensitivity and can be applied only after long experience and practice.

But with the advent of modern science and technology many other sophisticated and sensitive tests are being employed for ascertaining the standards of the Bhasma prepared. These include metallographic study, Spectrophotometer, Scanning electron microscopy (SEM), X Ray Diffraction, Atomic Absorption Spectrophotometer, Particle size analysis etc. The analytical study of metallic bhasmas reveals that physical and chemical changes take place after each and every process. Hence chemical analysis on the level of ash content, acid soluble / insoluble content, moisture content, specific gravity, loss on ignition, loss on drying etc. should be determined.

These recent methods give for different percentage of presence of elements in particular bhasmas and incase of raw drug for any presence of toxic substance. Also in recent advances the study of minerals includes Petro logical studies to analyze the structural changes in the samples before (raw), in process and after (finished) processing.

In Case of Kastausadhi:

Herbal formulations have reached extensive acceptability as therapeutic agents for several diseases. Like Panchavidha kashaya kalpana, Asava, Arista, Vati, Churna etc. For each dosage forms are having proper parameters mentioned to assess the quality.

In Ancient time medicines were prepared by the physician and they were well qualified to identify the materials were trained in various processing. They were following guidelines of Shastra and experienced teachers. According to the immediate need of patients they were modifying the formulations as per their occupied understanding. In ayurvedic system identification of the genuine raw drugs is done on the basis of their morphology and rasa panchaka and has particular siddhi lakshanas for particular dosage forms. Those siddhi lakshanas were considered as the proper test for analyzing the formulations.

But at present scenario Physicians are more involved with diagnosis and treatment. Drug manufacturing has gone into the hands of Pharmaceutical companies. The crude drugs are mostly in the hands of shopkeepers who supply them to the pharmaceutical industries. They are using their own methods. In large scale production they compromised with quality and quantity of material. Equivalent substitutes are added in the compounds are not validated. The exact important procedures either alternated or made shortcut. This lead to the decline in the quality of ayurvedic drugs. The standardization of ayurvedic drugs is thus felt necessary. So the recent techniques will able helps to find out the presence of compound and helps for find out the adulteration technique like chromatographic (for qualitative and quantitative analysis) and thermos gravimetric techniques individually and/or in combination with the relation

to herbal drugs. Capillary electrophoresis and polarographic techniques contributions towards standardization of herbal drugs is also reported. Nanotechnology based Chinese herbal drugs possess improved solubility and enhanced bioavailability. In addition, the recent advancements like DNA finger printing, identification of biomarker compound also add for authentication and discrimination of genuine raw drugs. In recent years, plant derived products are increasingly being sought out as medicinal products, nutraceuticals and cosmetics and are available in health food shops and pharmacies over the counter as self-medication or also as drugs prescribed in the non-allopathic systems.

Example of churna like in ayurvedic aspect it has to be comes in sukshma churna after vastra gaalana, but for making Kwatha it has to be in the form of yavakuta. But in modern parameters like Particle size, Total ash, Acid/water soluble ash, Alcohol soluble extractive, Loss on Drying, Bulk Tap Density, pH, Test for heavy metals and micro-organisms, TLC/HPTLC/HPLC/GCMS, Test for pesticide residue, Test for specific pathogen, Test for aflatoxins.

With new advanced technique like atomic emission spectrometry helps to find out the heavy metal percentage and pesticide presence.

Need of Recent Advancement Techniques in Quality Control

- To prove the authenticity of medicaments scientifically
- For large scale production
- For Standardization

Also in the process of evolution many new ways of presentation such as different dosage forms have revolutionized. To achieve the reproducibility, efficacy and safety of the product standardized protocol of Quality control is very essential.

DISCUSSION

As there is an increase in demand and use of ayurvedic medicines, there is a need for bulk manufacture for the fulfillment of demands without compromising the quality. So there is a need to standardize and maintaining the quality of the product. There are few ancient principles comprising of raw material collection and storage according to Desha, Kala, Ritu and Bhumi. These help in maintenance of the quality of formulations. To know the standard and shelf life of ingredients used in the formulation's quality control is done. Quality control is of much relevance these days as the pharmaceutical industries are profit oriented due to increased competition and thus more prone to cause drug adulteration in order to meet increasing demands. So, for this SOP and good QC by integration of modern scientific technology and traditional knowledge is important.

CONCLUSION

The advent of globalization has focused the need to establishment of standards for ayurvedic drugs and formulations, so as to ensure proper use of the medicines so prepared for the benefit of the end user without any unwarranted complications. Thus, standardization is needed to establish quality control parameters for all traditional drug before it is released for use without the

fear of toxicity and contamination. The rules of present era focus on the standardization of formulations to achieve global acceptance. Thus, the quality control plays an important role.

REFERENCES

1. Anonymous. Ministry of Health and Family Welfare, Government of India, Department of Ayush. Protocols for testing of Ayurvedic, Siddha, Unani medicines by CCRAS.
2. Ravindra Angady. A text book of Bhaishajya kalpana Vijnana, 1st ed. Varanasi: Chowkamba; 2009
3. Sarma S. Rasatarangini. 11th ed. Kashinath S(ed.). Delhi: Motilal Banarasidas
4. Anonymous. Ministry of Health and Family Welfare, Government of India, Department of ISM & H. Ayurvedic Pharmacopeia of India. Ayurvedic Pharmacopeia of India. 1st Ed. New Delhi. The Controller of Publications Civil Lines; 2004