

STANDARDIZATION PROTOCOL OF RASS FORMULATIONS; AYURVEDA AND MODERN PERSPECTIVES

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ABSTRACT

Rasaushadhies are considered most efficacious medicines amongst the many classes of drug of Ayurveda. They impart quick action even in minute dose minute dosage and offer advantage of easy palatability. Rasaushadhies are made by using herbs along with minerals and metals. The Rasa converted into non toxic form that after utilizes for therapeutic purposes. Rasaushadhies are gently absorbable and digestible thus provides quick and potent responses in many pathological conditions including skin diseases, digestive problems, sexual disorders, respiratory diseases and gynecological problems, etc. The quality standardization of such medicine is big issue since they can exert harmful effects if not meet the desirable quality standard. Ayurveda as well as modern science presented many approaches to establish quality standard of Rasaushadhies. Nischandrika, Rekhapurnatvam, Varitaratavam, Apurnabhava and Avami, etc. are some parameters which can be used to check quality of Rasaushadhies. The standardization protocol needs to be follows properly during and after the preparation of Rasaushadhies to confirm their quality standard.

KEYWORDS: Ayurveda, Rasaushadhies, Quality, Nischandrika, Varitaratavam.

INTRODUCTION

Ayurveda medicines are made up from various sources including minerals, metals, animals and plants, etc. The Ayurveda formulations prepared from minerals, metals and herbs using specific procedures like *Shodhana*, *Bhavana*, *Marana*, *Murchana* and *Jarana*, etc. are considered *Rasaushadhies*. The toxic metals converted into non-toxic forms by purification and processed with herbs and other materials to acquire therapeutically active formulation. The *Rasa* formulations are very potent and offer health benefits in many pathological conditions. The improper uses of these drug may causes toxic effects, similarly if *Rasaushadhies* not prepared properly then their quality may compromises leading to the health consequences. Therefore the accuracy in

preparation and quality checking is prerequisite when dealing with *Rasaushadhies*.^[1-4]

The texts of *Rasa shastra* is enriched processing techniques of formulations prepared from metals and minerals. The quality controls of metallic formulations especially *Bhasma* mentioned in ancient texts and modern literatures also available regarding the quality testing of herbo-mineral formulations. Standardization of these formulations is very essential to ensure quality of final formulation. The ancient parameters of quality control (**Figure 1**) for metals and minerals containing formulations are easy to perform and low cost with ability to confirm safety and quality of formulations.^[4-7]

Physical & Chemical Characteristic				
<i>Verna</i>	<i>Nishchandravtm</i>	<i>Varitara</i>	<i>Apunarbhavata</i>	<i>Niruttha</i>

Figure 1: Quality parameters for *Rasaushadhies* especially *Bhasma*.

Standardization Protocol

- ✓ Standardization of *Rasaushadhies* involves number of processes and standardization should not only be done of final product but quality standardization of intermediates is also required. Thus it can be stated that the quality testing should be performed during the every stages of preparation to ensure complete safety and efficacy of formulations.
- ✓ The quality of raw materials also needs to be check.
- ✓ The working efficiency and calibration of instrument also suggested during the preparation of *Rasaushadhies*.
- ✓ Heating devices, heating temperature, processing steps and purification protocols, etc. also need to be check.
- ✓ Colour, fineness, odour, taste and safety profile, etc. should be confirmed as quality standardization.
- ✓ Validation of method of preparation should be done by manufacturing same product using similar method and instrumentation for number of times, the outcome should be reproducible with specification of parameters considering acceptable deviation.
- ✓ The analysis of should be done many times to confirm accuracy of results, even change in analyst also suggested many time to confirm specific human error.
- ✓ Process variables, effects of quantity on quality parameters and effects of climatic conditions/place, etc. also need to be consider while performing quality standardization of *Rasaushadhies*.^[6-9]

Standardization of Physical Characteristics

Varna, *Rekhapurnata*, *Nishchandravam*, *Varitara*, *Nisvadutam*, *Amla pariksha*, *Avami*, *Nirdhuma*, *Anjana Sannibham* and *Susakshamata*, etc. are major parameters can be used to ensure safety and efficacy of micronized *Rasa* formulations. These parameters not only confirm quality of final products but also validate steps involved in manufacturing process.

Varna (colour)

Varna (colour) is specific to many *Bhasmas*; any changes may suggest improper quality of product. The metallic compound possesses specific *Varna* thus formulation should represents their processed colour.

Rekhapurnata

This test confirm fineness of formulation, very minute amount of formulation rubbed in between the index finger and thumb, the particles should embeds into finger prints to confirm fineness of formulation. This quality helps in easy absorption and assimilation of formulation inside the body.

Nishchandravam (luster)

Nishchandravam (luster) is an important feature of metals which should be removing after incineration. The luster of metal should not remain present in final formulation due to the effects of processes employed for formulations. The presence of luster can be observed in

sunlight which indicates more requirements of incineration and processing to get luster free formulation.

Varitara

This property confirms *Laghuta* (lightness) and fineness of herbo-mineral formulation. The formulation sprinkle over the water, it should float over the water.

Nisvadutam

The formulation should be tasteless when kept on tongue; it should not offer metallic taste which proves complete processing of formulation.

Amla pariksha

In this test formulation mixed with little amount of *Dadhi* and observed for any changes in colour, there should not be any changes in colour of formulation.

Nirdhuma

The *Bhasmas* should not produce any smoke when put on fire.

Anjana Sannibham

The *Bhasma* formulation should be smooth in character, should not cause irritation when tested for smoothness.

Standardization of Chemical Characteristics

Apunarbhava

This indicates incapability to regain its original form, in this test *Bhasma* mixed with *Mitra panchaka varga dravya* then put in a *Musha* and subjected for heating along with appropriate *Putra*. There should not be any changes in the quality and quantity of *Bhasma*, this represents incapability of formulation to regain its original form.

Niruttha

This test indicates absence of free metal left in formulation after processing. Formulation mixed with *Rajata* then put in a *Musha* and subjected for heating, formulation (*Bhasma*) should not adhere to *Rajata* (silver), this indicates that there is no any free metal left out in the formulation and formulation prepared properly.^[9-11]

Modern Approaches

Solubility test, Loss on Drying, Total Ash value, Acid insoluble and Water soluble Ash value, Water soluble extractive value and Alcohol soluble extractive value, etc. can be performed to ensure quality and safety of herbo-mineral formulations mainly *Bhasma*.

The instrumental methods like XRD (X-ray powder diffraction), XRF (X-ray fluorescence), FTIR, SEM (Scanning electron microscope), ICPAES (Inductively coupled plasma atomic emission spectroscopy) and Particle size Analysis by TEM, etc. are evolved in past few years as authentic techniques to establish quality standardization of *Rasaushadhies* mainly *Bhasma*.

X-ray diffraction is a technique used for the phase identification of crystalline material and provides information about unit cell dimensions of the molecules. The X-ray diffraction helps in the characterization of crystalline solids.

SEM (Scanning Electron Microscope) is technique which gives information about external morphology, crystalline structure and chemical composition of the sample.

ICPAES (Inductively coupled plasma atomic emission spectroscopy) is technique used for the determination of trace metals.

Particle size Analysis by TEM helps to assess particle size and surface area, the less particle size increase surface area thus improves dissolution of drug and rapid absorption.

CONCLUSION

Rasaushadhies are prepared from herbs, minerals and metals. The *Rasaushadhies* offers advantages of palatability, quick action and long shelf life, etc. These drugs are used for treating skin diseases, digestive problems, sexual disorders, respiratory diseases and gynecological problems, etc. The quality standardization of *Rasaushadhies* is prerequisite requirements to ensure their safety and quality. There are many parameters which can be used to establish quality standard of *Rasaushadhies*, these parameters are *Nischandrika*, *Rekhapurnatvam*, *Varitaratavam*, *Apurnabhava* and *Avami*, etc. The standardization protocol needs to be followed properly during and after the preparation of *Rasaushadhies* to confirm their quality standard, safety and efficacy.

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