



World Journal of Pharmaceutical Science & Technology

Journal homepage: www.wjpst.com

Review Article

EXPLORATION OF QUALITY CONTROL APPROACHES IN THE PRODUCTION OF AYURVEDIC FORMULATIONS, WITH EMPHASIS ON RASASHASTRA.

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Received: 12-03-2024, Revised: 12-04-2024, Accepted: 12-05-2024

ABSTRACT

Introduction: *Rasashastra* constitutes a pivotal domain within the realm of medicine, devoted to the meticulous fabrication of pharmaceuticals. The process of drug synthesis necessitates adherence to precise benchmarks encompassing raw materials, methodologies, and protocols. In contemporary times, the imperative of producing medicines of impeccable quality has become increasingly pronounced. Integrating quality criteria enshrined within *Rasashastra* texts with contemporary analytical methodologies holds the promise of engendering a paradigm of Good Manufacturing Practices. **Materials:** Ayurveda texts, *Rasashastra* Texts. **Methodology:** Enlisting and analysing the various parameters and methods from classical Ayurveda texts and *Rasashastra* texts and using them in accordance with modern analytical tools. **Discussion:** Paramount among the prerequisites for efficacious drug production is the utilization of superior-grade raw materials, a linchpin in ensuring the eventual potency of the pharmaceutical output. The multifaceted landscape of drug synthesis mandates stringent quality oversight at diverse junctures spanning raw material acquisition, procedural intermediate stages, and ultimate finished product attainment. Notably, the formulation of Ayurvedic remedies is meticulously orchestrated in consonance with a meticulous observance of foundational tenets underpinning pharmaceutical manufacturing. **Result:** Understanding the *Rasashastra* texts

in proper way can lead to Good Manufacturing Practices. *Rasashastra* texts provide assistance right from assortment of the raw material to analyse the end products.

KEYWORDS

Drug manufacturing, Drug standardization, GMP, Quality control, *Rasashastra*.

INTRODUCTION

Quality Control is a process or a set of procedures followed by a company, in order to assure that the product meets the set standards and requirements. ISO 9000 defines quality control as "a part of quality management focused on fulfilling quality requirements". One of the basic tools for the proper management of disease treatment is a drug. The manufacturing of drug is utmost important in any branch of medicine and though its quality control also. *Rasashastra* have its own methods of preparing quality medicines. *Rasashastra* texts are enriched with such quality parameters to prepare good medicines. One should have to understand the meaning of *Rasashastra* texts properly for Good Manufacturing practices. *Rasashastra* texts provide guidance right from selection of the raw material to examine the finished products.

AIM

To understand the methodology of quality controlling in the manufacturing of Ayurvedic medicines with special reference to *Rasashastra*.

OBJECTIVES

- To study the *Rasashastra* texts in the context of quality control methods in drug manufacturing.
- To highlight the importance of standardization criteria from the *Rasashastra* texts.

MATERIALS

- Classical Ayurveda Texts
- *Rasashastra* Texts

METHODOLOGY

Quality control in *Rasashastra* texts¹

Quality control of drugs is very much emphasized in *Rasashastra* texts as they directly deal with the manufacturing of drugs. *Rasashastra* texts have described quality parameters and principles of testing them at various levels of drug manufacturing such as raw material QC, IPQC, finish product QC.

जातिमद्भिः वशुद्धैश्च वधना परिसाधतैः |

रसोपरसलोहाद्यैः सूतः सद्धो नान्यथा || ...र.र.स.५/

A. जातिमद्भिः - Raw material quality control

Raw material should have originated from a standard quality source. *Rasashastra* texts have provided multiple tools for selection of quality raw materials.

1. Exact Identification of Raw material

Exclusion of adulterants/substitutes

- *Suvarna makshika* – Currently Iron Pyrite (*Vimala*) is sold as Suvarnamakshik in market.
- *Rasaka* – Market sample of *Rasaka* is not having Zinc in it or in very trace amount.
- *Sasyaka* – According to the textual criteria Bornite can be identified as *Sasyaka* but Copper sulphate which is the artificial variety of *Sasyaka* named as *Tutha* is sold in market as *Sasyaka*.

2. Criteria for selection of Raw material : *Grahya-Agrahyatva*

● Nomenclature

In many cases the nomenclature of *Rasadravya* gives clear idea about its structure and external nature; helps in the identification of raw material.

*Suvarnamakshika*² – स्वर्णसन्निभं, पञ्चवर्णसुवर्णवत् | र.र.स.२/८१,

*Sasyaka (Shikhigreeva)*³ – मयूरकण्ठसच्छायं | र.र.स.२/

● Structural characters

*Vaikranta*⁴ – अष्टास्रश्चाष्टफलकः षट्कोणः मसृणो.... | र.र.स.२/

*Gairika*⁵ – अत्यन्तशोणतं स्निग्धं मसृणं स्वर्णगैरिकं | र.र.स.२/

● Place of origin

Suvarnamakshika – तापीज/ताप्य – Originated at the banks of Tapi river.

Pandiloha (Lohasarvasvam) – Can be identified as Molybdenum according to its source of origin in *Pandya* dynasty

Kankshi – सौराष्ट्री refers to its source of origin in Gujarat.

- **Therapeutic uses** in accordance with the source of origin and other structural characters therapeutic uses confirm the identity of raw material.

*Kampillaka*⁶ – सौराष्ट्रदेशे च उत्पन्नः, चन्द्रिकाढयोऽतिरेचनः

3. Raw material quality tests.

- **Streak test** : *Suvarna*⁷ – कषे कुंकुमप्रभं
- **Solubility test** : *Shilajatu*⁸ – सलले

B. वशुद्धैश्च वधना परिसाधतैः रसोपरसलोहाद्यैः | - In-process quality control

1. वशुद्धैश्च - *Shodhana* of Raw material :

Raw materials undergo number of processes till the final product. *Shodhana* is the most important and basic procedure in manufacturing of drugs. *Rasashastra* texts clearly stated the importance of purified raw materials and the hazards of unpurified raw materials.

The method of *shodhana* of these raw materials is explained with all the guideline in *Rasashastra* texts.

- **Parada**

Samanya Shodhana

Sanskara – *Ashtasamskara and Ashtadasha samskara.*

- **Gandhaka (Dhalana process)** – Melting of *Gandhaka* and pouring it in the milk.
- **Abhraka (Nirvapa process)** – Quenching of red heated Mica in certain liquid.
- **Suvarnamakshika (Bharjana process)** – Frying of Copper Pyrite powder in *Eranda Taila*.
- **Dhatu** – Common *shodhan* process for all *Dhatu* and also separate *shodhan* process for each *Dhatu* for quality enhancement.
- **Haratala, Manashila & Somala** – Being Arsenic compounds compulsory *shodhana* is mentioned.
- **Visha & Upavisha** – To reduce the toxic effects and to utilize their beneficial qualities.

2. वधना परिसाधतैः - Standard manufacturing procedure.

- **Direction of using Bhasma form of Metals and Minerals⁹**

Rasadavyas whether it is Gemstones, metals, aquatic materials like cowry, oyster shell and other minerals have to be subjected to the process of incineration to make them ready for the processing of *Parada*.

रत्नानि लोहानि वराटशुक्तपाषाणजातंखुरशृङ्गशल्यम् |

महारसाद्येषु कठोरदेहं भस्मीकृतं स्यात् खलु सूतयोग्यम् || र.र.स.५/

- **Method of preparation of Bhasma**

a. Specific type of *Putra*: *Gaja, Varaha* etc. (Calculated measure of heat)

*Abhraka*¹⁰ – पुटेद् वंशतिवारेण वाराहेण पुटेन हि |र.र.स.२/

*Heeraka*¹¹ – पुटेत् पुटैः वराहाख्यैः त्रिंशद्वारं ततः परम् |र.र.स.४/३७

*Tamra Amrutikarana*¹² – शुष्कं गजपुटे पच्यात् सर्वदोषहरं भवेत् |र.र.स.५/५५

b. Specific number¹³ of *Putra*

“पंचक्रोडपुटेर्दग्धं म्रयते माक्षकं खलु |” (र.र.स.)

c. Specific material for processing of raw drug (*Marana Dravya*)

Abhraka Maraka Gana, Loha Maraka Gana etc.

d. Standard operating procedure for *putra*.

Size of *Putra* – अरत्नमान in case of *Varaha Putra*.

Size of *Vanyopala*

Size of *Sharava* – having volume of 350-400ml capacity.

Quantity of material to be kept in *Sharava*

शराव = मानिका = 32 = 320gm approx.

● **Method of preparation of Kupipakva Rasayana**

Specific size of Kupi

Specific size of Valukayantra

Specific size of Valuka - मुद्रमान

Specific types of Agni – क्रमाग्नि – Mrudu, Madhyam and Teekshna

Duration of Agni – Specific according to the formulation.

a. *Rasasindoora* – 24 Hrs.

b. *Sameerpannaga*¹⁴ – 24 Hrs. क्रमाग्निना पचेत्सम्यग् यामाष्टेन च मुद्रयेत् |

c. *Chandrodaya*¹⁵ – 72 Hrs. दिवसत्रयं च पचेत् क्रमाग्नौ | र.चं.

d. *Svarnavanga*¹⁶ – 12 Hrs. पचेत् यामचतुष्टयं | (आयु.- वै.धामणकर Page-93)

e. *Manikya Rasa*¹⁷ – 48 Hrs. वह्न षोडशयामकम् | र.यो.सा.

f. Stages of *Kajjali* in the bottle.

● **Method of preparation of Parpati**

Specific yantra for preparation of Parpati – Palika Yantra

Specific platform for the flattening of molten *Kajjali* – Cow dung

Specific fuel as a medium of heat - बदरखदिर कोकलैः

In-process paka lakshanas¹⁸

सूतं पङ्कसमं वलाप्य रुचरं पाकक्रयाकोवदः |

शीघ्रं गोमयसंस्थिते तु कदलीपत्रे ततो निक्षेपेत् || र.त.६/

● **Shodhana of Gandhaka**¹⁹

Stage of pouring *Gandhaka* powder in Ghee during *shodhana* process

तप्ते घृते तत्समानं क्षेपेत् गन्धकजं रजः | आ.प्र.२/

● **Svarnavanga preparation**²⁰

Parada should be added to liquefied *Vanga*

प्रक्षेपेत् भाजने वङ्गं आयसे वाऽप मृण्मये |

वद्रुते वह्नित्वापेन तस्मिन् तन्मानकं रसं || भै.र. (आयु. औषधीकरण- वै.धामणकर Page-93)

● **Satva extraction from Minerals**²¹

बीजावर्त – In process observations during *Satva* extraction

द्राव्यद्रव्यनिभा ज्वाला दृश्यते धमने यदा |

द्रावस्योन्मुखता सेयं बीजावर्तः स उच्यते || र.र.स.८/

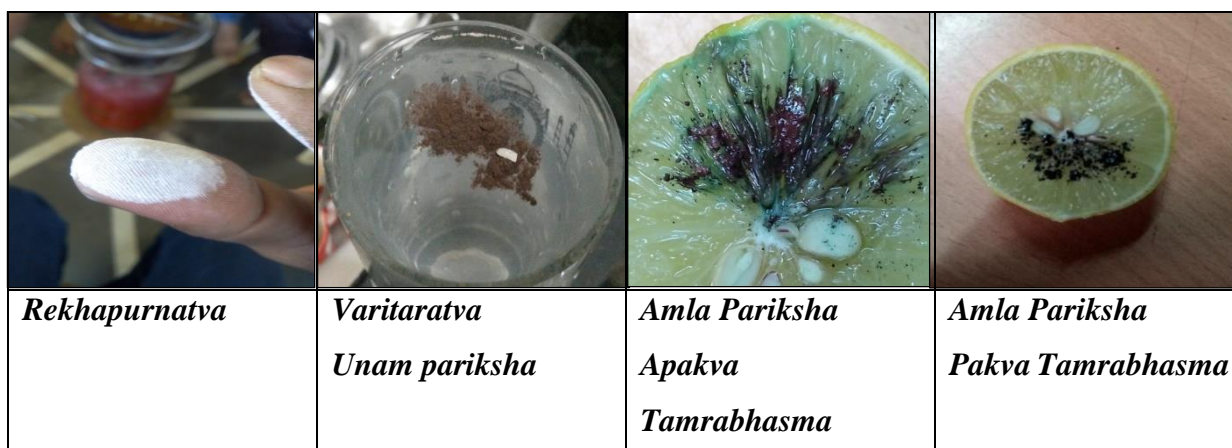
A. सूतः सद्धो - Finish product quality control

B. The said verse is in the context of processing over *Parada* but the principle is applicable to the quality control of entire drug preparation. The *siddhi lakshanas* are described in many *Rasashastra* formulations. *Siddhi lakshanas* provide the quality control parameters for the prepared drug.

1. Bhasma Pariksha

Common examinations for *Bhasma*

- *Rekhapurnatva* – Defines the fineness and smoothness of *Bhasma*
- *Varitaratva & Unam pariksha* - Shows the lightness of *Bhasma*
- *Apunarbhavatva & Nirutthatva* – Defines the completeness of *Bhasma*



- Specific criteria for the completion of *Bhasma* process

a. *Abhraka Bhasma*²²

The finalized *Abhraka Bhasma* is void of any luster, have color of rising sun, clean, fine and soft in to touch.

निश्चन्द्रश्वारुणं स्वच्छं सुसूक्ष्मं स्पर्शकोमलं |

अभ्रं मृतं वजानीयाद् रसतन्त्रवचक्षणः || र.त.१०/

b. *Haratal Bhasma*²³

The completed *Haratal Bhasma* if put in the fire does not produce any fumes.

तालं मृतं तदा ज्ञेयं वह्स्थं धूमवर्जितम् |

सधूमन मृतमाहुः वृद्धवैद्याः इति स्थितिः || आ.प्र.२/

Texture of *Bhasma* – Soft to touch, unctuous, and without having any luster.

2. Color of final product

- *Rasasindoor* - जपाकुसुमसंकाशं, माणक्यनिभं, सन्दूराभं, पक्वबिंबीफलच्छायं
- *Swarnavanga* – पाकात् संजायते चत्रं कीर्णं हेमकणैः इव | भै.र.
- *Maanikya Rasa* – भवेन्माणक्यवर्णोऽयं | र.यो.सा.
- *Kshara* - क्षारो ग्राह्यः सतप्रभः |
- *Kajjali* – सुश्लक्ष्णः कज्जलाभः |

Color of Bhasma

- *Abharaka* – सन्दूराभं... र.र.स.२/
- *Makshika* –
सन्दूराभं भवेद् भस्मं माक्षकस्य न संशयः | आ.

धातुसंनिभम्र.र.स.२/८५ सुवर्णगैरिकसमान

- *Haratala* – हिमकुन्देन्दुसंकाश.. आ.प्र.२/२०१
- *Rasaka* - पीतवर्णं ...आ.प्र.२/
- *Suvarna* - जाम्बवाभं सुवर्णस्य भस्म प्राहुर्भषग्वराः | आ.प्र.३/
- *Vanga* – खटिकाप्रभम् ..आ.प्र.३/
- *Naga* - सन्दूरभो भवेद् ध्रुवम् | आ.प्र.३/१९७
- *Kantaloha* – पक्वजम्बुफलच्छायं कान्तलोहं तदुत्तमम् | र.र.स.५/

3. Siddhi lakshanas of Finished products

- *Kajjali Siddhi lakshana*²⁴

मर्दनजन्या मसृणकाया कज्जलरूपा कज्जलीका सा | र.त.६/१०७

- *Parpati Siddhi lakshan*²⁵

मयूरचन्द्रिकाकारं लङ्गं यत्र तु दृश्यते |

तत्रसद्धं वजानीयात् वैद्यो नैवात्र संशयः || भै.र.ग्रहणी चकत्सा

- *Mrudu Paka*... मृदौ न सम्यक् भङ्गोऽस्ति |
- *Madhyam Paka*... मध्ये भङ्गश्च रौप्यवत् |
- *Khara Paka*... खरेऽलघुर्भवेद्भङ्गो रुक्षः श्लक्ष्णोऽरुणच्छव |

- *Pottali Siddhi lakshan*²⁶

मन्दाग्निना पचेद्यावद् व्योमवर्णं भवेत् यत् | भा.भै.र.८६६४ हेमगर्भ

- *Sneha Siddhi lakshan*²⁷

वर्तिवत् स्नेहकल्कः स्याद्यदङ्गुल्या वमदितः |

शब्दहीनोऽग्निनिक्षसः स्नेहः सद्धो भवेत्तदा ||

यदा फेनोद्गमस्तैले फेनशान्तिश्च सर्पष |

गन्धवर्णरसोत्पत्तः स्नेहः सद्धस्तदा भवेत् || शा.सं.म.खं.९/१२-

- *Avaleha Siddhi lakshan*²⁸

सुपक्वे तन्तुमत्वं स्यादवलेहोऽप्सु मज्जति |

खरत्वंपीडते मुद्रा गन्धवर्णरसोद्भवः || शा.म.खं.८/३

DISCUSSION

- Quality control being a major part in any process, acquired prime importance in the manufacturing of *Ayurvedic* formulations also.
- *Rasashastra* texts exquisitely mention the quality control methods in the manufacturing of medicines at various levels such as raw material, in process and finished products.
- The QC parameters mentioned in *Rasashastra* texts are designed accordingly with the basic principles of *Rasashastra* which can be assessed through the current quality testing methods.
- The collaboration of these standards with the modern quality testing parameters surely leads to the great achievement in the field of Drug manufacturing.
- It is the need of time to open the new scope in the field of research regarding this subject.

CONCLUSION

- *Rasashastra* being exclusively dedicated to the drug designing and manufacturing have developed its own way of quality control at different levels of drug preparation.
- The proper understanding of *Rasashastra* texts in the purview of drug standardization surely leads to the quality medicine.

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