

Quality Control and Safety Aspect of Rasaushadhies W.S.R. to Bhasma - A Review

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Abstract: *Most of populations about 80% of the world rely almost on exclusively on traditional medicine for their primary health care need as per W.H.O. But recently many questions were raised regarding the safety, quality, and standard of Ayurvedic drugs. Ayurvedic Rasaushadhies have good preventive, curative, rejuvenating potential and remarkable efficiency in curing chronic and degenerative diseases. Bhasma are safe when prepared and used properly, If when prepared in improper can lead injurious to health. This led to the decline the quality of Rasaushadhies. Quality and safety is a burning topic in Ayurvedic drug industry today. Tremendous work is going on Ayurvedic drug standardization, but it is not an easy task as preparations described under diverse. In this article an attempt has been made to focus on the Ayurvedic Rasaushadhies & to summarized various methods available for quality & safety of Rasaushadhies i.e. Shodhana, Marana, Standardization techniques according to Ayurvedic parameters, Physiochemical evaluation, Qualitative analysis will be discussed.*

Keywords: Rasaushadhies, Standardization, Ayurvedic and modern analytical methods

1. Introduction

Rasaushadhies being most efficacious drug in Ayurveda, is known for its minute dosage, easily palatable and quick action¹. Bhasmas are one among such Rasaushadhies which is made by special procedure and complex compound forms of preparing from minerals and metals. Rasayana²(immunomodulation and anti aging quality) and Yogavahi(ability to target drugs to site) are characteristics of a properly prepared herbo-minerals, metals preparations which is also non toxic, bioassailable, gently absorbable, adaptable and digestible in the body³. In present time Ayurvedic medicines profusely use made up from minerals, metals, animals as well as vegetable sources. In recent past, concerns have been raised on the quality and safety issue of ayurvedic preparations using Bhasma containing minerals and metals origin. Rasa shastra texts are enriched with pharmaceutical processing techniques of metals and minerals. The quality controls of metallic bhasma and side effects or adverse effects are already mentioned in ancient texts if we use this medicine not made properly and cover all the aspect of its internal administration so for as safety and efficacy is concerned.

In Ayurveda the variation in the collection process, timing, temperature, quantity, duration and procedure of making Bhasma, may yield same Bhasma with different qualities. In many cases wrong manufacturing process may lead to production of inferior quality products, which reduces efficacy and safety of bhasma. In order to minimize variability and to strengthen the quality of Ayurvedic products, standardization of Bhasma is essential⁴. Pharmaceutical standardization of Bhasma can be defined with the number of processes like Shodhana, Bhavana, Marana, murchana, Jarana, etc converts metallic preparations into non toxic and acceptable form. Ancient

quality control parameters for metals and minerals containing Bhasma are very systematic, easy and low cost with confirmation of its safety and efficacy which is time tasted and also proved by modern tools and techniques are essential in relation to current language⁵.

Classification of Bhasma

- 1) Herbo-Metal based Bhasma.
- 2) Herbo-Mineral based Bhasma.

2. Materials and Methods for Preparation of Bhasma

The prime objective of pharmaceutical process is to produce a safe, effective and quality drug. Efficacy and safety depend on the quality of the drug. The quality of the pharmaceutical drug depends on the care taken in its preparation, confirming that the genuine raw materials have been used and the material has been correctly processed.

1) Raw material characteristics-

Physical characteristics like that colour, size, shape, touch, taste, smell etc as well as Grahya lakshana mention in our Rasashastra text. i.e. Gomutragandhi Shilajatu, easily separation of layers of Abhakra Bhasma.

2) Shodhana-

In Ayurveda great emphasis is placed in Shodhana and defoxication of metals and minerals. Shodhana is first and most important step before preparing any Bhasma. Shodhana is a process in which mala (organic and inorganic impurities) are removed by means of peshana etc⁶. Classical Shodhana is ultimately an addition and separation process. Its main purpose is to being size reduction and compounding with plant materials that we have their molecules between the metal molecules. Shodhana is also an ancient standard technique for separating strong metallic bonds to make the materials

Volume 8 Issue 4, April 2019

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brittle, soft, smooth and amenable to size reduction⁷. The toxic substances are minimized or removed and desired qualities are imparted to the material.

3) Bhavana-

Bhavana facilities uniform mixing exposes the surface area of the particle by lining with suitable media and promoting reduction of metallic bonds, acting as a catalyst⁷. By the process of Bhavana the raw material with specific liquid needs a special emphasis as it has an ability to alter the original properties of substances. At specific instances it adds some special properties without altering the original properties. Hence the final result of Bhavana depends on the specific purpose⁸.

4) Marana-

Marana term denotes the meaning of complete incineration or calcinations. Marana is done by either puta or Kupipakva method, where metals (elements) and minerals (compounds) are subjected for heating on moderate to intense heat, compound material converted to certain other compounds where as elements get reduced to certain compounds. Nature of compound formed depends upon the material used for Marana⁹, it may be sulfide, oxide, chloride, sulphates etc. In some cases post operative procedure are also followed to achieve safe, effective and desired Bhasma. Amritakarana samskara⁹ to removes the remaining blemishes of the Bhasma and to enhances the therapeutic properties of the Bhasma i.e. in case of Abhraka and Tamra Bhasma. Lohitakarana samskara⁹ to get desired red colour in case of Abhraka Bhasma.

Importance of Rasaushadhies (Bhasma)¹⁰

- 1) Potent in smaller doses.
- 2) They can act quickly.
- 3) The taste of Bhasma is generally neutral, does not have any specific taste.
- 4) The assimilation of Bhasma in the body is much faster because of various samskaras during its preparation.
- 5) Available as very fine particles.
- 6) Longer shelf life.
- 7) The preservation is easy and less tedious.
- 8) Protect body from free radical damage¹¹.

3. Characterization of Bhasma¹²

Physical characteristics

1) Varna (colour)

A specific varna is mentioned for each bhasma. Any differences suggest that the Bhasma is not prepared properly, because a particular metallic compound is formed during Bhasma preparation and possesses specific varna.

2) Rekhapurnata-

This test is used to study fineness of Bhasma. A pinch of Bhasma is rubbed in between index finger and thumb to observe the Bhasma particles enters and embeds into finger prints, it indicates enough fineness and accepted as standard for easy absorption and assimilation in the body.

3) Nishchandravam-

Chandravta (luster) is a characteristic of metal, so Bhasma must be nishchandravta (lusterless) before therapeutic application. After proper incineration, luster

of metal should not remain. For this test, Bhasma is observed under direct sunlight, if luster is present it indicates further incineration is needed. i.e. in case of Abhraka Bhasma. Swarna Bhasma etc.

4) Varitara –

This test is applied to study laghuta (lightness) and fineness of Bhasma. If a pinch of Bhasma is sprinkle over the stable water the Bhasma should float over the water. Here the incinerated metallic Bhasma will be so fine that, it fails to even break the surface tension of water.

5) **Nisvadutam-** The prepared Bhasma was found to be tasteless when it was kept on tongue i.e. the Bhasma was proper incinerated.

6) **Amla pariksha-** A pinch of Bhasma was mixed with a little amount of dadhi (curd) and observed for any colour change i.e. in case of Tamra Bhasma if curd noted bluish shade, it indicates the Bhasma is not appropriately done and subjected for further puta.

7) **Avami-** The proper prepared Bhasma was taken did not produced any nausea / vomiting sensation. i.e. in case of Tamra, Swarnamakshika Bhasma etc.

8) **Nirdhuma-** A pinch of Bhasma is put on fire, if it does not produce any smoke, it indicates the Bhasma was properly prepared i.e. Hartala Bhasma.

9) **Anjana Sannibham-** The prepared Bhasma is smooth in character similar to Anjana, it does not create any irritation whenever applied.

10) **Susakshamata-** Prepared Bhasma should be in churna form, it indicates fineness of Bhasma. Particles size of Bhasma will be like ketkirajah sannibham (pollen grains of Pandanus odoratissimus flower, so it can be easily absorbed and assimilated in the body.

Chemical characteristics of Bhasma-

1) Apunarbhava-

The Bhasma is mixed with equal quantity of mitra panchaka varga dravya then kept in a masha (crucible) and it is subjected for intense heat with a suitable puta. If no changes are observed in the quality and quantity of bhasma means the Bhasma incapable to regain its original form. i.e. Swarna Bhasma, Rajata Bhasma etc.

2) Niruttha-

In this test the Bhasma is mixed with equal quantity of Rajata (silver) and then taken in a masha and subjected for intense heat in a suitable puta, if bhasma does not adhere to the silver means there is not increase weight of silver leaf is noted. It indicates the bhasma is properly made and there is not any free metal is left out in the Bhasma. i.e. Tamra Bhasma, Abhraka Bhasma etc.

4. Modern Analytical Methods

Analytical study is the application a series of process in order to identify and/or quantity a substance, the components of a solution or mixture or the determination of the structures of chemical compounds.

According to W.H.O. guidelines Bhasma has to be standardized by following modern parameters.

Physiochemical characterization of Bhasma¹³ -

- 1) Colour, Odour, Taste.
- 2) Solubility.
- 3) Loss on Drying at 105°C.
- 4) Total Ash value. Acid insoluble and Water soluble Ash value.
- 5) Water soluble extractive.
- 6) Alcohol soluble extractive.
- 7) pH determination.
- 8) Particle size estimation.
- 9) Estimation of Heavy Metals.

Quality and Quantity modern sophisticated method1) **XRD (X-ray powder diffraction)**¹⁴ -

X-ray powder diffraction is a rapid analytical technique primarily used for phase identification of crystalline material and can provide information on unit cell dimensions of the molecules present in the sample. The most widespread use of X-ray diffraction is in the identification and characterization of crystalline solids, each of which produces a distinctive diffraction pattern.

2) **XRF (X-ray fluorescence)**¹⁵ -

XRF is a physical method of analysis which directly analyses almost all chemical elements of the periodic system in the sample. It helps in detection of major, minor as well as trace elements which are present in the drug.

3) **FTIR**¹⁴ -

This test to detect functional groups and to characterize the covalent bonding information. FTIR is based on the fact that bonds of particular groups in a molecule vibrate at specific frequencies when exposed to infrared rays. During FTIR analysis, a spot on the specimen is subjected to modulated IR beam. The specimen transmittance and reflectance of infrared rays at different frequencies is translated into an IR absorption plot consisting of reserve peaks and a resultant graph is produced which is then correlated to the reference table.

4) **SEM (Scanning electron microscope)**¹⁶ -

This technique which revealed the information of external morphology, chemical composition, crystalline structure and orientation of materials making up the sample.

5) **ICPAES (Inductively coupled plasma atomic emission spectroscopy)**¹⁷ -

This technique used for the detection of trace metals. It is a type of emission spectroscopy that uses the inductively couple plasma to produce excited atoms and ions that emit electromagnetic radiation at wavelengths characteristic of a particular element. The intensity of this emission is indicative of the concentration of the element within the sample.

6) **Particle size Analysis (By TEM Method)**¹⁵ -

Particle size is one of the factors which will affect dissolution and absorption of drug. Particle size and surface area are inversely proportional to each other, as particle size decreases surface area increases. This leads to increase in dissolution of drug and rapid absorption.

5. Discussion

The structural and chemical transformation of metal into compounds form called Bhasma, Bhasma are claimed to be

biologically produced nanoparticles. It has been therapeutically used for treatment of various diseases since century ago without developing any major adverse effects, so that it is very important to prepare Bhasma of standard quality to achieve this by following systematic Ayurvedic classical references and standard by following scientific quality control procedures. To check whether the Bhasma is properly formed or not, Rasashastra texts have laid down certain Bhasma parikshas. These Bhasma pariksha are qualitative in nature and they do not reveal anything about the characterization on the scientific aspect. Hence to overcome this problem modern analytical parameters like XRD, XRF, SEM, FTIR, ICPAES etc are very helpful to know the final product in detail. Hence Tests of both classical parameters as well as modern analytical parameters are to be used for justification of proper preparation of Bhasma have proved the fineness of Bhasma and also help for the quality standardization of the Bhasma. Important factors which are affected to quality, efficacy and safety of Rasaushadhies i.e. Pre operative procedure that is Proper identification and authentication of raw material, in Process standardization all processes are done as per classical references Shodhana, Bhavana, Marana and Putpaka and all observations recorded as per stepwise. Finished product standardization as per bhasma pariksha mention in our Ayurveda text as well as modern analytical parameters. Also all the Bhasma are not recommended for all the patients. The indications, dose, anupana, period of drug administration, duration of treatment, prakruti of patient, pathyaapathya etc. are major factor which should be considered by the physician before they use these Rasaushadhies to the patient.

6. Conclusion

The Ayurvedic text is not very clear about the presence of metallic particles in the Bhasma and its therapeutic effect, but number of visual and alchemical tests (Bhasma pariksha) have been described to test the quality of the Bhasma before its use to the patient. It can be concluded that Ayurvedic procedure of Shohana, Bhavana, Marana (Puta) etc are ancient technique of nanoscience. To get properties from rasaushadhies / Bhasma SOP & SMP should be followed as mentioned in ayurvedic literature followed by modern techniques. The success of preparing a genuine Ayurvedic Bhasma depends on the systematic technique followed. Therefore synthesis of these Bhasma is a complicated and tedious procedure and Ayurvedic experts prepared these Bhasma on certain SOP and GMP norms notified by department of Ayush.

References

- [1] Vidvotini Hindi Commentary by Indra Deva Tripathi, Varanasi Chaukhamba Orientalia 4th Mishra S editor, Rasendra Sara Sangraha of Bhatt Gopal Krishna. Rasa edition, 2006, 1/4.
- [2] Vyalil P K, Kuttan G, Kuttan R. Rasayanas, Evidence for the concept of prevention of diseases. AM J Chin Med 2002,30,155-71.
- [3] Mishra L C, Adra T, Batchu SV, Bhatt H A. Scientific basis for ayurvedic therapies. LLC Boca Raton, Florida, CRC Press, 2004.p. 84-99.

- [4] [http:// www.ancientscienceoflife.org](http://www.ancientscienceoflife.org) on Thursday, December 28, 2017, IP: 47.247.248.2.
- [5] Mohapatra Sudhaldev and Jha C. B, Ancient pharmaceutical techniques of Bhasma and its quality control with special reference to Swarna Makshika Bhasma. Biomed. And Pharmacol. J, Vol. 3(1), 241-245 (2010).
- [6] Shastri S K, translater. Rasatarangini of Sadananda Sharma, Motilal Banarsidas Publication, 11thedition, reprinted-2014,New Delhi 2/52 p. 22.
- [7] B Bhattacharya, Jha C. B. The evolution of ancient chemistry from Rasa- Aushadhi to modern pharmacy. Journal of traditional & natural medicines, dec 2015 , vol 1 , issue 3, 1- 8.
- [8] Madhulika Priya, Govinda Sharma K, Critical review on importance of Bhavana in Rasoushadhi. IAMJ: volume 2, issue 4; 2014, p 450- 455.
- [9] Dr Angadi Ravindra, A Text Book of Rasasastra, Published by Chaukhamba Surbharti Prakashan first edition 2014,p 24.
- [10] Dr Angadi Ravindra, A Text Book of Rasasastra, Published by Chaukhamba Surbharti Prakashan, first edition 2014,p 11.
- [11] Sharma DC. India raises standards for traditional drugs. Lancet 2000; 356: 231 (pub med)
- [12] Mishra Siddhinandan , Ayurvediya Rasashastra , Published by Chaukhambha Orientalia. Varanasi, 14th edition 2004, p 99- 102.
- [13] Dr Angadi Ravindra, A Text Book of Bhaisajya Kalpana, Published by Chaukhamba Surbharti Prakashan, second edition 2016,p 481.
- [14] [https:// www. Researchgate.net/ publication/ 281676792.](https://www.Researchgate.net/publication/281676792)
- [15] Dr. Suman lata, Dr.Rudrambika S. Biradar, Physio-Chemical analysis of Pravala Bhasma- prepared by using Praval Mool as raw material,International journal of Ayurvedic and Herbal Medicine 5: 4 (2015) 1954-1963.
- [16] [http://www.serc.carleton.edu/ research- education/ geochemsheets/techniques/ SEM.html.](http://www.serc.carleton.edu/research-education/geochemsheets/techniques/SEM.html)
- [17] Dr Angadi Ravindra, A Text Book of Bhaisajya Kalpana, Published by Chaukhamba Surbharti Prakashan, second edition 2016,p 493 .

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