



A CRITICAL REVIEW ON STANDARDIZATION OF BHASMA: AYURVEDIC AND MODERN VIEW

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ABSTRACT

Ayurvedic medicines are serving the needs of ailing humanity since many centuries. Particularly *Bhasmas* have good preventive, curative and rejuvenating potential. *Bhasma* are the unique Ayurvedic metallic, non-metallic or mineral preparations with herbal juices widely used for treatment of a variety of diseases. In most of Ayurvedic medicines i.e. *Rasuashadhies*, *Bhasmas* are widely used as a single drug or in combination, so standardisation of Bhasma is utmost necessary to confirm its identity and to determine its quality and purity. It will also make sure the safety, effectiveness and acceptability of the product. But the most important challenge faced by these formulations are the

lack of complete standardisation by physico-chemical, microbiological and analytical evaluation. *Bhasmas* are safe when prepared and used properly. Use of *Bhasma* when prepared improper and in short cut ways can prove injurious to health. So, there is a need of systemic and well organised coordination of allied sciences along with adequate infrastructure and facilities to solve various problems related to standardisation of Bhasma.

Here an attempt is made to review the need of standardisation of Bhasma and also summarize the various methods available for standardisation of Bhasma.

KEYWORDS: bhasma, rasaushadhi, standardization, formulations, physicochemical, analytical evaluation.

1. INTRODUCTION

Ayurveda is the holistic science of life and the system of medicine which recognise the importance of metallic micronutrients and minerals in our body. Metals and minerals play

very important role in human body. Their excess, deficiency or imbalance in the body results in various diseased conditions. It has been observed that the metal and mineral based formulations especially effective in prevention and cure of the diseases related to the organ where they act. Rasashastra is the part of Ayurveda which describes the use of metals, gems, minerals and poisons for manufacturing special formulations called as Bhasma. In Ayurveda, metals and minerals are termed as *Dhatus* and *Updhatus*, because of their role in biological system. In Rasashastra seven metals -Dhatus named Gold, Silver, Copper, Iron, Tin, Lead and Zinc are described as essential elements for body. These Dhatus are present in different concentration and combination in our body and for maintaining good health, it is attributed to the state of equilibrium of these metals in body tissues.

In earlier days, medicines for the patients were prepared by the physicians themselves as they were well experienced and well trained in processing medications; and also prepared medicines were in limited quantity. In practice, it was commonly found that the drug preparations were modified as per the need of patients and disease. Now a days, the drug preparation is done in large scale and in short time, so addition of substituents has become common and chances of adulteration increases. As the chances of adulteration has become common, it has become mandatory to standardise the Ayurvedic preparations especially Rasaushadhies as they are widely used because of their *alpamatra* (minute quantities) and *shighravyapi* i.e.quick action, also in Modern medicine harmful effects of metallic and mineral preparations are well documented.

In order to have a good co-ordination between quality of raw materials, in process materials and the final product it has become essential to develop reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of Analysis.

2. BHASMA

Bhasmikaran is a process in which bio-incompatible substance is converted into bio-compatible form by certain samskaras or processes. This concept of reduction in particle size is prevailing since *Charak Samhita* (1500BC). Bhasma is unique Ayurvedic preparation in which metallic, non-metallic and mineral preparations are treated with herbal juices or decoction and exposed to certain quantum of heat i.e. Puta. In Ayurveda Bhasmas are widely recommended for treatment of various chronic diseases.

Bhasma Nirmana involves 4 basic steps such as selection of acceptable form of metal (*grahya rasa dravyas*), its purification by Ayurvedic method (*shodhana*), levigation (*bhavana*) and incineration (*marana* or *puta*). As per classical texts, preparation of Bhasma is an elaborate process involving mainly *Shodhana*, *Bhavana* and *Maarana*.

i) *Shodhana* (purification): Metals are first purified through a process called *Shodhana* in which the metal is repeatedly heated and then cooled in herbal extracts like juices or decoctions, it helps in removing impurities, adulteration from it and at the same time helps in reducing particle size.

ii) *Bhavana* (Levigation): In this, repeatedly trituration with liquid media like herbal juices or decoction is done, which helps in reducing the particle size and makes it homogenous also improves therapeutic efficacy.

iii) *Jarana*: It is intermediate and essential prerequisite process in between *shodhana* and *marana*, through which low melting point metals (*puti lohas*) like Lead, Tin, Zinc are first melted in an open iron pan and then added with prescribed herbs/*jarana* materials and heating continues till material converts into whitish black powder form i.e. ash and may tolerate more heat than their melting point during *marana* process.

iv) *Maraana*: In this process, pelletization i.e. *chakrika* are prepared, dried in sunlight and calcinated in closed earthen crucibles (*sharavsamputikaran*) in a pit, by burning cow dung cakes (a process called *puta*), to obtain final product called *Bhasma*.

This systematic and elaborate step-wise procedure to manufacture Bhasma known as *bhasmikaran*, which converts the metal from its zero valent state to a form with higher oxidation state, which is crucial from the point of view that during this synthetic process the toxic nature of the metal and its oxide is fully destroyed while rendering the metal oxide with high medicinal value. In present Era due to the need of time, characterization of Bhasma using scientific techniques is necessary to determine the effect of the process and to judge its safety and efficacy.

Various minerals like iron pyrite, copper pyrite; salts such as common salt, alkaline salt, black salt and fossil salt; certain compounds like realgar, iron sulphate, copper sulphate and antimony sulphide were used in the preparation of Bhasmas due to their medicinal value. Some of the commonly used Bhasmas are *Abhraka Bhasma*, *Naag Bhasma*, *Vanga Bhasma*,

Yashad Bhasma, Tamra Bhasma, Mandoor Bhasma, Swarnamakshik Bhasma, and Lauha Bhasma etc. They will be available as Nanoparticles and are taken along with milk, butter, honey or ghee thus making them easily assimilable, eliminating their harmful effects and enhancing their biocompatibility.

3. Relation Between Bhasma and Nanomedicine

Bhasmas are said to be biological nanoparticles due to their small particle size. In terms of Nanotechnology, nanoparticles are generally defined as structures with sizes less than 100 nm that have a very large surface to volume ratio leading to different, novel properties compared with bulk particles of the same chemical composition. Ayurvedic concepts of *Shodhana* (purification), *mardana* (trituration) and *bhavana* (levigation) are used to reduce particle size. There are various methods that are used to detect nanoparticles in Bhasma like Scanning Electron Microscopy, Transmission electron Microscopy, Fluorescence microscopy, X-ray photoelectron spectroscopy etc. Rasashastra advocates some peculiar properties of Bhasma like *Rasibhavana* which implies that accurately prepared Bhasma must be readily absorbable, adaptable and assimilable in the body and must be non-toxic. Another property of bhasma is *Shighravyapti*, which indicates that after *Maarana*, Bhasma quickly dispersed in the body and the third one is *Agnideepan* which increase metabolism at cellular level and acts as catalyst. These properties of Bhasmas are comparable with the action of nanoparticles which are biodegradable, biocompatible and non-antigenic in nature. In this view, the use of Ayurvedic metallic preparations like Bhasma may prove to be very effective in medicinal purpose. But Bhasma cannot be considered scientifically valid if the drug tested has not been authenticated, characterized and standardised.

4. Standardization

Standardisation is a measurement for ensuring the quality and safety of Bhasma and is also used to describe all measures which are taken during the manufacturing process and quality control methods for ensuring the good quality of Bhasma. In case of Rasaushadhies, it is generally claimed that metals and minerals used for preparation are detoxified during the manufacturing process as described in Rasashastra Texts. But in present era of developing herbo-metallic preparations, proper validation and standardisation is of utmost importance.

Classical texts of Rasashastra have mentioned various methods for analysing the quality of bhasma preparation, starting from the selection of raw material to the final product. Raw materials of good quality are identified by their *grahyalakshana* (characteristics of superior

quality) mentioned for each drug. Standard Operating Procedures(SOPs) are mentioned for individual bhasma preparation like the method of *shodhana* (vishesh shodhana for each metal, e.g.rajat shodhana in Agastipatra swarasa), levigation material, quantum of heat required for incineration, (e.g. for swarna bhasma-kukkutputa, lauha bhasma-gaja put) etc. Regarding the final product various tests i.e. *Bhasmapariksha* are enumerated to make sure that the bhasma is safe, effective, assimilable and non-toxic.

4 types of Marana drugs are mentioned on which basis we can prepare a good quality bhasma

1. Mercury and its compounds- First(best) category (Uttama)
2. Herbal drugs used as bhavana – Second category (madhyama)
3. Sulphar, hartaal, manshila etc – Third category (adhama)
4. Arilohas(anti-lohas)- Fourth category (durgunpradam) and not recommended

Marana dravya for each metal is also mentioned for preparation of good quality bhasma, as shown in below table.

Table. I. Dhatu and their marana dravya.

Dhatu/metal Maran drug	
1.	Suwarna(gold) - Naag(lead)
2.	Rajat - Swarnamakshika
3.	Tamra - Gandhaka(sulphar)
4.	Naag - Manshila
5.	Vang - Hartaal
6.	Lauha - Hingul,, stri-rajah(aartavsrava)
7.	Uplauha - Gandhaka

For standard Bhasma preparation, there is need of scientific analytical studies to be carried out and even existing ones may suffer from incomplete analysis. Thus there is an imperative need for a scientific approach; which includes the following steps.

- a) Physical Characterisation and elemental analysis of raw material and final product.
- b) Pharmacokinetics of the prominent metallic component of bhasma using tracer technique
- c) Metal accumulation studies in different tissues and organs.
- d) Acute and chronic toxicity study
- e) Effect of Bhasmas on normal physiological and antioxidant properties.
- f) Therapeutic response of Bhasmas on the recommended diseases at cellular and molecular level based on claims written in classical texts.
- g) Role of Bhasmas as drug carriers

h) Role of Bhasmas in body as immunomodulator and physiology of GI tract (site of Jatharagni). These studies will provide evidence for the safety behind the use of Bhasma and also provide knowledge regarding their mechanism of action.

4.1. Standardisation Techniques

The standardisation process includes following methods

A) Bhasma pariksha (preliminary tests): Ayurveda provides a list of tests for assessing the accurate endpoint of the Bhasmikaran process called as Bhasma pariksha. The tests are essentially qualitative and serve to ensure that the resulting Bhasma is absolutely fine in texture, has no metallic shine and the metal in the final product cannot be regained its original form even at higher temperature. Following classical parameters for Standardization of Bhasma have been mentioned in textbooks of Rasashastra. Ayurveda says that prepared Bhasma must pass following bhasma pariksha,

Tests for Physical characterisation

1) Colour: A specific colour is mentioned for each Bhasma as shown in table 1. Alteration in specific colour suggests that Bhasma is not prepared properly. Because a particular metallic compound is formed during Bhasma preparation and every chemical compound possesses specific colour. Specific color for each metal Bhasma is mentioned by Yogratnakara.

Table. II. Bhasma Varna of Metals.

Metals Colour of Bhasma	
1.	Swarna bhasma Gairikvarnabham (dark brown Colour)
2.	Rajat bhasma Krishnavarna (black colour)
3.	Tamra bhasma Krishnavarna (black colour)
4.	Lauha bhasma Pakva Jambuphalopam (brownish red)
5.	Naag bhasma Paravatprabha
6.	Vang bhasma Shweta (white colour)
7.	Abhraka bhasma Ishtikabham (reddish brown)
8.	Kansya bhasma Dhusarvarna (whitish coloured)

2) Nishchandravam

Bhasma must be Nischandra (lusterless) before therapeutic application. Chandratva i.e. luster is the character of metal. After proper inceneration luster of metal should not remain. For this test, Bhasma is observed under bright sunlight, to assess the presence of any lustre. The of presence of lustre implies that the Bhasma still needs further incineration.

3) Varitara

Vari means water and *tara* means to float. This test is applied to assess lightness of bhasma. This test is based on law of surface tension. In this test, little amount of Bhasma is taken in between index finger and thumb and sprinkled slowly on stagnant water from slightly above it. Properly incinerated Bhasma will float on water surface.

4) Unnama

This test is subsequently performed after Varitara test as it is further assessment of Varitara test. For this, a grain of rice is to be kept carefully on the layer of floated Bhasma. If grain remains on the layer without sinking, then Bhasma can be considered as properly incinerated.

5) Rekhapurnatva

This test is applied to assess fineness of Bhasma. Bhasma particles should be of minimum size for easy absorption and assimilation in the body. Bhasma should be so fine that it should be able to enter fine creases of finger tips. A little amount of Bhasma is rubbed in between index finger and thumb to observe whether particles can fill fine creases of finger tips. This is a classical qualitative assessment for assessing particle size.

6) Slakshnatvam

It is a tactile sensation produced by simple touch with finger tips. Properly incinerated Bhasma attains this quality. Slakshna Bhasma indicates uniformity in texture of the Bhasma.

7) Susukshma

Sukshma' implies fine form, and the prefix 'Su' added to 'sukshma' means very fine form of Bhasma. This test suggests that the Bhasma particles have to be absolutely fine.

8) Anjana Sannibha

Anjana (collyrium) is so smooth in character that it can be very safely applied in the eyes without any irritation. Properly incinerated Bhasma should be smooth and should not create any irritation to mucous membrane of gastrointestinal tract.

9) Gatarasatvam/ Tastelessness

Properly incinerated Bhasma should be devoid of any particular taste. It indicates transformation of particular metallic taste to neutral, tasteless final product.

10) Ketaki Rajahsannibha

This test is for assessing the particle size. Properly incinerated Bhasma should be fine powder. The powder of the prepared Bhasma should appear like the pollen grains of Ketaki flower (*Pandanus odoratissimus*).

Tests for Chemical Characterisation-

1) Apunarbhavata

This implies incapability of Bhasma to regain its original metallic form. For this test, Bhasma is mixed with equal quantity of Mitra Panchak (seeds of *Abrus precatorius*, honey, ghee, borax and jiggery) and it is sealed in Sharava Samputa (earthen pots), thereafter, similar grade of heat used for preparation of particular Bhasma is applied and on self-cooling product is observed. Lustrous particles in it show presence of free metal, which is indicative of improper incineration.

2) Niruttha

Niruttha is to test inability to regain metallic form of metallic Bhasmas i.e loss of metallic state. In this test, Bhasma is mixed with a fixed weight of silver sheet, kept in earthen pots and similar grade of heat is applied and after self cooling weight of silver is taken. Increase in weight of silver sheet indicates improperly prepared Bhasma. If there is no increase in weight of silver sheet indicating no alloy formation takes place, thus confirming the metal has totally transformed into Bhasma, its oxide form.

Thus *apunarbhavatwa*, *niruttha* etc ensure the absence of free metal in the bhasma. However, the major drawback of these tests is that they are predominantly qualitative and hence do not provide any quantitative information about the composition and the structure of the final drug. For such a characterization of Bhasma, basic principles and applications of various modern techniques are described below.

B) Analytical evaluation

Though above methods are excellent and time tested and the bhasmas passing all these tests are indeed of high quality, there is lack of knowledge regarding the structural and chemical aspects of various bhasma and also the complex reaction taking place between the metallic ions and the 'phyto' constituents of plants used in the pharmaceuticals of bhasma preparations. Thus the ancient methods become inadequate for the characterization of bhasma for its global acceptability.

The various modern analytical instruments are used for the purpose of Analytical evaluation as described below.

1) SEM (Scanning Electron Microscopy): Scanning Electron Microscopy (SEM) is the method of choice to investigate particle size, shape and structure. SEM shows very detailed three dimensional images at much high magnifications (up to x 300000) as compared to light microscope. The surface structure of nanocomposites, fracture surfaces, nanoparticles and nanocoating can be imaged through SEM with great clarity, very high resolution images of the dimensions 1-5 nm can be obtained. SEM is most suitable process to study the morphology and elemental composition of the Bhasma samples.

2) EDAX (Energy dispersive x-ray spectroscopy): EDAX is a widely used technique to analyse the chemical components in a material under SEM. This method detects the X-rays produced as the result of the electron beam interactions with the sample. SEM-EDAX are many times routinely used to obtain morphological information of the surface and identification of chemical composition. A biocompatibility and characterization study by Paul and Sharma provides EDAX results it was confirmed that 90% of Swarna bhasma contains pure gold.

3) TEM (Transmission Electron Microscopy): Transmission Electron Microscopy (TEM) is a vital characterization tool for directly imaging nanomaterials to obtain quantitative measures of particle and/or grain size, size distribution, and morphology. Transmission Electron Microscope was used for particle size estimation of Swarna bhasma by Christopher L Brown. It was observed that the particle size of Swarnabhasma to be 57 nm with globular morphology. The nano-analytical modes (x-ray and electron spectrometry) depict elements that are present even in tiny volume of material. These materials include most metals (e.g., silver, gold, copper, aluminum), most oxides (e.g., silica, aluminum oxide, titanium oxide), and other particles.

4) DLS (Dynamic light scattering): Also known as Photon Correlation Spectroscopy, this technique is one of the most popular methods used to determine the size of particles. For particle size analysis of Jasada Bhasma samples Bhowmick TK, used Dynamic Light Scattering method confirming the size of particles within nanometer range present in fractionated part of Jasada Bhasma. For biological applications, the surface coating should be polar to give high aqueous solubility and prevent nanoparticle aggregation. Such structural

information is absolute necessary for the Bhasmas containing heavy metals like lead, mercury etc.

5) ICP-MS (Inductively coupled plasma-mass spectrometry): Inductively Coupled Plasma Mass Spectrometry or ICP-MS is an analytical technique used for elemental determinations. Dissolved solid sample into a nebulizer or using a laser to directly convert solid samples into an aerosol. Once the sample aerosol is introduced into the ICP torch, it is completely desolated and the elements in the aerosol are converted first into gaseous atoms and then ionized towards the end of the plasma. The elemental composition in Jasada bhasma was measured by ICP- AES technique. Because of the difficulty of dissolving Bhasma in solvents, a novel two step method was developed for sample preparation for ICPAES technique.

6) XRD (X-ray powder diffraction): XRD is one of the most powerful techniques for qualitative and quantitative analysis of crystalline compounds. The information obtained includes types and nature of crystalline phase present, structural make-up of phases, degree of crystalline, amount of amorphous content, microstrain & size and orientation of crystallites. A study by Dubey N. revealed calcium as the major element (40.22%) in Muktahouktik bhasma through X-ray analysis.

7) XPS (X-ray photoelectron spectroscopy): This technique quantitatively measures the elemental composition, atomic concentrations and chemical states of elements present at a samples surface. XPS used to detect all elements with an atomic number greater than 3, therefore, Hydrogen and Helium are not possible to detect. The area of analysis is typically 10mm but small areas down to 150 μ m x 150 μ m are possible. A physicochemical characterization study of Jasada Bhasma detects substantial oxygen deficiency on the surface of the material analyzed by XPS technique.

8) FTIR (Fourier transform infrared spectroscopy): The Principle of FTIR is based on the fact that bonds and groups of bonds vibrate at characteristic frequencies. A molecule that is exposed to infrared rays absorbs infrared energy at frequencies which are characteristic to that molecule. The resulting FTIR spectral pattern is then analysed and matched with known signatures of identified materials in FTIR library. A FTIR study by Tripathi A et al. showed mainly the presence of iron oxide in Lauha Bhasma and 100 puti Lauha Bhasma. In this study, it appears that iron attains its final chemical phase, Fe₂O₃, in one cycle of heating only but the matrix in which this oxide is dispersed evolves continuously as more heating cycles are

given. It supports the fact that the pattern of absorption of the medicine in the body depends on the number of heating cycles of the Bhasma, is then related to the role of the base material in response of the body with different kinds of diseases.

9) AAS(Atomic Absorption Spectroscopy)

The technique is a spectro analytical procedure for quantitative determination of chemical elements using absorption of optical radiation. It is used for determining the concentration of particular element in a sample. More than 70 different elements can be determined in solutions or in solid samples by AAS.

10) NMR(Nuclear Magnetic Resonance): NMR spectroscopy is an analytical chemistry technique that provides detailed information about the structure, reaction state and chemical environment of molecules. It can quantitatively analyze known compounds. For unknown compounds it can be used to match against the spectral libraries or to infer basic structure directly.

C) Physicochemical evaluation: There are various methods for physicochemical evaluation like colour, odour, pH, taste, fineness, loss on drying, total ash value, acid insoluble ash, water soluble ash and particle size mesh test.

i) Tests for heavy/ toxic metals should be carried out for standard formulation and their permissible limits as per WHO/ FDA is given in Table 2.

Table. III. Permissible limits of heavy/toxic metals as mentioned in API.

Heavy/toxic metals Permissible limits (ppm)
1. Lead 10.0
2. Cadmium 0.30
3. Mercury 1.00
4. Arsenic 10.0

ii) **Determination of Total Ash:** Required quantity of sample was weighted and taken in silica crucible, spread uniformly and incinerated at a temperature 450°C until free from carbon and cooled and weighted. Difference between the empty crucible weight and crucible with incinerated ash gives total ash value. It is the criteria for identity and purity of Drugs.

iii) **Determination of Acid insoluble Ash:** The residue from Total ash was boiled for 5 minutes with Dil.HCl. Insoluble matter was washed with hot water and collected in a

crucible, dried and weighted. Difference between empty crucible weight and crucible with incinerated ash gives the acid insoluble ash value. Less acid insoluble ash value refers less adherent dirt and sand particle, which is good for quality of Bhasma.

iv) Determination of Water soluble ash: The residue from Total ash was boiled for 5 minutes with 25 ml of distilled water, cooled and collected the insoluble matter which was washed with hot water and ignited/dried at 450°C and weighted. Subtract this weight of insoluble ash from the total ash taken, which gives the water soluble ash content.

v) Determination of Loss on drying: The samples are taken in china dish and deird in hot air oven at 105 °C, the weight was observed in every half hour till same weight was observed. Difference between initial weight and final weight gives weight loss on drying. This weight loss is due to the removal of water and volatile ingredients.

vi) Determination of pH: Aqueous solutions are prepared and measurements are carried out at 25°C using pH meter.

D) Pharmacological evaluation: Here the samples are tasted for specific pharmacological activity using animal models. Animals have to be selected and they are treated according to GLP guidelines. Specific pathological conditions are produced by inducing agents. This animal studies include specific activity studies like hepatoprotective, antihyperlipidemic study and toxicological (acute and chronic toxicity study) and histopathological studies of Bhasma. Some laboratory studies like antifungal, antimicrobial study also carried out for ensuring the therapeutic efficacy and quality control of Bhasmas.

4.2 DISCUSSION

In this review, an attempt is made to gather the physical, chemical and biological evaluation of bhasma and to develop a systemic approach for the quality control measures of bhasma and thus make them more appreciable by the world. Now-a-days, the methods of preparation of ayurvedic medicines have changed tremendously due to commercial interest of the pharmacies, for eg. in spite of putapaka system, most of the pharmacies use electric muffle furnace to prepare bhasma on large scale. Ancient scholars of Rasashastra have mentioned the analytical parameters for standards and quality of the product, which are deals with different standpoints to test the perfectness of bhasma. Although most of the tests are based on organoleptic methods of examination, some specific chemical assessment tests are also

indicated to ensure their safety and quality. Although bhasmas are complex materials, standardisation of bhasma has to be done according to WHO guidelines using classical as well as modern techniques will most important for building the confidence in use of such products for medication by ensuring safety, quality, efficacy and batch to batch uniformity and also acceptability of the product by body tissues.

4.3 CONCLUSION

Bhasma are most ancient form of herbomineral formulation used in Ayurveda still plays an important role due to its nano particle nature and also having pharmacological activities like analgesics, antiinflammatory, immune-modulatory, antioxidant etc. As Bhasma is said to be ancient nano medicine, they can be used for different ailments and are made target oriented with increased therapeutic efficacy, but due to lack of quality control methods, nonsystemic standardisation procedures made them unacceptable by modern world. So it's urgent need to develop systematized standardisation procedure to prove their therapeutic efficiency, purity and quality. No doubt, preparation of rasa medicines by stringently adhering to our classical methods has always resulted in quality products, but lack of standardization has degraded the quality of medicines compromising on its safety and efficacy. At one instance, bhasma is regarded as the nano medicine of the ancient times but at the same time questions are raised regarding its safety profile. Thus standardization of bhasma has become imperative to break away from this dilemma. So implementation of these modern techniques into Rasashastra can play a major role in the characterization and standardization of bhasmas. A strenuous effort from multidisciplinary experts in various sciences is necessary in bringing the bhasma preparations to the level of universal acceptance.

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