



# EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES

<http://www.ejbps.com>

ISSN 2349-8870  
Volume: 6  
Issue: 4  
199-201  
Year: 2019

## A REVIEW ON STANDARDIZATION OF BHASMA

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Article Received on 04/02/2019

Article Revised on 26/02/2019

Article Accepted on 19/03/2019

### ABSTRACT

Bhasmas are unique Ayurvedic metallic preparations with herbal juices/fruits widely used for treatment of a variety of chronic ailments. Standardization 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 challenges faced by these formulations are the lack of complete standardization by physicochemical, microbiological and analytical evaluation. An attempt has been made to summarize various methods available for standardization of bhasma.

**KEYWORDS:** Standardization, Bhasma, Physicochemical evaluation.

### INTRODUCTION

Metals play an important role in human body, the deficiency of which leads to various disorders. In Ayurveda, seven metals such as gold, silver, copper, iron, tin, lead and zinc are described as essential elements for the body. These metals are present in human body in different concentration and combination at various sites, and help the respective body tissues to perform their normal activities. And perfect health is attributed to the state of equilibrium of these metals in body tissues. Any imbalance, whether excess or deficiency, disturbs the body metabolism. It has been described that metal based formulations, called Bhasma, are highly effective in prevention and cure of various diseases related to the organ where they are naturally found. Bhasmas are unique Ayurvedic metallic preparations with herbal juices/fruits, used in the Indian subcontinent since the seventh century BC and widely recommended for treatment of a variety of chronic ailments. The Bhasmas are in fact products of classical alchemy in organic compounds of certain metals and gems in a very fine powdered form, mostly oxides, made in elaborate calcinations process known as bhasmikarana. It is believed that bhasmikarana process converts the metal into its specially desired chemical compound which eliminates the toxicity of the metal and has the necessary medicinal benefits. Various minerals like iron pyrite, copper pyrite and bitumen; 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 Kajjali, Abhrak BhasmaNaag Bhasma, Vang Bhasma, Jasad Bhasma, Tamra Bhasma, Mandoor Bhasma, Swarnamakshik Bhasma, Rasa Sindoor, Makardhwaj and Lauha Bhasma. They will be available as nanoparticles and are taken along with milk, butter, honey or ghee; thus making the metals easily assimilable, eliminating their harmful effects and enhancing their biocompatibility.

### METHODS

The methods of bhasma preparation vary so much for each metal such that bhasma with different colours are produced. The resultants are considered to be same medicinal substances with the ascribed indications even though these may differ in the composition between them and should ideally be addressing different ailments. In short, there is no standard bhasma of a metal as such. Ayurveda provides a list of tests for the efficacy of the bhasmikarana process. The tests are essentially qualitative and ensure that the resulting drug is very fine (small grains), has no metallic shine and does not alloy with silver even at higher temperature to which it was subjected. However, these qualitative tests do not provide any quantitative information about the composition and the structure of the final drug. For any drug containing heavy metals (for example lead, mercury), such structural information is an absolute necessity. In view of such ambiguity and the risk due to their inconsiderate use, there is an urgent need to bring about a standardization of the preparation-process and

the end product, as also to resolve the prospective indications and strengthen the regime to monitor the manufacturing, and administration of these preparations.

### Correspondence Between *Bhasma* and Oxides of Metals

A correspondence between a few metal *bhasma* and oxides and sulfides of the same metals has been drawn. A plurality of *bhasma* of some metals has been noticed. This is not surprising since for a given metal, more than one method is available to make its *bhasma* while treated respectively with different drug materials. The resulting *bhasma* show up with different colours and with different physical and chemical characteristics. This can be attributed to any of the following or some combination among them such as formation of oxides where a metal takes on different valence states; these compounds have different crystal structure and physical

For standard *bhasma* preparations, there is dearth of scientific analytical studies carried out, and even the existing ones suffer from incomplete analysis. Thus there is an imperative need for a scientific approach, which includes the following steps:-

- a) Physical standardization and elemental analysis of raw material and finished products.
- b) Determination of oxidation state of metals and association of these metals with acidic radicals in the finished product.
- c) Pharmacokinetics of the prominent metallic component of *bhasma* using tracer techniques or by metal extraction from tissues.
- d) Metal accumulation studies in different tissues and organs.
- e) Acute and chronic toxicity.
- f) Expression of heat shock proteins.
- g) Effect of *bhasmas* on normal physiological and antioxidant parameters.
- h) Therapeutic response of *bhasmas* on the recommended disease model at cellular and molecular level (based on claims written in ayurvedic texts).
- i) The role of *bhasmas* as drug carriers, and
- j) The role of *bhasmas* in body immunomodulation and physiology of gastrointestinal tract (GI) (site of jataragani).

These studies will provide evidence for the safety behind the use of *bhasmas* and also provide knowledge regarding their mechanism of action.

### Standardization techniques

The standardization process include following methods:

#### 1. Preliminary tests

1. Floating test: If a small quantity of *bhasma* is sprinkled on water surface it should float on the surface.
2. Fineness test: On rubbing a small quantity of the sample between the fingers it should enter into the lines on the fingers.

3. Loss of metallic luster: When visually examined preferably in presence of sun light no metallic luster should be observed.
4. Loss of metallic state: This involves heating of a very thin silver sheet (600 nm thickness) along with a small quantity of *bhasma* to red hot for about 5 min. After cooling the sheet to room temperature, no traces of this sample should permanently stick to the silver sheet indicating no alloy formation takes place, thus confirming the metal has totally transformed into *bhasma*, its oxide form.

### 2. Physicochemical evaluation

The various physicochemical evaluation include colour, odour, pH, taste, fineness, loss on drying at 1050C, total ash, acid insoluble ash, water soluble ash and particle size mesh test. Tests for heavy/toxic metals should be carried out for standard formulation and their permissible limits as per WHO / FDA is given in.

### Relation Between *Bhasma* and Nanomedicine

*Bhasmas* are biological nanocrystals. In terms of nanotechnology nanocrystalline materials are solids composed of crystallites with size less than 100 nm in at least one dimension. Milling parameters like milling temperature and nature of product influence the attainable grain size. Ayurvedic concepts of mardana (trituration) and bhavana (levigation) are used to reduce particle size. The various methods that are used to detect nanoparticles in *bhasma* are Scanning electron microscopy, Transmission electron microscopy, Fast freeze fracture, Fluorescence microscopy, X-ray photoelectron spectroscopy, Atomic absorption spectroscopy, Gel electrophoresis and Enzyme expression.

The process of nanoparticles testing in *bhasma* involved 5 steps:

1. To establish presence of nanoparticle in test sample.
2. To ascertain whether chemical compound is homogenous.
3. Whether nanoparticles are crystalline or amorphous.
4. Nature of defects in the sample.
5. Sample has to be biologically tested to check their bioactivity.

Finally convergence of all these factors in mechanism of action for particular application needs to be tested as well.

### 3. Standardization

Standardization is a measurement for ensuring the quality and is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality. For herbals formulations, it place major role from birth of a plant to its clinical application. It also means adjusting the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity respectively by adding excipients or by mixing herbal drugs or herbal drug preparations. Standardization is not

an easy task as numerous factors influence the bio efficacy and reproducible therapeutic effect. In order to obtain quality oriented herbal products, care should be taken right from the process of preparation. And chemical properties; compounds formed by the metal with the accompaniments, and, drugintermediates; doping of the *bhasma* crystals with impurities (foreign atoms) present even in very minute proportions; in doping foreign metal atoms substitute in the structure of a crystal for atoms of similar size.

#### 4. Microbiological evaluation

The various microbiological evaluation includes total viable aerobic count, total *Enterobacteriaceae* and total fungal count, test for specific pathogen: *E. coli*, *Salmonella spp.*, *S. aureus*, *Pseudomonas aeruginosa*. The permissible limits of microbial load and pathogens according to WHO/FDA are given in.

#### 5. Analytical evaluation

The various modern analytical evaluation include Atomic Absorption Spectroscopy (AAS), Atomic Force Microscopy (AFM), X-Ray Diffraction (XRD), X-Ray Fluorescence (XRF), X-Ray photo electron microscopy, Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), Energy Dispersive X-Ray Analysis (EDAX), Infrared spectroscopy (IR), Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES), FT-IR and Thermal Gravimetric Analysis (TGA) [18-20]. The various analytical instrument used and their purpose of analysis are given in Table 5.

**Table 5. Analytical instruments and their purpose of analysis.**

##### Instrument Purpose

1. EDX-SEM Chemical nature, size and morphology of particles
2. TEM, AFM Particle size, size distribution
3. EPMA Distribution of individual elements
4. XRD Phase analysis
5. XRF, PIXE Analysis Bulk chemical analysis after making pellets Detecting metal as element
6. ESCA Electronic Nature and oxidation state of metal
7. Single crystal XRD To confirm exact molecular structure of crystalline intermediates or products
8. Extraction and Chromatography To extract out organic matter if any
9. HPLC, NMR, IR, MALDI & ESI - MS Characterization of organic matter (if > 20% wt/wt)
10. Wet inorganic analysis, Anion and cation analysis AAS or Ion chromatography

#### CONCLUSION

In view of high demand for the use of *bhasma*, the herbo-mineral ayurvedic formulation, there is an urgent need to bring about standardization of their preparation process and the end product. In this article, an attempt has been made to bring forth the importance of standardization of

*bhasma* and the various physicochemical, microbiological and analytical methods available for standardization.

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