

STANDARDIZATION OF BHASMA CLASSICAL & MODERN VIEW

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Standardization???

- Standardization is a measurement for ensuring the quality and is used to describe all measures which are taken during the manufacturing process & quality control leading to a reproducible quality.
 - WHO guidelines for herbal drug stdn....

Need of standardization...??

- Safety & efficacy
- Ayurveda medicines are serving the needs of ailing humanity since many centuries. Particularly bhasmas have good preventive, curative and rejuvenating potential. There is a need of systematic and well-organized coordination of allied sciences along with adequate infrastructure and facilities to solve various problems related to the standardization of Rasaushadhies / Metallic bhasmas.
- Bhasmas are safe when prepared and used properly. Use of bhasmas when prepared in improper and short cut ways, can prove injurious to health.

Past Scenario

- Earlier medicines were prepared by the physician themselves for their patients.
- The physicians were well qualified to identify the materials.
- They were trained in various processing. They were following guidelines of Shastra & experienced teachers.
- According to the immediate need of the patients they were modifying the formulations as per their occupied understanding.

Present Scenario

- Physicians today are more involved with diagnosis and treatment.
- The drug manufacturing has gone into the hands of pharmacy.
- In large-scale production they compromised with quality and quantity of material.
- Compromised with longer and lengthy procedures.
- Equivalent substitutes are added in the compounds are not validated.
- The exact important procedures either altered or made shortcut
- This led to the decline in the quality of Ayurvedic drugs.
- **So Standardization of Ayurvedic drugs is thus felt necessary**

STANDARDIZATION

RAW MATERIAL

PROCESS

FINAL PRODUCT

RAW MATERIAL

1

- Metal/Mineral
- Prakrita/Kritrima/Lab prepared

2

- Animal origin

3

- Herbal
- Species/Season of collection/part used

Process/Methodology

- Shodhana/jarana/marana
- Classical methods /apparatus
- Advanced apparatus
- Valuka yantra, puta, = furnace

Final product / Bhasma

PHYSICAL / ORGANOLEPTIC

CHEMICAL

INSTRUMENTAL

PREPARATION OF BHASMA AS PER RASA TEXTS

Important procedures for making Bhasmas

1. Purva Karma: Shodhan (Purification)
2. Pradhana Karma: Marana (incineration /calcinations)
3. Paschat Karma: Lohitakarana, Amritikarana.

For the production of Bhasmas, Shodhan (Purification / Pretreatment) and Marana (incineration /calcinations), these two -fold procedures are the important steps (including some intermediary procedures in respect of particular materials like Dhanyabhraka for Abhraka and jarana for lead, tin and zinc).

Effect of Shodhana

Shodhana is an addition and separation process, it is a pre process for marana.

Following effects are observed during Shodhana,

1. Material becomes free from visible and invisible impurities.
2. Masses of minerals converted into fine and brittle.
3. Development of fineness and brittleness facilitates the bhavana process.
4. Partial reduction takes place.
5. Induction of organic therapeutic property in the inorganic material

Bhavana and its effect

It is a wet trituration process; Advantages of Bhavana are following,

- Materials are mixed uniformly
- Materials divided into fine.
- Surface area of material exposed and expended which facilitates reaction during firing (Marana)
- Develops softness, smoothness and stickiness in the material facilitates better binding of material
- Enhances the therapeutic property of minerals and metals.





Pellatization

1. Small disk of Bhavita material should be made.
2. Dry in sun or in dryer

Drying of pellets:

1. Before putting it in Sharava (casseroles) for sealing it should be dried completely.
2. Wet pellets should not be allowed.
3. Wet pellets if subjected for puta desired colour will not appears.
4. Desired smoothness will not develop.

Sarava samputikarana



- Arrange pellets in a earthen sharava
- Covered it with another sharava
- Joints of earthen lids should be sealed 7 layers with cloth and mud
- Again dry it in sun or in dryer.
- Properly sealed prevents the escape of volatile material.
- It prevents interference of out side gases and dirt.
- Finally sealed sharavas subjected to puta system of repeated heating till the material completely converted into bhasma with desired characteristics.

Putra system of heating

1. Putra is a specific system of heating for the incineration metals and minerals.
2. For the hard, soft, organic, inorganic, volatile, inflammable and according to heat resistance various putra have been described.
3. According to the quantity of fuel Mahaputra, Gajaputra, Varahaputra, Kukkutaputra, kapotputra, Gorbarputra, Bhandra and Tusha etc putra are mentioned.
4. Each and every putra have different diameters.
5. Intensity of heat, Mode of Temperature and Time duration depends upon the putra.
6. According to the heat resistance of the material putra are selected and applied for the marana purpose. Such as,
for Gold & Silver Laghu or Kapot putra, Vanga, Naga, Yashada Kukkutaputra or Ardha gajaputra, Tamra in Varaha or kukkutaputra and for Abhraka and Loha in Varaha or Gajaputra are applied.

Marana(Incineration)

- Marana term denotes the meaning of incineration or calcinations. When minerals (compounds) and metals (elements) are subjected for heating on moderate to intense temperature, compound material converted to certain other compounds where as elements get reduced to certain compounds.
- Nature of compound depends upon the material added in to the main material and exposure of environment.
- Various system of heating is applied for this purpose but the puta system of heating is common for marana.
- Marana is an Association and dissociation process.
- Elements are converted into certain compounds
- Metals are reduce to ash (forms compound)
- Compounds are converted into certain other compounds.
- Nature of compound formed depends upon the material used for marana.
- It may be sulphide, oxide, chloride, sulphates etc.
- Macro forms of material converted into micro form
- Heavy and solid material converted into light and soft.



Samskaras of Bhasma

(Post operative Specific treatment)

Lohitakarana

Amritakarana

In some cases post operative procedures are also followed to achieve safe, effective and desired Bhasma.

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Amritikarana, Lohitikarana

Amritikarana:

1. It removes the remaining blemishes of the bhasma
2. It enhances the therapeutic properties of the bhasma.

Lohitikarana:

1. It develops desired red colour in case of loha and Abhrakā bhasma.

Process reaction

Rasaushadhies are mainly based on minerals (compound state) and metals (elemental state). The basic material when treated frequently with plant extractives and heated on fire the following reactions are observed.

- Marana is a compounding / reduction and dissociation process.
- Plant extractives are converted into ash or solid organic / inorganic forms depend upon the intensity of heat applied.
- Compounds are reduced and converted into another compounds.
- Elemental metals gradually reduced and converted into compounds.
- Nature of compound depends upon the media as catalyst added.
- Herbal residue participates in formation of compound or it may present with the mineral compounds.
- Wet grinding after each firing exposes the surface of metallic particles.
- Exposed surface coated with the media of catalysts for further reaction.

Bhasma Pareeksha

PHYSICAL	CHEMICAL
Varna (Colour)	Gatarasatva (tastelessness)
Varitara (float)	Nirdhuma (absence of fumes)
Rekhapurna (furrow filling)	Apunarbhava (irreversibility)
Unama	Nirutha (irretrievable)
Anjana sannibha (softness)	Amla pareeksha (sour test)
Nischandra (lusterless)	Aksharatwa (lack of alkaline taste)
Sukshmatva (fineness)	



Rekhapurnatva



Varitaratwa



Unama



Nirutha



NPST- Yashada bhasma



NPST-Tamra bhasma

Dhatu	Bhasma varna
Abhraka	Istika varna
Vaikranta	Raktabha
Makshika	Rakta
Vimala	Rakta
Rasaka	Rakta
Chapala	Rakta
Kasisa	Rakta
Kankshi	Shweta
Kaparda	Krishna
Sudhavargeeya dravya	Shweta
Loha	Pakwa jambuphala sadrusha
Swarna	Champaka
Rajata	Krishna
Tamra	Krishna
Naga	Kapota
Vanga	Chandrama
Yashada	Peeta

Dhatu Jwala varna

Dhatu	Jwala varna
Teekshna Loha	Krishna
Kanta Loha	Kapila
Swarna	Peeta
Rajata	Shweta
Tamra	Neela
Naga	Dhumra
Vanga	Kapota
Abhraka	Pandura
Tutha	Lohita
Vajra	Aneka

Modern parameters

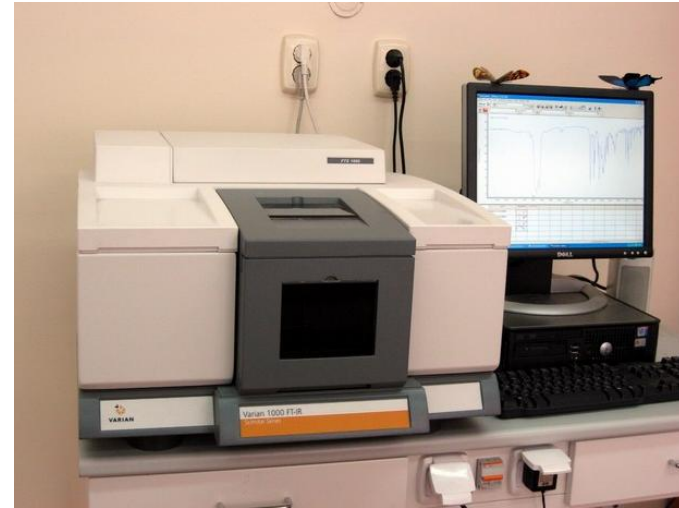
Sl.No.	Parameter	Purpose
01	EDX-SEM	Chemical nature, size & morphology of particles
02	TEM, AFM	Particle size, size distribution
03	EPMA	Distribution of individual elements
04	XRD	Phase analysis
05	XRF, PIXE	Bulk chemical analysis after making pellets, Detecting metal as element
06	ESCA	Electronic nature & oxidation state of metal
07	Extraction & Chromatography	To extract out organic matter if any
08	HPLC,NMR,IR, MALDI,	Characterization of organic matter

- EDX- Energy Dispersive X ray analysis
- TEM- Transverse Electron Microscopy
- AFM- Atomic Force microscopy
- EPMA- Electron Probe Micro Analyzer
- XRF- X ray Fluorescence
- PIXE- Particle Induced X ray Emission
- ESCA- Electron spectroscopy for Chemical Analysis
- NMR- Nuclear Magnetic Resonance
- IR- Infrared spectroscopy
- MALDI- Matrix Assisted Laser desorption / ionization

Instrument photos



NMR



IR-Spectrometer



AFM



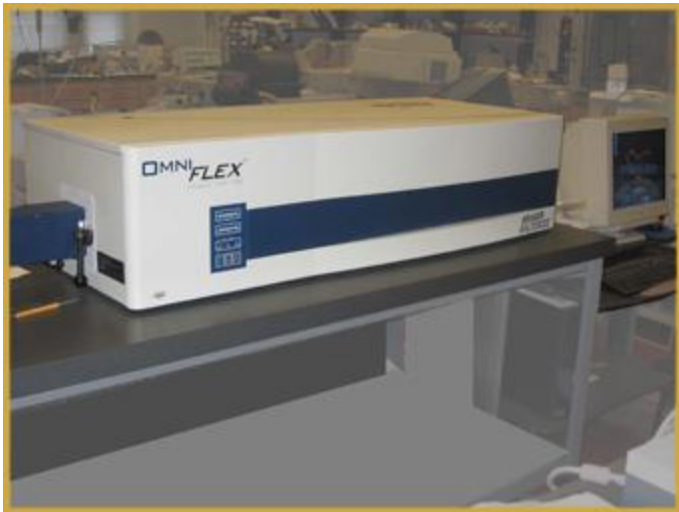
ESCA



EPMA



EDX



MALDI



TEM

Permissible limit As per API

Sl No.	Heavy metals	Limit (ppm)
01	Lead	10
02	Cadmium	0.3
03	Mercury	1
04	Arsenic	3

Physico-chemical Analysis

- Colour
- LOD
- Total Ash (% of ash)
- Acid insoluble ash (% of acid insoluble inorganic content)
- Water soluble ash
- Solubility
- Particle size
- NPST
- Essay of elements

Example as per PSAF-CCRAS Delhi

Sl.no.	Parameter for Swarna bhasma	Result
01	Description	Fine, reddish brown powder, odourless and tasteless
02	Identification	Yields the reactions characteristics of gold
03	LOD	Not more than 0.50% w/w
04	Loss on ignition	Negligible
05	AIA	90-95% w/w

Sl.no.	Parameter for Abhraka bhasma	Result
01	Description	Fine, reddish brown powder, odourless and tasteless
02	Identification	Yields the reactions characteristics of silicates, Ca, Mg, Al, Fe
03	LOD	Not more than 0.50% w/w
04	Loss on ignition	Not more than 1 % w/w
05	AIA	40-65% w/w

Bhasma-Nanomedicine

Benefits of nanoparticles/ nanosizing of drugs

- Increase surface area
- Enhance solubility
- Increase rate of dissolution
- Increase oral bioavailability
- More rapid onset of action
- Decrease of dose needed

Conclusion

ALPAMAATROPAYOGITWAT
ARUCHERAPRASANGATAH |
KSHIPRAMAROGYADAYITWAT
OUSHADHOBHYO ADHIKO RASAH||

- To get these properties from Rasoushadhis / bhasma SOP & SMP should be followed as mentioned in ayurvedic literature followed by modern techniques.

PROJECTS

- National Networked Project on Standardization
Safety & Efficacy of metal based formulations
By-Dept of Science & Technology (DST)
Technology Bhavan, New Delhi (Oct-2008)
- Kajjali, Abhraka bhasma, Naga bhasma, Vanga
bhasma, Yashada bhasma, Tamra bhasma,
Mandura Bhasma, Swarna makshika bhasma,
Rasasindhura, Makaradhwaja, Loha bhasma

Ongoing project

- Traditional method & modern method of Bhasma Preparation-A comparative study and role of Mitrapanchaka in deciding Apunarbhava of Bhasma

By- Bhide foundation Pune

Thesis

- Ranga Rao S P-Standardization test of Sudhavargeeya bhasma-1983
- Joshi Renuka-Pharmaceutical stdn of yashada bhasma-2004
- Solanki Tushar- A pharmaceutical stdn of somanathi-tamra bhasma & its effect on Grahani roga-2004
- Rathor AS-Stdn of Vaikranta bhasma in relation to its identification, experimental studies & clinical observations-1995
- Singh AK- stdn of different samples of tamra bhasma-1998
- Kotrannavar vijay kumar- Stdn of Mayur picha bhasma & its comparative antiemetic effect with meclixine hCL in morning sickness-2002

- Savalagi pavan- stdn of Abhraka bhasma & assesment of its clinical efficacy in Rajayakshma with trikatu, vidanga & amalaki churna-2003
- Simpi Praveen – Stdn & toxicity study on Loha bhasma prepared with different methods-2004
- Benade Shekhar- Comparative analytical study & stdn of different samples of shankha, & shankha bhasma

Articles Published

- Pharmaceutical stdn of Pravala Bhasma (ASL Jan 1998)
- Pharmaceutical stdn of Naga Bhasma (Ayu)
- Nanomedicine – A Review (The Antiseptic)
- Classical and modern analytical parameters for evaluation of bhasmas (Journal of ayurveda)
- Compliance of pharmacopoeial quality standards of ayurvedic medicine (Ayu)
- Ayurvedic bhasma-the most ancient application of Nanomedicine (JSIR Dec 2010)
- Concept of Bhasmeekarana (IJRAP 2011)
- Standardization of Shringa Bhasma (ASL Jan 2002)
- Standardization of Trivanga Bhasma (ASL Jan 1987)
- Stdn & Bioavailability of Loha Bhasma (ASL Oct 1995)

List of Approved Ayurveda, Siddha & Unani Drug Testing Laboratories Under Rule -160 A to J of the Drugs and Cosmetics Rule 1945

Sl.No.	NAME OF THE LABORATORY
01	M/S Varun Herbals Pvt Ltd 5-8-293/A HYD
02	M/S Sipra Labs Pvt Ltd 407 Aditya enclave HYD
03	Captain Srinivasa Murti Drug Research, Institute for Ayurveda (CCRAS), Arumbakkam, Chennai - 600 106.
04	M/s Sowparnika Herbal Extracts & Pharmaceuticals Pvt. Ltd., No.31-A/2A, North Phase, SIDCO Industrial Estate, Chennai - 600 098.
05	Regional Research Laboratory (CSIR), Canal Road, Jammu Tavi, Jammu - 180 001.
06	ARBRO Pharmaceuticals Ltd., 4/9, Kirti Nagar Industrial Area, New Delhi - 110 015
07	Shriram Institute for Industrial Research, 14 & 15 Sathyamangala Industrial Area, Whitefield Road, Bangalore - 560 048.
08	Bangalore Test House, 65/20th Main Morenhalli, Vijayanagar, Bangalore.
09	FRLHT, 74/2 Jarakabande Kaval, Post Attur Via Yelahanka, Bangalore - 560 064.

Sl.No.	NAME OF THE LABORATORY
10	M.S. Ramaiah Drugs and Allied Products Testing Laboratories, M.S. Ramaiah Nagar, M.S.R.I.T (POST), Bangalore - 560 054.
11	Ozone Pharmaceuticals Ltd., (Analytical Lab) MIE, Bahadurgarh, Dist. Jajjhar, Haryana -124 507.
12	M/S Standard Analytical & Research Laboratories, 358/4, Laxmibai Nagar, Industrial Estate, Kilamaidan, Indore, M.P -452 004.
13	M/S Quality Control Laboratory, Plot No. 17, Malviya Nagar, Bhopal, M.P - 462 003.
14	J.R.D. Tata Foundation for Research in Ayurveda and Yoga Sciences, Arogyadham (Deendayal Research Institute) Chitrakoot, Satna, M.P - 485 331.
15	Shriram Institute for Industrial Research, University Road, Delhi.
16	M/s Sitharam Ayurved Pharmacy Ltd., Nedumpuzha, Thrissur, Kerala.
17	Vaidya Rathnam, Aushadhshala, Ollur, Thrissur.
18	M/s Natural Remedies Pvt. Ltd., Bangalore.
19	Drug Testing Laboratory, Niper, Mohali, Chanidgarh.
20	M/s Amol Pharmacuetical Pvt. Ltd., Sanganer Jaipur, Rajasthan.
21	Laboratories Service Division, Sargam Metals Pvt. Ltd. Chennai.
22	Arya Vaidyashala Kotakkal, Malapuram.

References

- API
- AFI part I and II
- PSAF
- Bhasma Vigyana
- Rasa Ratna Samuchaya
- Rasendra chudamani, R chintamani
- Rasamritam,
- Ayurveda Prakash
- www.indianmedicine.com
- www.ccras.nic.in
- www.pubmed.com
- www.scribd.com
- www.ayupharm.com

THANK YOU.....