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 Rasaushadhdhies / 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)


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. Dried

3. Before putting it in Sharava (casseroles) for sealing it should be dried completely.
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.
- 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.
Puta system of heating

1. Puta 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 puta have been described.
3. According to the quantity of fuel Mahaputa, Gajaputa, Varahaputa, Kukkutaputa, kapotputa, Gorbarputa, Bhanda and Tusha etc puta are mentioned.
4. Each and every puta have different diameters.
5. Intensity of heat, Mode of Temperature and Time duration depends upon the puta.
6. According to the heat resistance of the material puta are selected and applied for the marana purpose. Such as, for Gold & Silver Laghu or Kapot puta, Vanga, Naga, Yashada Kukkutaputa or Ardha gajaput, Tamra in Varaha or kukkutaputa and for Abhraka and Loha in Varaha or Gajaputa 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.
- Elements are converted into certain compounds
- Metals are reduce to ash (forms compound)
- 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)

Lohitikarana
Amritikarana

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

<table>
<thead>
<tr>
<th>PHYSICAL</th>
<th>CHEMICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Varna (Colour)</td>
<td>Gatarasatva (tastelessness)</td>
</tr>
<tr>
<td>Varitara (float)</td>
<td>Nirdhuma (absence of fumes)</td>
</tr>
<tr>
<td>Rekhapurna (furrow filling)</td>
<td>Apunarbhava (irreversibility)</td>
</tr>
<tr>
<td>Unama</td>
<td>Nirutha (irretrievable)</td>
</tr>
<tr>
<td>Anjana sannibha (softness)</td>
<td>Amla pareeksha (sour test)</td>
</tr>
<tr>
<td>Nischandra (lusterless)</td>
<td>Aksharatwa (lack of alkaline taste)</td>
</tr>
<tr>
<td>Sukshmatva (fineness)</td>
<td>Avaami</td>
</tr>
</tbody>
</table>
Rekhapurnatva

Varitaratwa

Unama

Nirutha

NPST- Yashada bhasma

NPST-Tamra bhasma
<table>
<thead>
<tr>
<th>Dhatu</th>
<th>Bhasma varna</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abhraka</td>
<td>Istika varna</td>
</tr>
<tr>
<td>Vaikranta</td>
<td>Raktabha</td>
</tr>
<tr>
<td>Makshika</td>
<td>Rakta</td>
</tr>
<tr>
<td>Vimala</td>
<td>Rakta</td>
</tr>
<tr>
<td>Rasaka</td>
<td>Rakta</td>
</tr>
<tr>
<td>Chapala</td>
<td>Rakta</td>
</tr>
<tr>
<td>Kasisa</td>
<td>Rakta</td>
</tr>
<tr>
<td>Kankshi</td>
<td>Shweta</td>
</tr>
<tr>
<td>Kaparda</td>
<td>Krishna</td>
</tr>
<tr>
<td>Sudhavargeeya dravya</td>
<td>Shweta</td>
</tr>
<tr>
<td>Loha</td>
<td>Pakwa jambuphala sadrusha</td>
</tr>
<tr>
<td>Swarna</td>
<td>Champaka</td>
</tr>
<tr>
<td>Rajata</td>
<td>Krishna</td>
</tr>
<tr>
<td>Tamra</td>
<td>Krishna</td>
</tr>
<tr>
<td>Naga</td>
<td>Kapota</td>
</tr>
<tr>
<td>Vanga</td>
<td>Chandrama</td>
</tr>
<tr>
<td>Yashada</td>
<td>Peeta</td>
</tr>
</tbody>
</table>
Rekhapurnatva

A pinch of the sample was taken and it was rubbed between the thumb and index finger. Thereafter it was observed that the particles of Bhasma found embedded in finger print this suggest that Bhasma possess Rekhapurnatva Pariksha.
Nischandratva

After Rekhapurnatva Pariksha, thumb and index finger was observed in sunlight. It was observed that no metallic lusture (Chandrika) found, this suggests that Bhasma passes Nischandratva Pariksha.
Varitaratva

A pinch of the sample was sprinkled on the surface of water and there after it was observed that particles of the Bhasma were floating on the surface of water. Nor particle found dipping in water. This suggests that particle size of the sample does not break the surface tension of water because of small particle size. This suggests that Bhasma passes Varitara Pariksha.
Unama

After Varitara Pariksha, a little amount of rice was put on the floating particle of the sample on water; even then particle of sample found floating along with rice. This suggest that Bhasma passes Unama Pariksha.
Dadhi pariksha

A pinch of sample was sprinkled on the surface of curd, which was in a little pot. After 24 hours it was observed that no discoloration founding curd, this suggests that Bhasma passes curd test.
Apunarbhava

The Dravyas of Mitrapanchaka i.e. Guda, Gunja, Madhu, Ghrita, Tankana were taken each 0.5gm and mixed properly and a round ball was made from it. 0.5gm of the sample was taken and put in between that ball and there after that ball was subjected to heat. After heating for 1 hour, the ball was taken out and triturated in Khalva Yantra. It was observed that no metallic particles found after trituation this suggests that Bhasma passes Apunarbhava Pariksha.
## Dhatu Jwala varna

<table>
<thead>
<tr>
<th>Dhatu</th>
<th>Jwala varna</th>
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</thead>
<tbody>
<tr>
<td>Teekshna Loha</td>
<td>Krishna</td>
</tr>
<tr>
<td>Kanta Loha</td>
<td>Kapila</td>
</tr>
<tr>
<td>Swarna</td>
<td>Peeta</td>
</tr>
<tr>
<td>Rajata</td>
<td>Shweta</td>
</tr>
<tr>
<td>Tamra</td>
<td>Neela</td>
</tr>
<tr>
<td>Naga</td>
<td>Dhumra</td>
</tr>
<tr>
<td>Vanga</td>
<td>Kapota</td>
</tr>
<tr>
<td>Abhraka</td>
<td>Pandura</td>
</tr>
<tr>
<td>Tutha</td>
<td>Lohita</td>
</tr>
<tr>
<td>Vajra</td>
<td>Aneka</td>
</tr>
</tbody>
</table>
## Modern parameters

<table>
<thead>
<tr>
<th>Sl.No.</th>
<th>Parameter</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>EDX-SEM</td>
<td>Chemical nature, size &amp; morphology of particles</td>
</tr>
<tr>
<td>02</td>
<td>TEM, AFM</td>
<td>Particle size, size distribution</td>
</tr>
<tr>
<td>03</td>
<td>EPMA</td>
<td>Distribution of individual elements</td>
</tr>
<tr>
<td>04</td>
<td>XRD</td>
<td>Phase analysis</td>
</tr>
<tr>
<td>05</td>
<td>XRF, PIXE</td>
<td>Bulk chemical analysis after making pellets, Detecting metal as element</td>
</tr>
<tr>
<td>06</td>
<td>ESCA</td>
<td>Electronic nature &amp; oxidation state of metal</td>
</tr>
<tr>
<td>07</td>
<td>Extraction &amp; Chromatography</td>
<td>To extract out organic matter if any</td>
</tr>
<tr>
<td>08</td>
<td>HPLC, NMR, IR, MALDI</td>
<td>Characterization of organic matter</td>
</tr>
</tbody>
</table>
• 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
# Permissible limit
## As per API

<table>
<thead>
<tr>
<th>Sl No.</th>
<th>Heavy metals</th>
<th>Limit (ppm)</th>
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</thead>
<tbody>
<tr>
<td>01</td>
<td>Lead</td>
<td>10</td>
</tr>
<tr>
<td>02</td>
<td>Cadmium</td>
<td>0.3</td>
</tr>
<tr>
<td>03</td>
<td>Mercury</td>
<td>1</td>
</tr>
<tr>
<td>04</td>
<td>Arsenic</td>
<td>3</td>
</tr>
</tbody>
</table>
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

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

<table>
<thead>
<tr>
<th>Sl.no.</th>
<th>Parameter for Abhraka bhasma</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Description</td>
<td>Fine, reddish brown powder, odourless and tasteless</td>
</tr>
<tr>
<td>02</td>
<td>Identification</td>
<td>Yields the reactions characteristics of silicates, Ca, Mg, Al, Fe</td>
</tr>
<tr>
<td>03</td>
<td>LOD</td>
<td>Not more than 0.50% w/w</td>
</tr>
<tr>
<td>04</td>
<td>Loss on ignition</td>
<td>Not more than 1 % w/w</td>
</tr>
<tr>
<td>05</td>
<td>AIA</td>
<td>40-65% w/w</td>
</tr>
</tbody>
</table>
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 |
KSHIPRAMAROGYADAYITIWAT
OUSHADHOBHYO ADHIKO RASAH||

• To get these properties from Rasoushadhis / bhasma SOP & SMP should be followed as mentioned in ayurvedic literature followed by modern techniques.
Though Ayurvedic parameters are well defined and found sufficient for quality assurance but any type of alteration & adulteration could not be checked.

The variation in the method of preparation and the ingredients used are also leads to variation in final products.

The modern analytical parameters provides the information regarding their component up to the ppm level yet not able to show the full picture of the final product.

Thus the modern techniques applied for analysis of Bhasmas are not found suitable because many of the actions of the Bhasma are unexplained.
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 & assessment 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)
• Stdardization of Shringa Bhasma (ASL Jan 2002)
• Stdardization 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

<table>
<thead>
<tr>
<th>Sl.No.</th>
<th>NAME OF THE LABORATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>M/S Varun Herbals Pvt Ltd 5-8-293/A HYD</td>
</tr>
<tr>
<td>02</td>
<td>M/S Sipra Labs Pvt Ltd 407 Aditya enclave HYD</td>
</tr>
<tr>
<td>03</td>
<td>Captain Srinivasa Murti Drug Research, Institute for Ayurveda (CCRAS), Arumbakkam, Chennai - 600 106.</td>
</tr>
<tr>
<td>04</td>
<td>M/s Sowparnika Herbal Extracts &amp; Pharmaceuticals Pvt. Ltd., No.31-A/2A, North Phase, SIDCO Industrial Estate, Chennai - 600 098.</td>
</tr>
<tr>
<td>05</td>
<td>Regional Research Laboratory (CSIR), Canal Road, Jammu Tavi, Jammu - 180 001.</td>
</tr>
<tr>
<td>06</td>
<td>ARBRO Pharmaceuticals Ltd., 4/9, Kirti Nagar Industrial Area, New Delhi - 110 015</td>
</tr>
<tr>
<td>07</td>
<td>Shriram Institute for Industrial Research, 14 &amp; 15 Sathyamangala Industrial Area, Whitefield Road, Bangalore - 560 048.</td>
</tr>
<tr>
<td>08</td>
<td>Bangalore Test House, 65/20th Main Morenhalli, Vijayanagar, Bangalore.</td>
</tr>
<tr>
<td>09</td>
<td>FRLHT, 74/2 Jarakabande Kaval, Post Attur Via Yelahanka, Bangalore - 560 064.</td>
</tr>
<tr>
<td>Sl.No.</td>
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<td>-------</td>
<td>------------------------</td>
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<tr>
<td>10</td>
<td>M.S. Ramaiah Drugs and Allied Products Testing Laboratories, M.S. Ramaiah Nagar, M.S.R.I.T (POST), Bangalore - 560 054.</td>
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<tr>
<td>12</td>
<td>M/S Standard Analytical &amp; Research Laboratories, 358/4, Laxmibai Nagar, Industrial Estate, Kilamaidan, Indore, M.P -452 004.</td>
</tr>
<tr>
<td>13</td>
<td>M/S Quality Control Laboratory, Plot No. 17, Malviya Nagar, Bhopal, M.P - 462 003.</td>
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<tr>
<td>15</td>
<td>Shriram Institute for Industrial Research, University Road, Delhi.</td>
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<td>16</td>
<td>M/s Sitharam Ayurved Pharmacy Ltd., Nedumpuzha, Thrissur, Kerala.</td>
</tr>
<tr>
<td>17</td>
<td>Vaidya Rathnam, Aushadhshala, Ollur, Thrissur.</td>
</tr>
<tr>
<td>18</td>
<td>M/s Natural Remedies Pvt. Ltd., Bangalore.</td>
</tr>
<tr>
<td>19</td>
<td>Drug Testing Laboratory, Niper, Mohali, Chandigarh.</td>
</tr>
<tr>
<td>22</td>
<td>Arya Vaidyashala Kotakkal, Malapuram.</td>
</tr>
</tbody>
</table>
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......