

## RASAUSHADHI (METTALO MEDICINE) – PHARMACEUTICAL FACTORS FOR SAFE AND EFFICTIVE MEDICINE

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### ABSTRACT

Science if used wisely serves as a boon to humanity and if used in a wrong way can be dangerous. Every system has some flaws, which needs to be noted and rectified no matter how good the system is. *Ayurveda* is one of the ancient system of medical science which has elaborated the causes and methods of drug-induced consequences along with preventive measures. However the available data in classical texts is scattered. The compilation and analysis along with modern concept drug safety is need of the hour. This aspect has been considered by the pioneers of *Ayurveda* in detail in addition to the other possible ways by which toxicity, untoward effects can occur and provided all the guidelines to avoid the occurrence of such incidences. Certain newer techniques like *Shodhana*, *Jarana* and *Marana* etc.<sup>1, 2</sup> have been developed with an intention to prepare more bio-assimiliable forms of *Rasaushadha dravya*'s. The indications, dose, vehicle, period of drug administration, interval or duration of treatment, disease diagnosed, nature or *Prakruti* of patient, *pathya-apathya* etc. are major factors which should always be considered by the physician before they recommend these *Rasaushadha dravya*'s to the patients. The flaws and precautions related to the rational use of *Rasaushadhi* in *Ayurveda* are mentioned here as an effort to understand and highlight the concept of drug safety in *Ayurveda* with special reference to *Rasaushadhi*.

**Keywords:** *Rasushadhi*, toxicity, safety, precautions

### INTRODUCTION

The drug toxicity in *Ayurveda* refers to the complications of a drug or any harmful action of the drug/ formulation in human body except the intended action. Such drug actions can be correlated with the adverse drug reactions of the modern pharmacology which includes the side effects, untoward effects, toxic effects and idiosyncratic effects. Many questions are now being raised by the scientific and non-scientific community worldwide regarding the documentation of safety and efficacy of Ayurvedic Medicines especially of *Rasaushadhadravya*'s. Some of the foreign studies also have raised very serious questions in this

regards.<sup>3,4,5</sup> Ancient Ayurvedic scholars were very much aware about the drug toxicity and keeping it in the mind they have described '*Aushadha vyapata*' in their classics elaborately which reflect their concern about adverse effect of Ayurvedic drugs. The *Rasaushadha dravya*'s refers to the herbo-mineral or metal or mineral formulations use for therapeutic purpose. Some of these formulations contain heavy metals like Mercury, Lead, Tin and Arsenic etc. The concerns raised are about metal content and related metal toxicities among populations resulting from use of such medicines.

### 1. MATERIALS AND METHOD:

### 1.1 Types of Rasaushadi

Rasausadhis although named after mercury ('Rasa' or 'Parada'), can be classified in two distinct classes- Mercurials and Non-mercurials. Based on the method of preparation, the mercury based drugs are classified as- *Khalvi rasa, Parpati rasa, Kupipakwa*

*rasa/sindura* and *Pottali rasa*. The non-mercurial preparations include *Dhatubhasma, Satva* and *Pisti*. Apart from these, there are some other herbomineral ayurvedic dosage forms (*kalpana*) also, where these *rasadravyas* are formulated along with herbal drugs.

Type of Rasaushadhi	Examples
<i>Khalvi rasa</i>	<i>Kajjali, Tribhuvankirti rasa, Aarogyavardhinivati</i>
<i>Parpati rasa</i>	<i>Rasa parpati, Panchamritaparpati, Swarnaparpati</i>
<i>Kupipakwa rasa</i>	<i>Makaradhwaja rasa, Rasa sindura, Sameerpannaga rasa</i>
<i>Pottali rasa</i>	<i>Hemagarbhapottali, Rasagarbhapottali</i>
<i>Bhasma&amp;Pisti</i>	<i>Abhrakabhasma, Swarnabhasma, Pravalapisti, Muktapisti</i>
<i>Lauha&amp;Mandura</i>	<i>Saptamrutalauha, Punarnavamandura</i>

### 2.2 List of Poisonous substances of mineral origin under Schedule-E<sup>6</sup> and some of their aushadhyogas-

S.No.	Name of Drug	Chemical Name	Aushadhyoga
1.	<i>Gauripashana</i>	Arsenic	<i>Sameerpannaga rasa, Mallasindura</i>
2.	<i>Hartala</i>	Arsenosulphide	<i>Kasturibhairava rasa, Taalkeshwara rasa</i>
3.	<i>Parada</i>	Mercury	<i>Rasa parpati, Rasa sindoor</i>
4.	<i>Raskarpura</i>	Hydrargyrisubchloridum	Used as formulation itself.
5.	<i>Tuttha</i>	Copper sulphate	<i>Mahamrityunjaya rasa, Jatyadi-ghrita</i>
6.	<i>Hingula</i>	Cinnabar	<i>Hinguleshwara rasa, Anandbhairava rasa</i>
7.	<i>Sindura</i>	Red oxide of lead	<i>Sinduradilepa</i>
8.	<i>Girisindura</i>	Red oxide of mercury	<i>Paadarimalhara</i>

### 2.3 Toxic effects of some Rasadravyas if consumed without proper purification/incineration/approved variety-

S.No	Name of Rasadravya	Toxic effects	References <sup>^</sup>
1.	<i>Parada</i>	<i>Vishadoshayukta- Mrityu, Vanhidoshayukta- Santaapa, Mala doshayukta- Moorchcha, Naag- vangayukta- Jadata, Adhyamana, Kushtha.</i>	R.R.S.11/20, Aa.Pra.19
2.	<i>Abhraka (Bheda)</i>	<i>Mala baddhata (Pinakaabhraka)</i>	R.R.S.2/5
		<i>Mandala kushtha (Naagaabhraka)</i>	R.R.S.2/6
		<i>Ashmari (Mandukaabhraka)</i>	R.R.S.2/7
	<i>Abhra-ka(ashuddhabhasma)</i>	<i>Hrudpaarshvapida, Shotha, Pandu, Kushtha roga, Agnimaandhya, Guru. Vata-kaphavardhaka</i>	R.T.10/16-17, Ayu.Pra.2/103, R.Sa.Sa n.1/152
	<i>Abhraka(Apakwa/ Chandrikayukta bhasma)</i>	<i>Pranahara (life threatening) like Visha, Vajra, Agni &amp; Shastra.</i>	R.Pra.Su.5/15

3.	Vaikrant (ashudhdha)	Kilasa, Kushtha, Daaha, Parshwapida&pandu.	Aa.Pra.5/168
4.	Swarnamakshika (ashudhdha)	Netravikara, Mandagni, Kushtha, Halimaka.	R.T.29/6
5.	Tuttha (ashudhdha)	Vaanti, Bhraanti.	Aa.Pra.4/39
6.	Kharpara (ashudhdha)	Vaanti, Bhraanti.	Aa.Pra.2/283
7.	Gandhaka (ashudhdha)	Kushtha, Taapa, Bhrama, Pittajavikara, Roopa-sukha-viryabalahara.	Aa.Pra.2/18
8.	Hartaala (ashudhdha)	Daaha, Kshobha, Kampa, Toda, Raktavikara, Kushtha, Vaatakaphaja roga karaka, Mrityukaraka.	R.T.11/13-15, R.R.S.3/69
9.	Manahshila (ashudhdha)	Ashmari, Mutrakruchcha, Mandagni, Malabaddhata.	R.R.S.3/92, Aa.Pra.2/219, R.T.11/107-108
10.	Hingula (ashudhdha)	Andhata, Kshaya, Klama, Bhrama, Moha, Prameha.	Aa.Pra.2/73, R.T.9/11
11.	Swarna (ashudhdha)	Sukha-viryabalanashaka, Rogakaraka.	R.R.S.5/11, R.T.15/14
12.	Rajata (ashudhdha)	Aayu-sukha-balahara, santaapa, malabaddhata, rogakaraka, Angasaada.	R.R.S.5/30, R.T.16/5
13.	Taamra (Ashtavishadosha)	Bhrama, Moorchcha, Vidaaha, Sweda, Kleda, Vaanti, Aruchi, Chittasantaapa.	Aa.Pra.3/115-116
	Taamra (ashudhdha)	Aayu-kanti-viryabalanashaka, Vaanti, Moorchcha, Bhrama, Utklesha, Kushtha, Daaha, Moha.	R.R.S.5/47-48
14.	Lauha (Saptadosha)	Guruta, Drudhata, Utkleda, Glani, Daaha, Ashmari, Dehadaurgandhya.	Aa.Pra.3/223
	Lauha (ashuddha)	Aayu-bala-kantinashaka, Hridpida, Shaithilya, Rogakaraka	R.R.S.5/75
15.	Vanga (ashudhdha)	Kantihara, Kushtha, Kilasa, Gulma, Prameha, Kshya, Paandu, Shotha, Shleshma-jwara, Bhagandara, Shukraashmari, Raktavikara.	R.T.18/6-7
16.	Naaga (ashudhdha)	Kantihara, Kushtha, Sandhivedana, Pakshaghata, Gulma, Prameha, Aanaha, Shotha, Bhagandara, Agnimandhya, Anshashotha, Udarashula, Kshya.	R.T.19/4-6, Aa.Pra.3/188
17.	Yashada	Gulma, Prameha, Kshaya, Kushtha.	R.T.19/17

^ (Ayu.Pra. – Ayurveda prakasha, R.Pra.Su. – Rasprakashasudhakara, R.R.S. – Rasaratnasamucchaya, R.Sa.San. – Rasendrasarasamgraha, R.T. – Rasatarangini)

#### 2.4 Important factors related to Rasaushadhi administration:

Following factors must be kept in mind during administration of *rasaushadhi* –

**a) Dose** (Proper/Lesser/Overdose or excessive dose)

All the *Rasadravya*'s mentioned in the classical texts are described with their individual therapeutic doses. Therapeutically it indicates the proper dose of the drug best suited for the patient. From pharmacological point of view during preparation of the medicines, if the raw drugs are not taken in the proper quantity then

desired action on body may not be obtained or the formulation may show unwanted actions.<sup>7</sup> Intake of drug in *Alpamatra* (lesser dose), or *Atimatra* (over dose) can lead to toxic or untoward effects on patients.

**b) Time (Appropriate/Inappropriate)**

Here time refers to the period (*kaala*) of administration of medicine (*Sevana Kaala*)<sup>8</sup> or duration of medication (*sevanaavadhi*). If the prepared medicine is not taken at proper time and at proper intervals as mentioned in the texts, then complications or inadequate action of the drugs may be noticed.

**c) Mode/Vehicle (*Anupana*) for drug administration**

(Appropriate/Inappropriate)

Each of the *rasaushadhi*'s mentioned in the classical texts is advised to be administered with specified *Anupana* or vehicle which helps in proper assimilation and absorption of the medicine<sup>9, 10</sup>. It also helps in controlling the untoward effects of the prescribed drug.

**d) Diet and Routine management (*Pathya/Apathya*)**

Each time a patient goes to a physician he/she is advised with some changes to be made while taking the medication. These are related to diet and life style and must be followed during or after the treatment. Unwholesome (*Ahitatama*) drugs are not suitable for therapeutic purpose, and administration of such drugs may induce the failure of treatment which in turn leads to unintended drug event.<sup>11, 12</sup>

**e) Shelf life (*Saviryata avadhi*)**

It is believed that most of the *Rasaushadhadravya* has infinite shelf life<sup>13</sup>, but it cannot be applied to the herbo-mineral formulations where the minerals are processed along with herbal drugs. There are various factors which may alter their efficacy. There is a chance of contamination by external environment, moister & temperature can affect the quality and efficacy of

finished product unless it is properly packed. Modern norms and guidelines related to drug manufacturing have made it mandatory to specify the manufacturing and expiry date of a product. Hence before administration the shelf life or expiry of the formulation must be noted. Consumption of an expired medicine may harm the patient.

**f) Processing**

Processing means '*Sanskara*'. It is a process of incorporating desired properties and removal of unwanted or toxic part of a drug<sup>14</sup>. The minerals as compared to animal and plant products were not compatible with human body constitution. They could not be consumed in their natural form. The belief that intensive and elaborate processing is required to make them fit for therapeutic utilization lead to the evolution of sophisticated processing procedures. A distinct principle of producing a drug, compatible with human body, is observed in the processing of mineral substances. The mineral or metallic material is treated with plant or animal substances, compatible with the body. In certain cases substances non-compatible with the human body such as minerals like orpiment (*Hartaal*), Realgar (*Manahshila*) are also used in processing. However in such cases the ultimate object of the processing is to produce an assimilable product for the human body, without producing harm in therapeutically effective dose.

**g) Parameters for Testing**

The processed or prepared *bhasma* samples must be tested on the basis of specified parameters given in classical texts as well as by the modern analytical techniques to ensure that their safety and efficacy.

**Analysis using parameters described in Ayurveda texts-<sup>15,16</sup>**

Physical parameters- Varitar, Unnama, Rekhapoonatva, Shlakshnatvam.

Chemical parameters- Varna, Gatarasatvam, Nishchandravta, Apoonarbhavatva.

- *Nischandravta*: The *bhasma* is taken in a Petri dish and observed for any lusture in daylight through magnifying glass. No luster was observed in the *bhasma*.
- *Rekhapurnatvam*: A pinch of *bhasma* is taken in between the thumb and index finger and rubbed. It is observed that the *bhasma* entered into the lines of the finger, and is not easily washed out from the cleavage of the lines.
- *Varitaratavam*: A small amount of the prepared *bhasma* is sprinkled over the still water in a beaker. It is found that the *bhasma* particles floated over the surface of the water.
- *Nisvadutvam*: The prepared *bhasma* is found to be tasteless when a small amount is kept on the tongue.
- *Amlapariksha*: A pinch of prepared *bhasma* is mixed with a little amount of *dadhi* (curds) in a clean and dry Petri dish and observed for any colour change. No colour change of *dadhi* is observed. The same procedure is followed with lemon juice taken in a test tube, and the same result is observed.
- *Avami*: Ingestion of 5-10 mg of the *bhasma* should not produce any nausea/ vomiting.

#### Analysis using modern parameters:

The *bhasma* as well as the starting material must also be analysed using the following techniques:

- X-ray diffraction (XRD)- qualitative.
- Scanning electron microscopy (qualitative)
- Analysis by advanced analytical techniques like particle size distribution (PSD) analysis, scanning electron microscopy (SEM), and inductive coupled plasma spectrometry (ICP).

#### h) Identification

Selection of wrong drug in manufacturing of *rasadravyas* can be

harmful for the patients. Before the manufacturing of any formulation either herbal or mineral, the proper identification of each drug or mineral is necessary to ensure the safety and authenticity of prepared medicine. Most of the classical ayurvedic texts have mentioned specific identification or morphological characteristics of unprocessed as well as processed drugs/formulations. Each of the metallic *bhasma*'s used in various formulations has individual colour and texture which can be helpful in their proper identification.<sup>17</sup>

#### i) Authentication/Approved variety

There is mention of different varieties of metals and minerals in ayurvedic texts along with the best desired varieties. It is essential to select the desired variety of metals and minerals for making any *rasaushadhi*. If the selected variety of *rasadravya* is different than what is approved by pioneers in texts then the prepared medicine will be of substandard or poor quality and it might be harmful for the patient.<sup>18</sup>

#### j) Concept of *Prakriti* (Constitution)

In Ayurveda the concept of *doshajaprakriti* or constitution of one's body is explained. It is very important to diagnose the specific body makeup or *Prakriti* of each patient before prescribing medication. The *Vataja*, *pittaja*, *kaphaja*, *dwandaja* or *tridoshajaprakriti* types<sup>19</sup> corresponds to specific qualities or *guna*'s. The prescribed drugs having same *guna*s the *doshajaprakriti* of the patient may cause aggravation of symptoms, and those having opposite *guna* can suppress them. Hence the physician must be aware of the *prakriti* of the patient and then prescribe the medication accordingly.

#### k) Over the counter (OTC) use of Medicines

Most of the time patients prefer to purchase drugs from the medical stores, without concerning the physicians, which might be dangerous as they are

unaware of the proper dose, mode of drug administration and precautions to be taken during medication.<sup>20</sup>

### l) **Lack of proper Knowledge**

The proper knowledge and skill (*Yukti*) about the drug administration<sup>21</sup> is a must for all the practitioners as well as pharmacists. If anyone of these don't know what to prescribe and how to prescribe, what precautions to be taken etc. then the patients are definitely going to suffer. The patient also must be fully aware of the precautions and instructions advised during the course of treatment must obey them. One can be spared by God *Indra's* thunderbolt (*vajra*) but medicine prescribed by an ignorant physician, will not spare the patient.<sup>22</sup>

### 2.5 Recommended precautions:

Ayurveda emphasizes on safe treatment hence, to prevent the drug-induced illness many restrictions have been suggested which include, GCP (Good Clinical Practices) concern on administration, prescription of expired medicines, knowledge of inappropriate drug, examination of patient and disease before prescription. The quality concerns are controlled by formulary guidelines called AFI (Ayurvedic formulary of India) developed by dept of AYUSH (Ayurveda, Unani, Siddha) and CCRAS (Central council for Research in Ayurveda and Siddha).

- a) Metallic preparations can be harmful and toxic if they are not prepared properly. It is necessary to ensure that all the mandatory GMP guidelines were followed by the manufacturers.<sup>23</sup>
- b) Manufacturing procedures are to be supervised by a qualified *Rasavaidya*/production managers at each and every stage.
- c) Identifying the source of raw material supplier and analysing the source material for its purity, biological activity/Biological assay e.g. Detection of adulterants / substitutes etc.
- d) Ayurvedic medicines should not be allowed to be sold as herbal medicines

or supplements and should not be available at grocery stores.

- e) People should consume these herbo-mineral-metallic preparations strictly only under medical supervision with appropriate dosage, *anupana* (drug vehicle) and for advised period only.
- f) Patients should also observe and follow the prescribed diet and life-style changes.
- g) Govt. departments like AYUSH (Ayurveda, Unani, Siddha) and FDA (Food and Drug Administration) should try to take research projects for evaluation of toxic effects of metallic formulations.
- h) The formula or the true list of all the ingredients contained in the drugs should be displayed on the label of every container and also clearly mention the presence of heavy metals and declare their quantity.
- i) Research work regarding short term and long term toxicities of these medicines should be supported and published according to global standards.
- j) With the introduction of Pharmacovigilance by WHO, the proper report and record of ADRs (adverse drug reaction) should be done. As it plays an important role in optimizing drug safety and improving treatment outcomes.

### DISCUSSION:

A drug can be panacea or poison. A drug fulfilling the criterion of a standard drug will always become Panacea provided, if it is used properly. On the other hand, a poorly prepared or manufactured drug however used skilfully will always prove to be a poison. These quality concerns are controlled by following the formulary guidelines called AFI (Ayurvedic formulary of India) developed by dept of AYUSH (Ayurveda, Unani, Siddha) and CCRAS (Central council for Research in Ayurveda and Siddha). Also all the *Rasaushadhadravaya's* are not recommended for all the patients. The indications, dose, vehicle, period of drug administration, interval or duration of

treatment, disease diagnosed, nature or *Prakruti* of patient, *pathyaapathya* etc. are major factors which should always be considered by the physician before they recommend these *Rasaushadhadravaya*'s to the patients. In the words of *Acharya Charaka*- A drug not perfectly understood is like poison (fatal), weapon, fire & thunderbolt, whereas a perfectly understood drug is life saver like ambrosia. A drug whose name, form and properties are not known, and when known, if improperly used can produce disaster.<sup>24</sup>

### CONCLUSION:

The risk related to toxic effects of *Rasaushadhi* can be considerably reduced by use by following Good Collection Process (GCP), Good Manufacturing Process (GMP) and Good Laboratory Practice (GLP) for quality control and quality assurance for good quality processed medications and following various guidelines mentioned in *Ayurveda* classics related to administration of drugs. By understanding the principles of drug safety mentioned in *Ayurveda* we can overcome such risks. We can see that *Ayurveda* has very elaborate explanation about the toxic effects and ways to prevent it. A rich textual knowledge is necessary while practicing to minimize the occurrence of such effects. There is also a need for extensive research to be carried so as to understand the reasoning and concept behind the classical principles related to drug administration and safety.

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