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Review Article

EVOLUTION OF AUTHENTIC *RASAUSHADHIS* TOWARD PHARMACEUTICAL REQUIREMENTS

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ABSTRACT

The preparation of rasaushadhis represents one of the great challenges in preserving authentic Ayurvedic knowledge. If society wants to heal difficult diseases, the wisdom in pharmaceutic processes of ancient chemistry developed by the 8th century CE must be better appreciated and brought into the modern pharmacy age. With the increasing demand for Ayurvedic products globally, production of medicines by an array of manufacturers has posed challenges due to resistance by smaller commercial units to adapt to GMP guidelines for mass production. In addition, authentic formulations made with standards genuine to Ayurvedic science are often not acceptable to current international modern pharmaceutical standards in the global community. GMP standards attempt to establish uniformity, quality and standards of Ayurvedic products using strict guidelines, but these guidelines may not preserve genuine Ayurvedic quality and discernment parameters. Authentication of raw material, proper processing, and quality assessment with proper storage and packaging of end products must be evolved to understand ancient tools, techniques and measures. To preserve the integrity of Ayurvedic science, labeling of classical polycomponent rasaushadhi formulas or single bhasmas should include Ayurvedic dosha-dhatu-prabhava theory as well as Ayurvedic clinical indications without adapting to modern medical language. These gaps currently prevent traditional successful chemist-clinicians of Ayurvedic rasa shastra from conveying their science accurately to the modern GMP and policy world.

Keywords: Ayurvedic pharmacy, bhasma, pharmaceutics, rasa shastra, rasaushadhis

INTRODUCTION

The successful preparation of *rasaushadhi*s is one of the boons of Ayurveda, the most ancient continuously-practiced healing system on the planet, developed using Indian philosophy and wisdom at the dawn of civilization and mankind. This knowledge evolved based on experiments and observation utilizing underlying philosophy of *dosha-dhatu-mala*, *panchmahabhuta* (five basic elements) and *tridosha* (*vata*, *pitta* and *kapha*) theory. For thousands of years, knowledge of healing was tested then documented in the *Vedas* then only

systematically propagated during the *Samhita* period as useful medicines for curing a variety of diseases using an algorithm of diet, lifestyle, yoga, and drug. The propagation of *rasaushadhi*s and incorporation into many formulations occurred during the golden period of *rasa shastra*, from the 8th century CE until the 17th century CE, while vast ancient chemistry was further discovered, tested and perfected, and works were written to preserve this wisdom. Ayurveda gained a reputation among all cultures and spread to Persia, Greek, and China, exchanging knowledge and using the science and technology of those times to advance its pharmaceutical processes. New dosage forms were developed using careful experimentation. This golden era ended abruptly with European invasions and the decline of Ayurvedic knowledge occurred due to various bans.

In post-British India, the knowledge of Ayurveda is again diffusing through its people and across the entire globe, through advancements in modern science and technology using fast communication systems. But with this recognition, a demand for Ayurvedic products has increased tremendously. To cope with this global demand, production of medicines has increased by a wide variety of manufacturers, some of whom have yet to adapt to proper guidelines for mass production. Authentic formulations must be made with standards that are both genuine to *Ayurvedic* science and also acceptable to international modern pharmaceutical standards in the global community. The Ministry of Health of India has introduced GMP standards to establish uniformity, quality and standards of Ayurvedic products using strict guidelines. Authentication of raw material, proper processing, and quality assessment with proper storage, packaging and labeling of end products have been considered with tools, techniques and measures. However, genuine Ayurvedic quality and discernment parameters have often been neglected or dismissed. This gap currently prevents traditional successful chemist-clinicians of Ayurvedic *rasa shastra* from conveying their science to the modern GMP and policy world.

Evolution of Ancient Parameters to Modern Standards

Several processes of Ayurvedic pharmaceutics have evolved regularly over a thousand years (1). Others have remained constant. The challenge of the *rasa-vaidya* is to know which parameters of medicine-making can be altered and which must remain as told in the oldest *rasa* literature. The needs of each era have determined which areas of pharmaceutics have been tested and evolved.

Overall, the processes of *shodhana* and *marana* have remained much as they were in ancient times (2). Small variations have included number and type of *puta* used to create the heat required for chemical separation, *dravyas* used for *bhavana* or *mardana* to incorporate essences of required dosha or dhatu-balancing effect, and *dravyas* used as subordinate materials for auxiliary processes. No major changes were tolerated as clinical effectiveness was dissipated with such departures. The manual process of *samskara*, *jarana*, and *marana* today also remains very close to classical instructions in the *rasa* literature from the 8th century CE (3). The use of *shodhita parada* is also mandatory for many processes and not to be substituted.

Adaptation of Ancient Parameters to Modern Standards

Areas of *rasa shastra* that have responded to change in the modern chemistry era include: a) working style, force, stamina, and continuity of labor required to make authentic *bhasma*s; b) quantitative instrumentation; c) scale of production; and d) storage of medicines during and after preparation.

The current crisis in *rasa* drug manufacturing involves satisfying the global demand for safe and effective medicines, with production of quality medicine on three levels: materials

(starting and auxiliary); processing (includes method, technique and devices) and the final product (assessment of products and their presentation).

Materials

The classical *Ayurvedic* literature gives many descriptions on identification and procurement of proper materials, using organoleptic features as well as Ayurvedic energetic parameters to identify plants and minerals/metals for making of *rasaushadhi*. However, with most people today less connected to their local flora and fauna, less experts are proficient at proper identification.

Finding raw materials for the process of making *bhasma* has changed. Whereas previous efforts emphasized the origin of a metal or plant, and care was taken to mark the place from which it came, modern identification does not usually cite exact origin of growth, though botanists, soil scientists, and agriculture expert all acknowledge variations that occur in different types of locations. Modern procurement utilizes labor intermediate to the preparer of the medicine and the prescriber. These intermediates are often wholesalers and traders whose main goal is profit, not clinical accuracy. For the most part, metals are no longer procured from native form in Nature. *Nepalika* vs. *Mleccha* copper is no longer utilized, in favor of using 99.9% pure copper pipe or sheet as the starting material for making *tamrabhasma*. It is nearly impossible today to distinguish the origin of a copper pipe, as import/export, and manufacturing have not maintained the parameters kept by ancient chemists.

The identification of minerals containing specific metals has also changed. Instead of sourcing directly from Nature and hunting in mines, where the ecosystem can be identified, minerals are now often procured from wholesalers. The identification of minerals and the metals that can be extracted from them, known as *satvapatana*, was highly precise earlier, using location of origin, flame colour and consistency to identify compounds such as *hingula* (containing *parada*) and *tuttha* (containing *tamra*).

The collection and authentication and storage of raw plant materials are now changed as well, with pickers and gatherers who are not well-versed in classical guidelines for identification. Rituals for timing of collections are also not maintained for many plants. Those going to the wild to procure plants are often not versed which part of the plant is to be picked at what time of day, which season, and from which direction. In addition, flora and fauna are changing as the wild forests continue to disappear and natural environments change. Cultivated plants in farms far from natural habitats are common for many medicinal plants.

The identification of plant materials is no longer assured due to the separation of knowledge. Even advanced methods of fingerprinting cannot identify the ecosystem from which a plant was taken, when, where and how it was picked. These parameters emphasized in the *shastras* are largely ignored today.

Material availability has also become a challenge for some animal, plant, and mineral sources. Some *rasaushadhis* require either items that are endangered species on the CITES list (4), such as jatamansi, kutki, and kushtha;or parts of animals such as deer horn or ivory, that are banned from collection. Therefore, the method of collection of those materials is often dubious. With growing challenges in environmental pollution, deforestation, and loss of biodiversity, some raw materials are facing extinction.

Authentication of raw material used for production of *rasaushadhi* also includes concerns for materials utilized during various steps of *bhavana* and *mardana*, called secondary and allied materials.

Processing

Proper processing of *rasaushadh i*s requires attention to method, technique, and devices. The major end products of *rasa-shastra*are still in use today.To achieve them, the important processes are proper*shodhana*, *marana*, *samskara*, *jarana*, *murchchhana*. Among all products,*bhasma* is considered the most important and essential constituent for the various other preparations. Hence *Shodhana* and *Marana* are very important processes for making other *rasaudhadhi*. *Shodhana* is a multi-step mandatory process for all materials and all purposes.

Materials used for utensils

Processing involves various utensils, equipments and heating devisees. According to needs of method and techniques these are altered time to time. Conventional utensils and heating devices have changed in the past century. In the place of earthen, copper, wooden, or iron vessels, which were the norm in procedures of ancient times, stainless steel and plastic are more frequently used today. Stainless steel is considered an inert, highly tolerant substance to heat and stress and has replaced many pots, utensils, oven frames, and sieves. It is the base also for most machinery. Plastic is less breakable, easy for transport, and usually cheaper. A comparative study detecting differences in quality of *bhasma* using new materials seems to indicate that stainless steel is a suitable replacement. Calibration and comparison of tools and devices such as mortar/pestle, spatulas, pulverizer and disintegrator are also required. However, any presence of alloys in these instruments that might be transferred to the *bhasma* must be evaluated.

The Tincture of Time

In previous times, the making of a *bhasma* had rituals involving the necessary manpower and setting so that uninterrupted work could continue through the phases of *shodhana* and *marana*. “Three days” was interpreted as 24 hours for three days continuously. In recent times, with manual labor conforming to modern schedules, three days now has changed to 8 hours of daylight daily for “three days.” Comparative studies to detect differences in quality of *bhasma* with a 16-hour gap of time seem to indicate no significant decrease in quality, though during this time heat, oxidation, humidity and the environment may affect the sample.

The Importance of Energy Waves

Mantras were an important part of *bhasma*-making, utilizing the proper mantra before starting phases of preparation. Preparations were also started or not done on certain days of the lunar calendar. Many believe that the energy from sound, *prana* or the effects of the moon can influence *bhasma*. The effect of such forces is not yet part of the language of pharmaceutical standards. Today, therefore, the Ayurvedic adaptation for modern labs is to have a recorded sound box emitting *mantras* into the room while the *bhasma* is being prepared, though traditionists still demand a live voice and active *drshti* or eyesight to watch the process.

Mechanization

The process of mechanization is one of the most significant advances in the past century. The need for continuous, homogenous and uninterrupted work in a *khalvayantra*, using manual laborhas been met by the introduction of machines that move the pestle in a *khalvayantra* with regularity of speed, pressure and time. It allows the trituration process – whether *bhavana*, *mardana*, *marana*, or *jarana* – to be completed in less time with less effort with reliable and measurable parameters.

Heating Devices and Fuel

Putas come in many shapes and sizes and were developed to accommodate different needs for arrival to a desired peak temperature, time of plateau at peak temperature, and time for cooling via heat diffusion back to atmospheric temperature (self-cooling time). They were

prescribed for specific metals and specific *bhasma* preparations, either underground or aboveground, to accommodate different amounts and types of fuel, from *cow*-dung to sand.

The process of shifting to furnaces is arguably the most significant advance in *rasashastra* in the past century. Electricity brought the advent of the muffle oven furnace, especially the advanced models in which heat can be directly modulated and monitored with high-temperature pyrometer. In addition, modern concerns about air pollution have created laws banning the burning of cow dung in open air, which is required for *puta* technology.

The ancient time heat generator used brick or sand for insulation and cow dung for fuel. In current times, LPG gas or electricity is used. Comparative studies to detect difference in quality of *bhasma* using different fuels seems to indicate that electric heat does not differ significantly from the heat produced by cow dung.

Calibration of Instruments

The earliest measurements were likely based on less quantitative observation. Stages of *sodhana*, *jarana*, *marana*, *kupipakwa* were monitored based on flame color, smell, and approximate time. Specific shapes of *kharalyantras* and their composition were precise. Analytical assessments occurred for parameters of the outer world such as season and lunar stage as well as steps of the process and outcomes. Now, measurements have become highly quantitative as the basis for standardization and uniformity of process. Analysis standards and procedures document temperature and time at peak temperature detailing types of furnaces, heat recorders, and settings of thermocouples and pyrometers, but do not document the surrounding environment and outer world.

Conveying Steps of *Bhasmikarana*

Materials from plant, animal or mineral sources are compiled and subjected to many levels of processing. Through the process of bhasmikarana, properties of the main component material are under covered from their dormant, suppressed or hidden state and are enhanced. Certain new properties are induced into the metal or mineral by the use of plants which are ground into the material, separating chunks of raw material and increasing surface area so that enzymes and heat can act upon them with each serial cycle of blending-heating-cooling-grinding. Processing involves contact with water, fire, sun, vessels, pounding, heating and deeping, filtering, fumigating, distillation, sublimation, *samskara – swedana*, *mardana*, *jarana*, *marana*, *murchchhana*, place, time duration, addition and separation, on multi-fold levels, specific to the materials and the end product.

Productsare assessed and presented very differently today than a century ago. First and foremost, until a few decades ago medicines were prepared by those who would dispense them directly in clinical treatment to a patient. Without this intimate connection of the medicine passing directly between healer and patient, the integrity of using a properly-prepared medicine for its intended purpose could easily be diluted.

***Bhasma* Authentication via Organoleptic Observation:**

The tests of *bhasma* (*bhasmapariksha*) involve basic principles of both chemistry and physics and emphasize the importance of organoleptics and the subtle abilities of the human perception. *Niruttha* identifies the property of pure silver to attract any metal and was used in the 8th century CE. *Rekhapurna* utilized the fine spaces of the friction ridge skin known commonly as friction ridges, furrows and sulci to measure fineness of particle size, which have been measured to be approximately 300µm-400µm (5); these furrows have only been analyzed in detail in modern science in the past 50 years but were understood by *rasa vaidya*s to be minute. *Apunarbhava* recognized that reheating of a properly-made *bhasma* to high temperature does not

convert it back to metal (6). *Bhasmas* float on still water (*varitara*) and can have a grain of rice placed atop that fine layer of *bhasma* (*unnama*). While these measures are not quantitative, they are relative and comparative and they serve as true standards that have stood the test of location and time in identifying the minute and chemical nature of bhasmas.

Analysis of intermediate and end-products to elucidate the effect of each step process and the quality of end product is done today in comparison to the use of classical organoleptic methods. Authentication is now validated using modern technology developed by modern physics and chemistry. To detect particle size, advanced scanning electron microscopy (SEM) and transmission electron microscopy (TEM) show particles at up to the current optimal limit of 10,000x magnification, taking particles from the naked visible limit of approximately400µm (=400,000nm) down to 40nm using diffraction technology.

To detect morphology, advanced computer-aided analysis is available for particle size in microscopes that utilize software to analyze particle diameter, linear absorption coefficient that identifies density across the length between two edges, crystal size, crystal-chemical composition, degree of compaction, polydispersity, skewness, kurtosis, and deformability. Many software programs identify 25-30 such parameters. To detect chemical entities, mass spectroscopy detects chemical groups attached to the main compounds that are separated from each other with chromatographic methods using polarity and capillary action.

Physico-chemical analysis

To detect the physical and chemical natures of end product, TLC, HPTLC, SEM, TEM, EDEX, XRD, XRF, AAS, ICP, and FTIR have recently come into use to supplement conventional qualitative and quantitative chemical analysis. These instruments allow better understanding of materials at different levels of observation. Qualitative and quantitative chemical analysis and characterization use sophisticated sensitive tools.

These include TLC, HPTLC, AAS (for the determination of element), FTIR (to elucidate the functional group in organic compounds), XRD (structure of any crystalline substance and its amount present), XRF (to determine the composition of solid material), EDEX, TEM, SEM (to see nanoparticles and typical heterogeneity of size reduction), and PAS for the characterization of raw, intermediary and end product.

The Revolution in Dosage Forms

Over the millenia, over 250 medicinal formswere invented to address the need for different delivery modes, practical issues of seasonal growth, strength of the patient's absorption, dispensing, storage, portability andmass productionconcerns. These dosage forms include materials created as intermediates for preparation of multi-component medicines,ready-to-use raw materials, as well as medicinals ready for consumption for specific diseases. A large number of dosage forms of Ayurveda occur in pancakarma (7) and in pathya kalpana (health food intake).

A revolution occurred in the medicinal community creating a golden period of ancient Indian chemistry from the 8th to 13th century CE, during which a wide number of new dosage forms of rasa medicines evolved to meet the needs of the times. They were effective in small doses, very quick to take action, have long shelf-life, are easy to transport, and penetrate the body independent of considerations of dosha and srotas.

In *rasashastra*, these dosage forms are *shuddha-dravya*, *bhasma*, *pisti*, *kajjali*, *kupipakwa-rasa*, *parpati*, *pottali*, *druti*, *drāva*, and *kharaliya/khalviya ras/rasayana*.Materials in common use that distinguished them from plant-based medicines (kāsttha ausadhi) were *abhraka*, *vaikranta*, *makshika,hingula*, *haritala,manahshila*, *swarna*, *rajata*, *tamra*, *lauha,nag*,

vanga, *vajra*, *manikya*, *mukta*, *pravala*, *shankha*, *varatika*, *vatsanabha*, *kupilu*, *ahiphena*. Different sources of these materials were used for the preparation of *rasaushadhi*. They were classified based on their affiliation with the liquid metal mercury into groups known as*maharasa*, *uparasa*, *sadharanarasa*, *loha*, *ratna*, *shudha*, and *visha-upavisha*. Today their manufacture is regulated by GMP rules that focus heavily on toxic emissions during processing and rudimentary labelling (8).

The making of medicines has evolved over time as society's needs have altered. The millenia-old *Ayurvedic* pharmaceutical process standardized medicine-making based on variables found in Nature. Ancient dosage forms maintained precision in making of compounds byobserving time cycles of treatment, contact with water, air, and fire for a set quantity, frequency and duration. These old algorithms still provide replicable and testable outcomes that align with Nature's consistent properties. Traditional *Ayurveda* processes during each formulation account for each material and each property. A wide variety of dosage forms specific to particular patient needs evolved with the main purpose of allowing the safe entry of metals and minerals into the minutest reaches of the body, with the theory that the body would be as strong and as resilient as the metal that was imbedded. The most sophisticated multi-formulations, *kharaliya rasayana*, were designed to contain several different *bhasma*s combined with multiple plant-based formulations. The processing of mercury evolved very specifically as an essential element of mineral processing and must be understood more deeply today to appreciate its value. Modern science has yet to evolve to validate the basis for safety and efficacy claims of *Rasa-shastra*. In terms of modern chemistry, most *bhasmas* have been found to be sulfides, sulfates, oxides or chlorides. The source of heat energy, its amount and intensity has been studied and has evolved to successful use of mechanization.

Materials Used in Transport and Storage

Any material that makes contact with the medicine during production or storage can potentially affect its composition. These can be foreign materials/contaminants, or they can be materials lining or composing the utensils, tubing, vessels, or transfer materials used during production, transport or storage. Commonly used components of vessels were pure copper for its anti-bacterial effects, brass for its durability, iron for its resistance and hardness, earthenware for its breathability, natural coolness and smell, and later, glass, wood and ceramic for storage. In the past century, plastic and stainless steel vessels, bottles and fibers have begun to dominate, as they are practical, cheap, durable and travel well. Some concerns exist about their inertness, but detailed studies are few and often not applicable to real scenarios.

Package labeling forIEC

Each country or state has its own laws regarding information, education and communication (IEC) of all medicines that enter the commerce sector. Packaging of Ayurveda medicines today often mimics mainstream pharmaceutical packaging and labeling to capture market attention. In addition, packaging regulations are usually outlined by advisors who think in the language of biochemistry, pharmacy or medicinal chemistry but have no training, clinical experience or analysis of *bhaisajya kalpana*, *rasa shastra*, *dravya guna*. Indeed, a vast majority of health laws for Ayurvedic medicines are copy-pasted from similar laws applying to allopathic medicine and done by people who neither practice nor advocate Ayurvedic theory. Ayurvedic medicines, while legally permitted throughout India, also withstand the ignorance and negative attention from the mainstream medical system.

Together, the package box, container label, and package insert provide information on ingredients and their quantity, route for administering the medicine into the body, dosage form,

therapeutic indications, dose, contraindications, side effects, shelf life, storage conditions, and the manufacturers name with contact details (9).

For an ayurvedic medicine-maker, the processing ingredients and tools are as important as the final ingredients. For example, the use of alcohol or parada that are evaporated during the processes of shodhana, marana, or arka distillation are important to know, even if they are not contained in the final product, because they alter the dosha of the final medicine. Auxiliary plants used in bhavana or mardana are important for the medicine maker, as well as the skilled clinician, who will consider their dosha and prabhava effects in the final medicine.

To propagate Ayurveda more authentically, labeling should be altered to include detailed parameters of time, origin of materials, and locations of preparation, not only the current references to classic texts that provide ciphered recipes which are often interpreted differently. Each lineage or manufacturer uses slightly different utensils, time factors, sources of botanicals that serve as unaccounted parameters, creating variability in the preparation of the same medicine from two companies.

Most crucial for the propagation of authentic Ayurveda, the medical indication on Ayurvedic medicines should not simply refer to a classic reference, or indicate treatment for a condition described in biomedical language. In truth, authentic Ayurveda remedies were not created for diseases named by modern biomedicine. The remedies were named, tested and maintained over millenia due to their effects on *dhatus, doshas, srotamsi*, and emphasizing the *guna*s that were altered by the use of the plant. Labeling that addresses the doshic changes or effects on agni anticipated by a formulation is a more authentic way of conveying the indication and proper use of any formulation.

For example, classical formulations used for prameha or madhumeha that are taken from ancient Ayurveda texts should not indicate effects on blood sugar or diabetes, as these were not the classical indications. Labels should state the Ayurvedic name of the clinical indication. The label should also indicate correctly whether the medicine is *pittahara, pittavardhaka, vatahara, vatavardhaka, kaphahara, kaphavardhaka, tridoshahara, deepana,* or *pachana*. Adjectives may be used according to the categories or families of effects that are outlined in the classical texts. *Prabhava* of a formulation should be noted.

If the formulations is patented or proprietary, developed using knowledge of a plant's action according to Ayurveda, then combined using biochemical or biomedical theory, and tested using modern medical parameters, then the label should indicate on the list of ingredients which plants have which Ayurvedic effects. The label should then indicate the clinical indication as tested. Examples include diabetic formulations that include ingredients such as *methika, karela, neem beej, babbul phal, trivanga bhasma, shilajit, yashada bhasma,* which are all known to lessen *prameha* and have also been shown to lower blood sugar. A proprietary formulation of such ingredients, as regulated by the DCA, section 3h (10), should include the pittahara effects of such tikta-kashaya (bitter-astringent) ingredients, and the net effect of working on prameha on the label, then state that testing indicates it is useful for lowering blood sugar. In this way, labeling will better reflect the interface of Ayurvedic medicines in the modern drug world, especially if they contain *rasa-aushadhi*s.

Conclusion

In modern times, most of the *rasaudhadi* production has been curtailed. Only a handful of companies now produce *rasaushadhi*s and many do not use the traditional processes, thereby raising doubts about their safety and clinical efficacy. The few manufacturers that do make

*bhasma*s and *pisti*s must limit their variety of *kharaliyarasayana* and other *rasausadhi* due to expense of time and opportunity cost.

Today, safety and toxicity issues involving heavy metals have raised growing health concerns in society. One key problems of today's scientific society, unlike ancient *Ayurvedic* scholar-scientists, is that physical scientists specializing in chemistry, physics and material science-based technology are usually not clinicians, botanists, biologists, or experts working daily witnessing living systems based in Nature. This presents the problem of misunderstanding languages of different sciences and an inability to translate across geology, soil science, botany, pharmacy to clinical pharmacology and medicine. Thus, there is an unchallenged belief that heavy metals and all their products are injurious to the vital organs. Better communication and education of Ayurvedic properties and the language by which *rasaushadhi*s are made will help researchers and clinicians to understand Ayurvedic medical concepts and propagate the preservation of Ayurvedic science.

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