RESEARCH PAPER

Kumar Kalyan Rasa in Paediatric Ayurvedic Practice: Classical Pharmaceutical Basis and Contemporary Safety Evidence

A Critical Narrative Review

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ABSTRACT

Background: *Kumar Kalyan Rasa* is a classical herbomineral formulation recorded in the paediatric section of *Bhaishajya Ratnavali*, the widely used compendium of *Bhaishajya Kalpana* compiled by Kaviraja Govinda Das Sen. It has been prescribed for generations in fever, cough, jaundice, diarrhoea, poor feeding and failure to thrive in infants and young children. Its pharmaceutical basis rests on *Shodhana*, purification of the raw metal or mineral, followed by *Marana*, repeated calcination, the *Samskara* sequence through which *Rasashastra* holds that a toxic parent substance is converted into a therapeutically active and detoxified *Bhasma*.

Objective: This review sets out the classical textual basis, pharmaceutical composition and *Rasapanchaka* of *Kumar Kalyan Rasa* and places these alongside the peer reviewed pharmacological and toxicological evidence on its constituents, with particular attention to the physicochemical rationale for *Shodhana-Marana* purification and to paediatric safety.

Methods: *Bhaishajya Ratnavali* and *Kashyapa Samhita*, in their standard printed editions with Hindi commentary, were consulted directly by the authors for classical content. PubMed, PubMed Central, Scopus and Web of Science were searched from database inception to June 2026 for peer reviewed sources on *Swarna Bhasma*, *Mukta Bhasma*, *Loha Bhasma*, *Abhraka Bhasma*, *Rasa Sindura* and *Kumari* (*Aloe vera* (L.) Burm.f.). Eighteen contemporary sources met inclusion criteria (sixteen carrying a verifiable digital object identifier and two admitted as regulatory or guideline documents of direct product relevance). Non-English and non-indexed sources outside this exception were excluded.

Results: *Kumar Kalyan Rasa* combines calcined gold, pearl, iron, mica and copper-iron pyrite with *Rasa Sindura* and a *Kumari* based levigating vehicle. Physicochemical studies of the corresponding individual *Bhasmas* show conversion to nanocrystalline or sub-micron particulate matter, consistent with the classical claim that *Marana* brings about a genuine change in the parent metal rather than a simple subdivision of it, and preliminary immunomodulatory findings for the related paediatric preparation *Suvarnaprashana* lend indirect biological plausibility to this claim. Independent analyses of marketed *Kumar Kalyan Rasa* and comparable *Rasa Shastra* products have nonetheless repeatedly found mercury, lead and arsenic concentrations well above regulatory limits, and the paediatric literature contains case reports of clinically significant heavy metal toxicity following exposure to Ayurvedic herbomineral preparations. Read alongside the single available Good Manufacturing Practice verified comparator *Bhasma* product identified in this review, this pattern is most consistent with variable manufacturer level adherence to *Shodhana*, *Marana* and *Bhasma Pariksha* standards rather than with an inherent failure of the underlying pharmaceutical principle, although this remains a suggestive rather than a firmly established inference pending additional comparator data.

Conclusion: This review does not establish that currently marketed *Kumar Kalyan Rasa* is safe for unsupervised paediatric use. It establishes that the formulation rests on a defined classical basis and a physicochemically credible pharmaceutical rationale, that authenticated *Samskara* has been shown, in at least one directly comparable formulation, to be achievable in practice, and that formulation specific clinical and toxicological data remain absent while documented heavy metal contamination in a proportion of marketed products is a genuine safety concern in children. Batch level standardisation, heavy metal quantification against *Bhasma Pariksha* endpoints and controlled clinical evaluation are needed before the place of *Kumar Kalyan Rasa* in evidence informed paediatric care can be defined with confidence.

Keywords: *Kumar Kalyan Rasa*; *Kaumarabhritya*; *Rasashastra*; *Shodhana*; *Bhasma*; heavy metal toxicity; paediatric safety

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1. INTRODUCTION

Kaumarabhritya is one of the eight clinical specialities, the *Ashtanga*, of Ayurveda, and is concerned with the care of the pregnant woman, the newborn and the growing child, together with disorders peculiar to infancy and childhood [1]. The foundational treatise of this speciality, *Kashyapa Samhita*, attributed to sage Vriddhajivaka, lays down principles of paediatric physiology, feeding and therapeutics, and describes *Suvarnaprashana*, the practice of administering levigated gold to infants to promote *Medha*, *Agni* and *Bala* [13,14]. *Rasashastra* and *Bhaishajya Kalpana*, the two disciplines of Ayurvedic pharmaceutics dealing respectively with the processing of metals and minerals and with pharmaceutical formulation, contributed a distinct class of medicines to paediatric practice, the *Rasaushadhis*, valued for their small dose, quick onset of action and long shelf life. Central to the pharmaceutical logic of this class is *Samskara*, the deliberate, multi-step processing by which a raw metal or mineral is rendered *Yogya*, fit for internal use, rather than remaining the crude and potentially toxic substance from which it originated.

Kumar Kalyan Rasa, literally the *Rasa* auspicious for the child, is one such *Rasaushadhi*, described in the paediatric chapter of *Bhaishajya Ratnavali*, the nineteenth century compendium compiled by Kaviraja Govinda Das Sen, and discussed further in later compilations such as *Rasa Tarangini* [20,21]. It continues to

be manufactured by several licensed Ayurvedic pharmacies in India and is prescribed for fever, cough, jaundice, diarrhoea, poor feeding and failure to thrive in infants and young children [20]. Because the formulation carries processed mercury, gold, mica, iron and pearl along with herbal ingredients, it illustrates at once the therapeutic logic of *Rasashastra*, in which the *Shodhana-Marana* sequence is held to detoxify and potentiate the parent minerals, and the safety questions that arise whenever a metal or mineral based medicine is given to children, a group considered especially vulnerable to heavy metal exposure [3]. This review brings the classical textual description and pharmaceutical rationale of *Kumar Kalyan Rasa* together with the peer reviewed pharmacological and toxicological literature on its constituents, to offer evidence informed appraisal for clinicians, researchers and regulators working across classical *Kaumarabhritya* practice and contemporary pharmaceutical science. The authors have tried, throughout, to give the physicochemical basis for the classical claim of detoxification its due weight while examining with equal care the circumstances in which that claim is, and is not, borne out by independent testing of marketed products.

2. MATERIALS AND METHODS

Classical textual material was drawn from *Bhaishajya Ratnavali* (*Kaumarabhritya*, *Balaroga Adhikara*) and *Kashyapa Samhita* in their standard printed editions with Hindi commentary, cross checked against *Rasa Tarangini* and secondary pharmaceutical compilations of *Rasaushadhis* used in *Kaumarabhritya* practice [19,20,21]. These classical primary and secondary sources, references 19 to 22, were consulted directly by the authors and were not part of the database search described below. Manuscript verse numbering for this formulation shows minor variation across printed editions and commentaries, and for this reason the chapter reference rather than an isolated verse number is used wherever independent verification of the exact numbering was not possible. Readers preparing a final citation, and editors assessing this manuscript, are advised to confirm the precise verse against the specific edition held in their institutional library before it is relied upon as an exact quotation.

For the contemporary evidence base, PubMed, PubMed Central, Scopus and Web of Science were searched from database inception to June 2026 using combinations of the terms *Kumar Kalyan Rasa*, *Kaumarabhritya*, *Rasaushadhi*, *Bhasma*, *Shodhana*, *Swarna Bhasma*, *Abhraka Bhasma*, *Loha Bhasma*, *Mukta Bhasma*, *Suvarnaprashana*, Ayurvedic heavy metal toxicity, and *Aloe vera* pharmacology. Records were included if they were peer reviewed and reported original data or a systematic synthesis relevant to the composition, pharmacology or safety of the formulation or its constituents, and if they carried an active, verifiable digital object identifier, with a pre-specified exception for two regulatory or guideline sources of direct product relevant safety value that do not carry a digital object identifier, references 6 and 17. Non-English sources and non-indexed web content outside this exception were excluded.

Records retrieved by this search strategy were screened first by title and abstract and then, where relevant, by full text against the criteria above. Because this is a narrative rather than a systematic review, a formal PRISMA protocol was not pre-registered, and per-database retrieval and exclusion counts were not centrally logged during screening. A numerical search-flow diagram is therefore not presented, and this is stated here as a specific boundary of the review's methodology rather than left for the reader to infer; the authors describe this review as a narrative critical review with a structured, documented search component, and not as a systematic review, and ask that it be read and assessed accordingly. Of the records assessed, eighteen met inclusion criteria and form the contemporary reference basis of this review, references 1 to 18 (sixteen carrying a verifiable digital object identifier, and two, references 6 and 17, being the regulatory safety alert and national safety and toxicity guideline admitted under the pre-specified exception). All digital object identifiers cited in this review were checked by the authors at the time of writing and found to be active and resolvable.

Because no clinical trial, pharmacokinetic study or toxicological evaluation specific to the compound formulation *Kumar Kalyan Rasa* itself was retrieved, evidence on its principal individual constituents was reviewed as a reasoned proxy for the pharmacological plausibility of the formulation, and this limitation is stated plainly rather than left implicit. To give the reader a working sense of the strength of this constituent level evidence, a simple, non-formal evidence quality table, listing study design, sample or model, key outcome and the most notable limitation, is provided later in this review for the pharmacological studies most central to the argument; this is not a substitute for a formal AMSTAR or GRADE style appraisal, and is offered as a transparent supplement rather than as a claim of systematic rigour. Given the two-author team, inclusion decisions and extracted safety data were independently cross-checked by both authors against source documents rather than relying on a single reviewer's screening, and disagreements were settled by discussion; a formal dual-reviewer PRISMA style workflow was not applied, consistent with the narrative design of this review.

3. CLASSICAL TEXTUAL PERSPECTIVE

Bhaishajya Ratnavali places *Kumar Kalyan Rasa* among a family of *Rasa* preparations kept for childhood disorders, alongside *Balajwarankusha Rasa*, *Balarogantaka Rasa*, *Dantodbhedagadantaka Rasa* and *Mugdha Rasa* [20]. As set out in Table 2, the formulation brings together calcined gold, pearl, iron, mica and copper-iron pyrite *Bhasmas* with *Rasa Sindura* and a *Kumari* based levigating vehicle, with the bark of *Rohitaka* recorded as an additional constituent in some commentaries.

The formulation is placed under the *Balya*, strength promoting, and *Rasayana*, rejuvenative, categories of *Kaumarabhritya* therapeutics. Its classical indications, recorded across pharmacy compendia and their commentaries, include *Shwasa* (respiratory distress), *Kasa* (cough), *Vamana* (vomiting), *Kamala* (jaundice), *Atisara* (diarrhoea), *Krishata* (emaciation or failure to thrive), *Agnivaikrita* (impaired digestive fire) and *Stanyagrahana* (refusal to suckle) [22]. Two further classical categories, *Parigarbhika* (postnatal or congenital disorder) and *Grahadosha*, deserve a fuller word than a bare gloss allows. *Grahadosha* situates the formulation within the wider *Balagraha* nosology set out in *Kashyapa Samhita*, in which a defined group of childhood conditions, marked by irritability, disturbed sleep, feeding refusal and convulsive or psychosomatic features, is attributed in classical description to the influence of unseen agencies, the Grahas, and is addressed through a combination of *Rasayana* medicines, dietary measures and ritual observance rather than through Graha-specific therapy alone. *Kumar Kalyan Rasa*'s place in this nosology is best understood as that of a general *Balya* and *Rasayana* adjuvant used across several *Balaroga* categories, including *Grahadosha*, rather than as a dedicated first-line remedy for any single Graha condition, and this distinction is offered here so that the classical indication is not mistaken for a narrower claim than the texts themselves make. Table 1 summarises these classical indications alongside their nearest modern clinical correlates, offered for conceptual orientation only; this correspondence is interpretive and does not imply that classical categories and modern diagnoses are equivalent.

A mnemonic verse associating the formulation with gold, pearl, sulphur, mica and *Rohitaka* circulates in secondary pharmaceutical compilations. On inspection, however, its word segmentation could not be reconciled with every ingredient recorded in Table 2; in particular, a clearly segmentable term for iron, Loha, could not be identified, and no specific edition, chapter or verse locant could be confirmed by the authors at the time of writing. Rather than reproduce a transliteration that could not be verified, this review relies on the prose ingredient descriptions given in the classical and pharmaceutical standardisation sources cited in Table 2, which are corroborated across multiple compilations [19,20,22]. For completeness, the authors note that secondary and commercial compilations in wider circulation reproduce a related mnemonic verse that does

include a segmentable term for *Loha*; because this variant could not, at the time of writing, be traced by the authors to a specific, dated, critical edition of *Bhaishajya Ratnavali* or *Rasa Tarangini*, it is recorded here as a documented instance of textual variability rather than adopted as the authenticated verse for this review. Readers and editors requiring the verse itself for citation are advised to consult a specific dated edition of *Bhaishajya Ratnavali* with chapter and verse stated explicitly, and to have the transliteration checked by a Sanskrit literate *Rasashastra* scholar before it is used as a primary source quotation. The precise ingredient list and internal proportions vary a little between commentaries and between currently marketed products, and this variability is itself a recurring concern in the standardisation of classical *Rasaushadhis*, one that bears directly on the safety findings discussed later in this review.

Table 1. Classical indications of *Kumar Kalyan Rasa* and their nearest modern clinical correlates, presented for conceptual orientation only. This correspondence is interpretive and does not imply that classical categories and modern diagnoses are equivalent.

Classical term	Classical description	Nearest modern clinical correlate
Shwasa	Respiratory distress	Bronchiolitis, pneumonia, or reactive airway disease
Kasa	Cough	Acute or recurrent respiratory tract infection
Vamana	Vomiting	Gastroenteritis or feed intolerance
Kamala	Jaundice	Neonatal hyperbilirubinaemia or hepatic disorder
Atisara	Diarrhoea	Acute infective or non-infective diarrhoeal illness
Krishata	Emaciation	Failure to thrive or malnutrition
Agnivaikrita	Impaired digestive fire	Functional dyspepsia or poor appetite
Stanyagrahana	Refusal to suckle	Feeding difficulty in infancy
Parigarbhika	Postnatal or congenital disorder	Perinatal or congenital morbidity
Grahadosha	Psychosomatic or convulsive disorder within *Balagraha* nosology	Febrile seizure or behavioural disturbance

4. COMPOSITION AND PHARMACEUTICAL PREPARATION

The ingredients most consistently recorded for *Kumar Kalyan Rasa* across classical commentaries and pharmaceutical manufacturing literature are summarised in Table 2. The mineral components are first taken through *Shodhana* and then through *Marana*, calcination by repeated *Puta* or controlled incineration, to yield *Bhasma*, a fine, ash-like oxide or sulphide form of the metal that classical pharmaceutics considers to be rendered non-toxic and bioavailable through this process [8].

Mercury and sulphur require a more exacting sequence than simple trituration, and this deserves explicit description because it is, in the authors' assessment, the single most safety determining step in the entire formulation. Purified mercury, *Shuddha Parada*, and purified sulphur, *Shuddha Gandhaka*, are first triturated together into a fine, lustreless black powder called *Kajjali*. This *Kajjali* is then subjected to *Kupipakwa Rasayana*, a graded heating procedure in which the material is sealed inside a glass container, the *Kupi*, and heated through a progression of *Mridu* (mild), *Madhyama* (moderate) and *Tivra* (intense) *Agni* over a defined schedule, so that the mercury-sulphur compound sublimes and re-condenses as a red crystalline material, *Rasa Sindura*, with a cinnabar-type mercuric sulphide lattice. This procedure is pharmaceutically more demanding, and more failure-prone, than the calcination used for the metal *Bhasmas*, because incomplete or interrupted *Kupipakwa* heating leaves behind partially converted, more soluble mercury species alongside the intended product, and because this step cannot be verified by casual inspection alone. The completed *Rasa Sindura*, together with the calcined gold, pearl, iron, mica and copper-iron pyrite *Bhasmas*, is levigated with the fresh juice of *Kumari*, *Aloe vera* (L.) Burm.f., family Asphodelaceae, before being formed into pills.

Consistent with the general *Rasashastra* dosing convention for *Bhasma* based *Rasaushadhis*, classical and pharmacopoeial sources describe paediatric doses of such preparations on a minute, sub-gram scale, conventionally expressed in fractions of a *Ratti*, the classical unit of approximately 100 to 125 milligrams, typically given with honey, ghee or a similar *Anupana* and reduced from the adult dose according to age [21]. A formulation specific, age graded dosing table for *Kumar Kalyan Rasa* could not be confirmed by the authors across the editions consulted. This precise classical dose bears directly on the safety discussion later in this review, since the margin between the classically intended microdose, prepared from correctly authenticated *Bhasma*, and a toxicologically significant heavy metal exposure arising from incompletely processed material, is the central quantitative question this review sets out to address.

A commercially manufactured *Rasaushadhi* such as *Kumar Kalyan Rasa* would, in principle, be anchored to a standardised compositional monograph in the Ayurvedic Formulary of India or the Ayurvedic Pharmacopoeia of India, the official Government of India compendia that set legally recognised standards of composition, quality and purity for licensed Ayurvedic manufacture [23]. The authors specifically checked both compendia: at the time of writing, a dedicated monograph for *Kumar Kalyan Rasa* could not be confirmed either in the Ayurvedic Pharmacopoeia of India (API), which sets analytical quality standards, or in Part I of *The Ayurvedic Formulary of India* (AFI), which lists standardised formulae for a number of comparable paediatric *Bal Rasayana* preparations. Readers, editors and manufacturers are advised to check current status directly against the latest AFI and API volumes and their amendment lists, since a confirmed monograph in either compendium would give ingredient proportions, and enforceable *Shodhana* and *Marana* endpoints, a firmer regulatory anchor than commentarial variation alone can provide.

Classical *Rasashastra* further sets out a group of organoleptic and physical quality control tests, together called *Bhasma Pariksha*, that a properly calcined *Bhasma* is traditionally expected to satisfy before pharmaceutical use. These include *Rekhapurnatva*, the *Bhasma* is fine enough to fill the natural lines of the skin when rubbed between the fingers, *Varitaratva*, a pinch of the *Bhasma* floats on still water, taken as evidence of adequate fineness and reduced particle density, *Unnama*, a lustreless and uniform appearance, *Nishchandratva*, absence of residual metallic lustre under light, and *Apunarbhava*, the calcined material does not revert to its original metallic form on renewed exposure to heat, taken as classical evidence of complete conversion [8,21]. A sixth test, *Amla Pariksha*, resistance of the calcined material to reversal on exposure to sour media such as lemon juice or tamarind extract, together with *Nirdhuma*, absence of fumes on reheating, complete the fuller *Ashta Vidha Pariksha* scheme described in *Rasa Tarangini*, to which the reader is referred for the complete enumeration [21]. *Amla Pariksha* deserves particular emphasis in a paediatric safety discussion, because the acidic environment it recreates is directly comparable to gastric pH, so that a *Bhasma* passing this classical test is being screened, in effect, for exactly the kind of gastrointestinal re-solubilisation that modern toxicology would independently want to rule out before considering a calcined metal safe for oral administration to an infant. These parameters are the classical explanation for why properly processed *Bhasma* is held to differ pharmacologically and toxicologically from the crude parent metal, and they are the traditional, empirically minded quality gate that a manufacturer is expected to satisfy before a *Bhasma* is considered fit, in classical terms, for paediatric use.

Table 2. Principal ingredients of *Kumar Kalyan Rasa* as recorded in *Bhaishajya Ratnavali* and standard pharmaceutical descriptions [19,20,22]. Some commentaries additionally record the bark of *Rohitaka* (*Tecomella undulata* (Sm.) Seem., family Bignoniaceae) as a constituent. Exact proportions are not uniformly specified across the editions and commercial monographs consulted.

Sanskrit name	Nature of the substance	Processed form used
Parada and *Gandhaka*	Purified mercury and sulphur	*Rasa Sindura*, red mercuric sulphide, via *Kajjali* and *Kupipakwa Rasayana*
Swarna Bhasma	Gold	Calcined gold ash
Mukta Bhasma	Pearl	Calcined pearl ash
Abhraka Bhasma	Purified mica	Calcined mica ash
Loha Bhasma	Iron	Calcined iron ash
Makshika Bhasma	Copper-iron pyrite	Calcined pyrite ash
Kumari Swarasa	*Aloe vera* (L.) Burm.f.	Fresh leaf pulp juice, used as the levigating medium, *Bhavana Dravya*

5. SAMSKARA: THE CLASSICAL PHARMACEUTICAL RATIONALE FOR DETOXIFICATION AND ITS MOLECULAR CORRELATE

A foundational axiom of Ayurvedic pharmaceutics holds that *Samskara*, deliberate pharmaceutical processing, brings about a genuine change in the inherent qualities of a substance rather than a superficial change in its outward form, a principle summarised as *Samskarena hi Gunantaradhanam Uchyate*, processing is said to bring about a change of qualities [21,22]. This principle underlies the *Shodhana-Marana* sequence used to prepare *Kumar Kalyan Rasa*, in which the native metals and minerals are not merely combined with the herbal vehicle but are repeatedly triturated, calcined and levigated with it. *Shodhana* itself is a multi-stage classical procedure, typically involving repeated heating and quenching, *Nirvapa*, of the metal in prescribed liquid media such as sour gruel, buttermilk or herbal decoctions, followed by trituration; this stage is classically held to remove gross physical impurities and to begin the reduction of the metal's inherent toxicity, *Doshahara*, before *Marana* proper is undertaken. *Samskara* in this sense denotes transformation rather than admixture, and the classical pharmaceutical assumption, set out centuries before the vocabulary of modern chemistry existed, is that the processed material is qualitatively a different substance from its unprocessed precursor.

Contemporary analytical chemistry offers a plausible molecular correlate for this classical claim. When an inorganic constituent is triturated and repeatedly calcined together with an organic medium such as *Kumari Swarasa*, the mineral does not remain chemically inert; the combined thermal and reductive-oxidative conditions of repeated *Puta* reorganise its crystal lattice and oxidation state into a new compound. Elemental mercury and sulphur, converted through *Kajjali* and *Kupipakwa Rasayana* into mercuric sulphide with a cinnabar-type lattice distinct from either parent element, are one example, and structural analyses of *Lauha Bhasma* using synchrotron X-ray techniques have similarly shown that repeated heating and cooling converts metallic iron into a magnetite-group iron oxide rather than leaving the metal chemically unchanged [12]. Electron microscopy, X-ray diffraction and energy dispersive X-ray studies of Swarna and *Swarna Makshika Bhasma* confirm that this reorganisation is accompanied by a reduction in particle size toward the nanocrystalline or sub-micron domain, with the organic levigating medium plausibly contributing to capping and dispersion of the resulting particles [9,10,11]. In modern chemical terms, *Marana* does not simply purify or subdivide the parent metal; it converts it into a compositionally and structurally distinct compound, with a different oxidation state, coordination environment and crystalline form than the elemental or salt form from which it began [7,8].

This molecular reorganisation is pharmacologically and toxicologically consequential, because solubility, dissolution kinetics and biological reactivity are properties of chemical form and particle size rather than of elemental identity alone [7,8]. A cinnabar-type mercuric sulphide lattice is markedly less water soluble, and correspondingly less bioavailable through the gut, than elemental or ionic mercury; comparative reviews of metals in Ayurvedic *Bhasmas* and related Tibetan Zuotai preparations conclude on this basis that chemical form and particle size, rather than parent metal identity, are the major determinants of both therapeutic effect and toxicity [7]. This is the physicochemical correlate of the classical claim that properly executed *Marana* renders a metal *Bhasma* non-toxic and bioavailable [8], a change of *Guna* arising from a demonstrable change of molecular form and not merely a claim that the underlying element has been diluted away. Read in this light, the *Bhasma Pariksha* tests function as the classical tradition's own empirical checkpoint for this transformation. *Apunarbhava*, the requirement that calcined material not revert to metallic form on reheating, is a pre-modern assay for completed lattice conversion; *Rekhapurnatva* and *Varitaratva* are pre-modern proxies for the particle fineness that later analytical chemistry characterises directly by electron microscopy and X-ray diffraction; and *Amla Pariksha*, as noted above, is a pre-modern proxy for resistance to the acid mediated re-solubilisation that gastric digestion could otherwise bring about.

This mechanistic rationale should be read as conditional on correct execution and not as an assured property of any product simply labelled *Bhasma*. The classical tradition appears to have anticipated that *Samskara* could be incompletely carried out, which is presumably why *Bhasma Pariksha* was prescribed as an empirical check on whether transformation had genuinely occurred, rather than accepting the nominal performance of *Shodhana* and *Marana* on trust. A compositionally altered mercury, lead or arsenic species is not automatically harmless either, since incomplete conversion, or partial re-oxidation and dissolution of an otherwise poorly soluble compound within the gastrointestinal tract, can restore a measure of systemic bioavailability to the parent toxicant. The heavy metal contamination data reviewed later in this article, Table 4, indicate that toxicologically significant, and in some analyses very high, concentrations of mercury, lead and arsenic are detectable in certain marketed *Kumar Kalyan Rasa* products. Read alongside the mechanistic picture above, this is best interpreted as evidence of variable or incomplete adherence to classical *Shodhana* and *Marana* standards at the manufacturing level, rather than as a refutation of the underlying pharmaceutical principle. The molecular transformation achieved by authentic *Samskara* is a scientifically plausible, and in properly verified preparations an analytically demonstrable, detoxification mechanism, but its actual achievement in any given manufactured batch remains an empirical, analytically testable question rather than a guaranteed consequence of the classical procedure being invoked on a product label.

6. RASAPANCHAKA: AYURVEDIC PHARMACODYNAMICS OF THE CONSTITUENTS

Rasapanchaka, the classical framework of *Rasa* (taste), *Guna* (qualities), *Virya* (potency), *Vipaka* (post digestive effect) and *Prabhava* (specific action), is used in *Rasashastra* to explain the pharmacodynamics of processed metals in a manner that runs parallel to, though is not equivalent to, the mechanistic pharmacology of modern medicine [7]. *Prabhava* is classically invoked where an action cannot be predicted from taste or potency alone, and while this is conceptually the nearest classical parallel to a dose-independent or substance-specific action in modern pharmacology, the two frameworks describe different explanatory systems and should not be treated as interchangeable. *Prabhava* is best understood as a classical placeholder for an observed but, within *Rasashastra*'s own terms, unexplained action, rather than as a proto-scientific mechanistic

hypothesis awaiting biomedical confirmation; the two frameworks remain conceptually distinct even where they appear, on the surface, to describe a similar phenomenon.

According to the classical pharmacodynamic descriptions recorded in *Rasa Tarangini*, *Bhaishajya Ratnavali* and *Rasendra Sara Sangraha* [20,21,22], *Parada* after *Shodhana* is described as sweet in taste, hot in potency and pungent in post digestive effect, with a special affinity for kindling *Agni* and acting as *Yogavahi*, a catalyst that potentiates the action of co-administered drugs. *Swarna Bhasma* is credited with *Rasayana*, *Medhya* and *Balya* properties; *Mukta Bhasma* is considered *Sheeta*, cooling, and useful in *Pitta* predominant conditions; *Loha Bhasma* is traditionally used in *Pandu*, anaemia; and *Abhraka Bhasma* is described as *Rasayana* and useful across a wide range of chronic disorders [20,21,22]. *Kumari* is described as *Pittahara* and *Deepana-Pachana*, a digestive stimulant, which gives a classical rationale for its use as the levigating vehicle in a formulation meant for digestive and febrile paediatric complaints [20].

7. CONTEMPORARY SCIENTIFIC EVIDENCE

No clinical trial, pharmacokinetic study or toxicological evaluation specific to *Kumar Kalyan Rasa* as a compound formulation was retrieved in the searched databases. The contemporary evidence available therefore relates to its individual mineral and herbal constituents, considered below, and this remains an important evidence gap for the formulation that should be kept in view throughout the rest of this review.

7.1 SWARNA BHASMA AND GOLD BASED PAEDIATRIC PREPARATIONS

Swarna Bhasma has been characterised by transmission and scanning electron microscopy, X-ray diffraction and energy dispersive X-ray analysis in several independent laboratories, confirming that properly calcined preparations consist predominantly of nanocrystalline or sub-micron elemental gold with variable agglomeration [9,10,11]. Free radical scavenging and blood compatibility studies on laboratory prepared *Swarna Bhasma* report antioxidant activity and an absence of overt complement activation or haemolysis in vitro, findings cited in support of its traditional description as a *Rasayana* [9,10]. The closest available clinical correlate to the paediatric use of gold preparations is *Suvarnaprashana*, the *Kashyapa Samhita* derived practice of giving minute doses of *Swarna Bhasma* with honey and ghee to infants. A randomised controlled trial in infants reported measurable improvement in selected immunological parameters after *Suvarnaprashana*, and subsequent reviews and observational studies report similar immunomodulatory and growth-related findings, although sample sizes have generally been small and blinding and long term follow up limited [13,14,15]. These findings offer indirect, plausibility level support for the traditional attribution of *Balya* and *Rasayana* properties to gold containing formulations such as *Kumar Kalyan Rasa*, and for the premise that correctly executed *Marana* yields a physicochemically distinct, well tolerated particulate form of gold, but they do not constitute direct evidence for the compound formulation itself.

7.2 MUKTA, ABHRAKA AND LOHA BHASMA

Physicochemical standardisation studies of other classical *Bhasmas*, including *Swarna Makshika Bhasma*, have likewise shown conversion of the raw mineral into fine, largely oxide or sulphide, particulate matter through the *Shodhana-Marana* process, and this particle level characterisation underlies the broader literature describing *Bhasmas* as an early form of nanomedicine [8,11]. A structural investigation of *Lauha Bhasma* using synchrotron X-ray techniques found that repeated heating and cooling converts metallic iron into a magnetite-group iron oxide present as agglomerates of nanoparticles, giving direct physicochemical support to the traditional description of *Loha Bhasma* as a processed, non-metallic iron preparation [12]. A broader comparative review of metals in Ayurvedic *Bhasmas* and Tibetan Zuotai preparations concludes, in the same vein, that chemical form and particle size resulting from alchemical processing, rather than the identity of the parent metal alone, are a major determinant of both therapeutic effect and toxicity [7]. Dedicated pharmacological or toxicological data on *Mukta Bhasma* specifically in the paediatric context remain limited in the indexed literature, and extrapolation of adult data to infants and young children should be made with caution given differences in body weight, gastrointestinal absorption, and hepatic and renal clearance at this age.

7.3 HERBAL CONSTITUENTS: KUMARI AND ROHITAKA

Aloe vera (L.) Burm.f. is a well characterised medicinal plant whose leaf gel and juice contain polysaccharides, anthraquinones and phenolic compounds with documented anti-inflammatory, antioxidant and wound healing activity in preclinical studies, giving a plausible pharmacological basis for its traditional use as a digestive and *Pitta* pacifying levigating medium. *Rohitaka*, *Tecomella undulata* (Sm.) Seem., when included in the formulation, contributes hepatoprotective, anti-inflammatory and antimicrobial activity documented in phytochemical and pharmacological reviews of the plant. This lends some indirect contemporary rationale to the classical indication of *Kumar Kalyan Rasa* in paediatric jaundice, although the cited review is a general ethnomedicinal and phytochemical survey of *Tecomella undulata* rather than data specific to jaundice or to this formulation, and the correlation should accordingly be read as indirect plausibility rather than direct supportive evidence [16]. As with the mineral constituents, these findings pertain to the isolated plant material rather than to the compound formulation, and confirmatory studies using standardised extracts at paediatric relevant doses are needed.

7.4 EVIDENCE QUALITY OF THE KEY CONSTITUENT PHARMACOLOGICAL STUDIES

Table 3 sets out, in simple descriptive terms, the design, sample or model, key outcome and most notable limitation of the pharmacological studies most central to the argument of this review. This is offered as a transparent supplement to the narrative account above and not as a formal risk of bias or GRADE assessment.

Table 3. Descriptive evidence quality summary of the constituent pharmacological studies most central to this review. This is a simple descriptive table and not a formal AMSTAR or GRADE style appraisal.

Source	Study design / model	Key outcome	Notable limitation
Mitra et al. (2002)	In vitro, laboratory prepared *Swarna Bhasma*	Free radical scavenging activity reported	In vitro only; no in vivo or clinical correlation
Paul and Sharma (2011)	In vitro blood compatibility study	No overt complement activation or haemolysis observed	Single laboratory batch; not linked to a specific manufactured product
Mohapatra and Jha (2013)	Physicochemical characterisation, *Swarna Makshika Bhasma*	Confirmed nanocrystalline / sub-micron particulate conversion	Characterisation only; no pharmacological or toxicological endpoint
Tiwari et al. (2023)	Synchrotron XRD structural study, *Lauha Bhasma*	Metallic iron converted to magnetite-group oxide	Structural study only; no biological or clinical endpoint
Bhaskaran et al. (2019)	Randomised controlled trial, infants, *Suvarnaprashana*	Improvement in selected immunological parameters	Small sample; limited blinding and short follow up
Jyothy et al. (2014)	Narrative appraisal of *Suvarnaprashana* literature	Summarises immunomodulatory and growth-related findings	Secondary appraisal; inherits limitations of primary studies
Nelaturi et al. (2021)	Observational study, *Swarna Bindu Prashana*	Reports improved infant immunity indices	Observational design; no control group
Vats et al. (2025)	Ethnomedicinal and phytochemical review, *Tecomella undulata*	Documents hepatoprotective and anti-inflammatory activity	General plant review; not specific to jaundice or to this formulation

8. SAFETY, TOXICITY AND REGULATORY CONSIDERATIONS

The safety profile of mercury and heavy metal bearing *Rasaushadhis* is the most consequential area of contemporary evidence relevant to *Kumar Kalyan Rasa*, and it is addressed here with the same care applied to the pharmaceutical rationale above. In an independent chemical analysis, the Australian Therapeutic Goods Administration reported that samples of a commercially available *Kumar Kalyan Rasa* product manufactured in India, marketed under the Unjha brand, contained extremely high concentrations of mercury, lead, arsenic and cadmium, and issued a public safety alert advising against its use, with particular emphasis on the vulnerability of children to lead poisoning [6]. This finding sits within a broader pattern reported in independent laboratory surveys of Ayurvedic herbomineral medicines, summarised quantitatively in Table 4. In a widely cited analysis of Ayurvedic herbal medicine products purchased in the United States, one in five products was found to contain lead, mercury or arsenic at concentrations capable of producing daily heavy metal intakes above regulatory reference doses, particularly for children [1]. A subsequent study of Ayurvedic medicines manufactured in India and sold over the internet found detectable heavy metals in a substantial minority of products, with *Rasa Shastra* formulations more than twice as likely to be affected as non-*Rasa Shastra* herbal products [2]. A more recent inductively coupled plasma mass spectrometry survey of over the counter Ayurvedic preparations purchased from licensed pharmacies in Chandigarh, India, again found that a proportion of products exceeded the permissible metal limits set by the Ayurvedic Pharmacopoeia of India and by the Food and Agriculture Organization and World Health Organization for herbal medicines [4].

The clinical consequences of such exposure in children have been documented in the peer reviewed literature. A recent case report described a four-year-old boy who presented with anaemia, arterial hypertension, abdominal pain and neurological impairment after prolonged exposure to an Ayurvedic herbal preparation taken for asthma, with a venous blood lead level of 123 micrograms per decilitre, a concentration associated with severe, potentially life-threatening lead poisoning [3]. Comparable reports of lead and mercury poisoning attributed to Ayurvedic medicines, including in pregnant women and young children, have been documented by public health authorities in the United States over the past two decades [1,2].

Table 4. Quantitative summary of measured or reported heavy metal findings from the principal safety sources cited in this review, including one comparator formulation manufactured under verified Good Manufacturing Practice conditions. The final column records whether the source product's Good Manufacturing Practice or batch verification status was stated in the original source.

Source	Study / sample	Metal(s)	Reported finding	GMP verification status
Saper et al. (2004)	70 Ayurvedic HMPs, South Asian manufacture, Boston-area retail	Lead / mercury / arsenic	14/70 (20%) contained detectable Pb, Hg and/or As. Median (range) micrograms per gram: Pb 40 (5 to 37,000); Hg 20,225 (28 to 104,000); As 430 (37 to 8,130).	Not stated; unregulated retail sample
Saper et al. (2008)	193 Ayurvedic medicines, US- and India-manufactured, purchased via internet	Lead / mercury / arsenic	20.7% contained detectable Pb, Hg and/or As. *Rasa Shastra* products were more than twice as likely to contain metals as non-*Rasa Shastra* products.	Not stated; unregulated internet sample
Bhalla and Pannu (2022)	80 over-the-counter Ayurvedic preparations, licensed pharmacies, Chandigarh, India (ICP-MS)	Hg, As, Pb, Cd, Zn, Fe, Cu, Cr	10% of samples exceeded at least one permissible limit set by the Ayurvedic Pharmacopoeia of India / FAO-WHO.	Licensed retail pharmacy; batch level GMP status not independently confirmed
Cericola et al. (2025)	Single paediatric case report (4-year-old)	Lead	Venous blood lead 123 micrograms/dL after prolonged exposure to an Ayurvedic herbal preparation, a level associated with severe lead poisoning.	Not applicable; clinical case report
TGA (2025)	Product-specific regulatory testing of *Kumar Kalyan Rasa* tablets (Unjha Ayurvedic Pharmacy)	Mercury, lead, arsenic, cadmium	Extremely high concentrations of all four metals reported; exact quantitative values not published in the public safety alert.	No; unregistered import, not assessed by TGA
Lavekar et al. (2010)	CCRAS-affiliated preclinical safety evaluation of Mahayograja Guggulu, a comparator *Bhasma*-containing *Rasaushadhi*	Pb, Hg, As, plus haematology, biochemistry, histopathology	Pb 25.8 micrograms/g, Hg 0.07 micrograms/g, As 5.19 micrograms/g, within acceptable limits; unremarkable safety profile.	Yes; CCRAS-affiliated, process-controlled preclinical batch

8.1 ILLUSTRATIVE DOSE MARGIN ANALYSIS: CLASSICAL MICRODOSE AGAINST MEASURED CONTAMINATION RANGES

The Therapeutic Goods Administration safety alert on *Kumar Kalyan Rasa* does not publish exact metal concentrations, and no formulation specific quantitative dataset for this product exists in the peer reviewed literature [6]. To illustrate, in bounding terms only, why manufacturing variability matters quantitatively and not merely qualitatively, Table 5 applies the metal concentrations independently measured in comparable *Rasa Shastra* and Ayurvedic herbomineral products by Saper and colleagues to the classical, sub-gram *Ratti* scale dosing convention described earlier in this review, approximately 15 to 125 milligrams per dose, and compares the resulting estimated single dose metal intake against paediatric reference thresholds already established in the cited toxicological literature, the United States Environmental Protection Agency reference dose for chronic oral mercury intake in a 10-kilogram child, 3 micrograms per day, and the California Proposition 65 maximum allowable dose level for lead, 0.5 micrograms per day, both as reported in the source publications [1,2]. Because these reference doses are defined for chronic, cumulative daily intake and the calculation below is a single administered dose, the two figures are deliberately not expressed as a ratio or "multiple" of one another in Table 5; a single-dose estimate divided by a chronic reference dose does not yield a toxicologically meaningful exposure multiple, and presenting it as such would overstate the precision of this illustrative exercise. This is explicitly a bounding calculation using literature derived contamination ranges from comparable products, not a measured value for *Kumar Kalyan Rasa* itself, and is offered as a conservative, illustrative reference point rather than as a formal risk assessment.

Table 5. Illustrative, bounding dose margin calculation combining published contamination ranges in Ayurvedic herbomineral products with the classical *Ratti*-scale paediatric microdose convention. Estimated intake equals concentration multiplied by dose weight; comparator concentration data are drawn from unregulated retail or internet samples of Ayurvedic herbomineral products generally, not from *Kumar Kalyan Rasa* specifically, and are not a substitute for direct analytical testing of this formulation. The paediatric reference doses shown are defined for chronic daily intake and are given for orientation only; because the estimated intake column describes a single administered dose, the two figures are deliberately not converted into a "multiple of reference dose" ratio, since doing so would imply a precision this illustrative bounding exercise does not support.

Metal	Paediatric reference dose	Reported concentration in tested HMPs, median (range), micrograms/g	Estimated single-dose intake at 15 to 125 mg (micrograms)	Comparison to chronic reference dose (qualitative, not a ratio)
Mercury	3 micrograms/day (EPA reference dose, 10-kg child)	20,225 (28 to 104,000)	0.3 to 2,528	At the lower end of the reported range this remains below the chronic reference dose; at the upper end it substantially exceeds it

Metal	Paediatric reference dose	Reported concentration in tested HMPs, median (range), micrograms/g	Estimated single-dose intake at 15 to 125 mg (micrograms)	Comparison to chronic reference dose (qualitative, not a ratio)
Lead	0.5 micrograms/day (California Proposition 65 MADL)	40 (5 to 37,000)	0.075 to 4,625	At the lower end this is comparable to the chronic reference dose; at the upper end it substantially exceeds it

Important interpretive note: the estimated intakes and qualitative comparisons shown above are hypothetical bounding calculations built from contamination ranges measured in comparable, unregulated Ayurvedic herbomineral products in general, not measured values for Kumar Kalyan Rasa itself, and are illustrative orientation only, not a formal exposure or risk calculation. They should not be read, cited or reported as an analytically confirmed exposure figure, or as a precise multiple of a safety threshold, for this formulation. Direct batch level analytical testing of marketed Kumar Kalyan Rasa remains the only way to establish an actual exposure figure, and readers are asked to treat Table 5 strictly as an illustrative reasoning aid.

For comparison, applying the same calculation to the measured concentrations for the Good Manufacturing Practice verified comparator Mahayograja Guggulu, mercury 0.07 micrograms/g, lead 25.8 micrograms/g [26], gives an estimated mercury intake of approximately 0.001 to 0.009 micrograms at the same dose range, roughly 0.03 to 0.3 percent of the paediatric mercury reference dose, but an estimated lead intake of approximately 0.4 to 3.2 micrograms, which stays within the AFI/API and FAO-WHO limits applied in the source study but approaches or modestly exceeds the considerably more conservative California Proposition 65 threshold at the upper end of the illustrative dose range [26]. This comparison makes two points at once. First, verified Good Manufacturing Practice processing is associated with metal concentrations one to several orders of magnitude below those reported in unregulated retail samples, consistent with the manufacturing variability explanation advanced in this review. Second, Good Manufacturing Practice verified and within the applicable pharmacopoeial limit should not be conflated with below every possible international regulatory threshold, since thresholds themselves vary considerably in stringency between jurisdictions. Batch level compliance should therefore be judged against the specific pharmacopoeial standard applicable in the country of manufacture and use, stated explicitly, rather than implied as an unqualified guarantee of safety.

9. MANUFACTURING VARIABILITY AND THE CONDITIONS FOR ACHIEVING AUTHENTIC DETOXIFICATION

The contamination data summarised in Table 4 should be read together with, rather than as a rebuttal of, the classical and physicochemical rationale for *Shodhana-Marana* purification set out earlier in this review. A Central Council for Research in Ayurvedic Sciences affiliated preclinical safety evaluation of Mahayograja Guggulu, a comparator *Bhasma* containing *Rasaushadhi* manufactured under documented process control, found heavy metal concentrations well within acceptable limits alongside an unremarkable haematological, biochemical and histopathological safety profile [26]. This is a genuine and useful data point: it shows, in a directly comparable product class, that a *Bhasma* containing formulation processed to verified classical and Good Manufacturing Practice standards can pass contemporary toxicological scrutiny, and it gives the classical *Shodhana-Marana* rationale at least one documented, independently tested, contemporary point of confirmation. At the same time, this comparator evidence is presently limited to a single study of a single product from 2010, and the authors regard it as an illustrative existence proof rather than as a demonstration that verified processing reliably achieves this outcome across all *Bhasma* containing *Rasaushadhis*, including *Kumar Kalyan Rasa* specifically. Additional, more recent, Good Manufacturing Practice verified comparator data, ideally on *Kumar Kalyan Rasa* itself, would be needed to move this argument from suggestive to well supported, and the authors flag this explicitly as a priority for future work rather than allow the strength of the single comparator to be overstated.

The Central Council for Research in Ayurvedic Sciences, under the Ministry of AYUSH, has separately issued general guidelines for the safety and toxicity evaluation of Ayurvedic formulations that formalise batch level heavy metal testing and other quality parameters as a regulatory expectation for licensed manufacture, reflecting an active and ongoing effort to anchor classical pharmaceutical claims to enforceable contemporary standards [17,18]. Against this background, the mercury, lead, arsenic and cadmium concentrations reported in marketed *Kumar Kalyan Rasa* products by the Therapeutic Goods Administration, and the elevated metal detection rates reported across the Saper and the Bhalla and Pannu surveys, are most plausibly explained by inconsistent adherence to *Shodhana*, *Marana* and *Bhasma Pariksha* standards at the point of manufacture, rather than by an inherent failure of properly executed classical processing. None of the products found to contain unsafe metal concentrations in the cited surveys were shown to have been manufactured under independently verified, batch tested Good Manufacturing Practice conditions with documented *Bhasma Pariksha* compliance; the one *Bhasma* containing *Rasaushadhi* in this evidence base that was manufactured and tested under such conditions returned an acceptable safety profile [26]. This distinction matters in practice: it indicates that the relevant safety variable for a prescribing physician or regulator is not whether a product is described as containing *Bhasma*, but whether its specific manufacturing batch can be shown, by independent analytical testing rather than by label claim alone, to have achieved the *Apunarbhava* and allied *Bhasma Pariksha* endpoints that classical *Rasashastra* itself requires as evidence of completed detoxification.

This distinction does not remove the safety concern; it reframes it as a quality assurance and regulatory enforcement problem rather than as an indictment of the classical pharmaceutical tradition. Infants and young children, the intended recipients of *Kumar Kalyan Rasa*, are known to be at disproportionately higher risk of heavy metal toxicity relative to adults, owing to greater gastrointestinal absorption, higher relative intake per unit body weight, and the vulnerability of the developing and not yet fully myelinated nervous system, together with comparatively immature hepatic and renal clearance. The margin for manufacturing error in a paediatric *Rasaushadhi* is therefore narrower than in an equivalent adult preparation. On current evidence, the use of this and comparable *Rasaushadhis* in children should be regarded as safe in principle when sourced from manufacturers able to demonstrate independently verified, batch tested compliance with classical *Shodhana*, *Marana* and *Bhasma Pariksha* standards under Good Manufacturing Practice conditions, and as carrying a meaningful and insufficiently quantified risk outside of that assurance. This regulatory concern is not confined to Australia. Comparable heavy metal alerts and case series involving Ayurvedic and related traditional Indian herbomineral medicines have been documented by regulatory and clinical bodies in New Zealand and among traditional Siddha preparations in Southeast Asia, indicating a consistent international pattern and, correspondingly, a consistent international need for batch level verification rather than reliance on classical description alone [24,25].

Verified Good Manufacturing Practice compliance is used throughout this review as a specific, checkable standard and not as a general reassurance. It is intended to denote the joint satisfaction of the following operational criteria: first, a product and batch specific Certificate of Analysis from an accredited, National Accreditation Board for Testing and Calibration Laboratories certified, or equivalent internationally accredited,

laboratory, reporting quantitative mercury, lead, arsenic and cadmium concentrations against the limits specified in the Ayurvedic Pharmacopoeia of India or Ayurvedic Formulary of India for that formulation; second, manufacture under a current Good Manufacturing Practice licence issued under Schedule T of the Drugs and Cosmetics Rules, 1945, independently verifiable through State Licensing Authority or Ministry of AYUSH records; third, documented performance of *Bhasma Pariksha*, including *Apunarbhava*, recorded in the batch manufacturing record, ideally supplemented by analytical confirmation of particle size and phase composition, for example by X-ray diffraction, rather than by organoleptic assessment alone; fourth, batch traceability linking the dispensed product to its Certificate of Analysis; and fifth, absence of the specific product and manufacturer from active international regulatory safety alerts, such as those issued by the Therapeutic Goods Administration, at the time of prescribing or dispensing. A product satisfying all five criteria corresponds to the Good Manufacturing Practice verified condition under which this review considers the classical detoxification rationale to be substantiated by available evidence; a product for which any of these criteria cannot be confirmed should be regarded as unverified, whatever label claims are made regarding *Shodhana* or *Bhasma* status.

10. CRITICAL DISCUSSION

The classical description of *Kumar Kalyan Rasa* reflects a coherent internal logic within *Rasashastra*, in which carefully purified and calcined minerals, combined with a digestive and *Pitta* pacifying herbal vehicle, are intended to address the febrile, hepatic, gastrointestinal and nutritional disorders of childhood through a combination of *Balya*, Deepana and *Rasayana* actions. Contemporary nanoparticle characterisation of several individual *Bhasmas* gives real physicochemical plausibility to the traditional claim that *Marana* transforms bulk metal into a fine, structurally distinct and potentially more bioavailable particulate form, and preliminary immunomodulatory data on related gold based paediatric preparations such as *Suvarnaprashana* give indirect support to a biological rationale [8-15]. The comparator safety evaluation of Mahayograja Guggulu further shows that this rationale can, under verified manufacturing conditions, translate into a *Bhasma* containing product that clears contemporary toxicological testing, although the authors reiterate that this remains a single data point and should be weighed accordingly [26]. Particle size reduction and altered bioavailability are not, however, synonymous with reduced toxicity in every manufactured batch, and the heavy metal content data reviewed above show that this assumption cannot be taken for granted across the range of *Kumar Kalyan Rasa* products currently available in the market [1-6]. The two observations are not in tension. Together they indicate that the classical pharmaceutical principle is sound so far as it has been tested, and that its clinical safety in any individual product depends on demonstrable, batch level adherence to that principle rather than on the principle's mere invocation.

A second limitation is the absence of any dedicated pharmacokinetic, toxicological or controlled clinical study of *Kumar Kalyan Rasa* as a complete formulation. All of the supportive pharmacological evidence discussed in this review concerns isolated constituents, generally in adult or in vitro model systems, and cannot be assumed to translate directly either to the paediatric population or to the compound preparation, in which mercury, gold, iron, mica and pearl are combined and may interact in ways not yet systematically studied. Future research priorities should include batch wise heavy metal quantification of commercially available *Kumar Kalyan Rasa* products against Ayurvedic Pharmacopoeia of India limits and against direct measurement of *Bhasma Pariksha* endpoints such as *Apunarbhava* and *Amla Pariksha*; pharmacokinetic study of its mercury and gold content in validated animal models; and, contingent on satisfactory safety data from verified Good Manufacturing Practice batches, a properly designed and ethically approved paediatric clinical trial with active comparator or placebo control. Strengthening pharmacovigilance reporting for classical *Rasaushadhis* within the Ayurvedic health care system, in coordination with the Ministry of AYUSH and the Central Council for Research in Ayurvedic Sciences and linking that reporting to batch level *Shodhana* and *Marana* verification records, would further help reconcile the classical therapeutic tradition represented by *Kumar Kalyan Rasa* with the safety standards expected of contemporary paediatric medicine.

11. LIMITATIONS OF THIS REVIEW

This is a narrative and critical review rather than a systematic review. A defined search strategy was applied, but formal risk of bias assessment and meta-analysis were not undertaken, because the constituent level literature is too heterogeneous in design for quantitative synthesis, and, as stated in Methods, a numerical search-flow diagram is not presented because per-database record counts were not centrally logged during screening. The descriptive evidence quality table provided in this review, Table 3, is offered as a transparent supplement to that narrative account and should not be read as a substitute for a formal PRISMA compliant systematic review; the authors have chosen to state this limitation plainly here and in Methods rather than to imply a level of methodological rigour the search did not follow. Only English language, predominantly database indexed sources were included, with a narrow, explicitly stated exception for two regulatory or grey literature sources of direct product specific safety relevance, so relevant Hindi or Sanskrit secondary commentarial literature outside the major printed editions consulted may not be fully represented. The classical verse and chapter locants cited should be independently verified by the reader against a primary institutional edition of *Bhaishajya Ratnavali* before formal citation, as stated in Methods and repeated at the point of quotation; both authors are affiliated with the same institution, and the classical textual identification was not additionally cross checked by an independent, external Sanskrit literate *Rasashastra* scholar, which readers and editors should weigh accordingly. The illustrative dose margin calculation presented in this review, Table 5, uses contamination data from comparable Ayurvedic herbomineral products rather than from *Kumar Kalyan Rasa* itself and should not be read as a measured toxicological finding for this specific formulation. The central manufacturing variability argument of this review rests on a single Good Manufacturing Practice verified comparator product from 2010, and this single data point limitation is acknowledged rather than allowed to stand as settled evidence. Finally, the contemporary reference base for this two-discipline critical review, eighteen contemporary and five classical or regulatory sources, is comparatively modest relative to some systematic reviews in this literature; the authors have prioritised the depth and verifiability of each citation over reference count, but a broader search incorporating additional Hindi language and pharmacopoeial sources may further strengthen future revisions of this work.

12. CONCLUSION

This review does not conclude that currently marketed *Kumar Kalyan Rasa* is, as a general matter, safe or beneficial for paediatric use; that claim would exceed what the assembled evidence supports and is not made here. *Kumar Kalyan Rasa* is a classical *Rasaushadhi* with a defined place in the *Kaumarabhritya* section of *Bhaishajya Ratnavali* and continued use in contemporary Ayurvedic paediatric practice, underpinned by a *Samskara* based pharmaceutical rationale that finds meaningful, though not yet formulation specific, support in contemporary physicochemical and pharmacological literature. Its individual mineral and herbal constituents show preliminary pharmacological plausibility on independent laboratory investigation, and a directly comparable *Bhasma* containing *Rasaushadhi* manufactured under verified conditions has shown an acceptable contemporary safety profile, indicating that the classical detoxification rationale is achievable in practice under conditions that can be specified and checked, though this remains supported by limited comparator evidence at present. At the same time, direct clinical and toxicological evidence for the *Kumar Kalyan Rasa* compound formulation itself is absent, and

documented heavy metal contamination of a proportion of marketed products represents a genuine and clinically significant safety concern in children when that verification is lacking. Until formulation specific standardisation, heavy metal quantification and controlled clinical evaluation are available, the use of *Kumar Kalyan Rasa* in children should be confined to preparations from manufacturers able to demonstrate independently verified, batch tested adherence to classical *Shodhana*, *Marana* and *Bhasma Pariksha* standards under Good Manufacturing Practice conditions, given under the direct supervision of a qualified Ayurvedic physician, with the same vigilance for adverse effects that would be applied to any pharmacologically active paediatric medicine.

CREDIT AUTHOR STATEMENT

Vinay Kumar Bholanath Singh: Conceptualization, Investigation (classical literature), Writing, original draft, Supervision. Sri Rama Siva Kalyan Pulipati: Methodology, Investigation (*Rasashastra* and *Bhaishajya Kalpana* literature), Writing, review and editing. Both authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

No new data were generated for this review. All sources analysed are cited within the article and are publicly accessible through the databases and publishers indicated.

ETHICS STATEMENT

Not applicable. This is a narrative literature review that did not involve human participants, animal subjects, or primary clinical data.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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