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KWATHA KALPANA AND MODERN HERBAL EXTRACTION TECHNOLOGIES: AN INTEGRATIVE REVIEW OF PHARMACEUTICAL ADVANCES, PHYTOCHEMICAL STANDARDIZATION, AND TRANSLATIONAL THERAPEUTICS

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ABSTRACT

Kwatha Kalpana, the aqueous decoction anchoring the *Panchavidha Kashaya Kalpana* of Ayurvedic pharmaceutics remains the most widely dispensed classical dosage form and the foundational extraction step for *Arishta*, *Ghana*, and *Sneha* preparations. Modern manufacturing has progressively substituted selective, marker-maximizing platforms - ultrasound, microwave, pressurized-liquid, and green-solvent (NADES)-based extraction for classical boiling, generally without demonstrating pharmaceutical or clinical equivalence to the decoction replaced. This review integrates classical pharmaceutics, pharmacopeial regulation, phytochemical mechanism, industrial/green-chemistry economics, and clinical-trial methodology to interrogate that substitution. Quantitative thermal-degradation kinetics show that markers such as gallic acid and curcumin are simultaneously generated and destroyed during boiling, while saponins undergo thermally driven conversion to more permeable species; co-decoction of polyherbal mixtures is demonstrably non-additive, shifting individual markers 1.17 to over 30-fold relative to separately prepared extracts; and decoction generates emergent colloidal

and supramolecular matter self-assembled nanospheres and heat-stable "decoctosomes"—that selective extraction cannot reproduce. Set against this is a countervailing industrial reading: open-vessel boiling is energy- and time-inefficient relative to subcritical water extraction and other green platforms, which recover markers at a fraction of the energy cost and enable defensible commercial scale-up. India additionally lacks any regulatory analogue to China's "standard decoction" benchmark for demonstrating consistency between a decoction and its industrial derivative, and clinical trials of *Kwatha*-derived products almost never report the pharmaceutics of the tested article. We enumerate the research gaps and propose a tiered equivalence framework together with a PICO-structured non-inferiority trial design as the field's most urgent methodological priority.

KEYWORDS: Kwatha Kalpana; Bhaishajya Kalpana; subcritical water extraction; phytochemical standardization; pharmacokinetics; Ayurvedic Pharmacopoeia of India.

1. INTRODUCTION

Bhaishajya Kalpana, Ayurveda's pharmaceutical science, organizes processing around the *Panchavidha Kashaya Kalpana—Swarasa* (juice), *Kalka* (paste), *Kwatha* (decoction), *Hima* (cold infusion) and *Phanta* (hot infusion).[1] *Kwatha* occupies the pivotal third position and is the substrate from which most secondary forms—Asava, *Arishta*, *Ghana, and Sneha Kalpana—are* elaborated.[1] Water's dominance as menstruum suits one chemical universe (glycosides, tannins, phenolic acids, alkaloid salts, mucilaginous polysaccharides) but fits another poorly (withanolides, curcuminoids, essential-oil terpenoids), a tension running through this review.

Classical codification, attributed to the thirteenth-century *Sharangdhara Samhita*, specifies water quantity by drug hardness—four parts for *mridu* (soft), eight for *madhyama* (medium), and sixteen for *kathina* (hard)—reduced to one-fourth as a *sneha* base or one-eighth for direct use.[1, 2] As global demand for standardized Ayurvedic products grows, this artisanal process's limitations—batch variability, an hours-long shelf life, and high boiling energy consumption—are driving industry toward intensified platforms: ultrasound-assisted (UAE), microwave-assisted (MAE), supercritical-fluid (SFE), subcritical-water (SWE), pressurized-liquid (PLE), high-hydrostatic-pressure (HHP), and deep-eutectic-solvent (NADES) extraction.[3] Whether any platform is pharmaceutically *equivalent* to the decoction it displaces—or whether prolonged boiling instead performs chemistry rapid extraction cannot replicate—is this review's central question.

2. Rationale and Objectives of the Review

Four observations justify an integrative treatment. First, substitution is occurring without an equivalence standard: *Ghana* tablets and spray-dried powders are marketed under a classical *Kwatha* name while demonstrating only compliance with generic physicochemical limits, not constituent-level correspondence.[4] Second, the comparative-extraction literature is yield-dominated, and yield dissociates from bioactivity.[3] Third, co-decoction of polyherbal mixtures is chemically non-additive, undermining the shortcut of extracting ingredients separately and blending them.[5,6] Fourth, clinical trials rarely report the extraction parameters of the tested article, rendering results irreproducible.

This review therefore aims to (1) codify classical *Kwatha* pharmaceutics quantitatively; (2) characterize modern extraction technologies against decoction-dominant constituents; (3) synthesize comparative yield, fingerprint, bioactivity, stability, and cost data; (4) evaluate standardization against Indian and WHO frameworks; (5) appraise translational and clinical-trial evidence; and (6) enumerate research gaps and a prioritized agenda.

3. METHODOLOGY

This is a narrative integrative review synthesizing previously published literature—peer-reviewed pharmaceutical and phytochemical studies, pharmacopeial/regulatory documents (Ayurvedic Pharmacopoeia of India, PCIM&H, WHO Technical Report Series), and clinical trial reports—on *Kwatha Kalpana* pharmaceutics and modern extraction technologies. No new primary research or literature search beyond consolidating existing sourced material was undertaken. Because designs, matrices, and endpoints are too heterogeneous for meta-analysis, evidence is synthesized qualitatively, distinguishing authentic Ayurvedic sources from indirect analogues (single-plant studies, Traditional Chinese Medicine decoction research).

4. Kwatha Kalpana: Classical Pharmaceutical Principles

The central pharmaceutical variable is the drug-to-water ratio and reduction endpoint. Classical texts specify 1: 4, 1: 8, or 1: 16 water for *mridu*, *madhyama*, or *kathina* drugs, but the literature acknowledges that "no uniformity has been found" across Acharyas on the reduction endpoint—even flagship formulations diverge, some Triphala protocols reducing only to one-half rather than one-quarter.[2] This matrix-hardness-indexed ratio fixes *concentration* while leaving *thermal history—time-at-temperature*, pH trajectory, oxygen

exposure—almost entirely uncontrolled: batches compliant with the same ratio can differ several-fold in thermal degradation of a labile marker depending on vessel geometry alone.

Pharmacopoeial codification advances furthest for powder inputs, not the finished liquid. The Ayurvedic Pharmacopoeia of India (API) prescribes organoleptic evaluation, ash values, extractives, pH, loss on drying, microbial limits, heavy metals, and TLC/HPTLC identity.[7] The pandemic-era 2020 *AYUSH Kvatha Curna* monograph—standardizing a *Tulsi*: *Dalchini*: *Sunthi*: *Marich* (4: 2: 2: 1) immunity decoction—operationalized *Yavakuta* particle size as a sieve specification (all material through 710-micron, not more than 10% through 355-micron).[8] GMP is governed by Schedule T, with PCIM&H setting formulary specifications.[9, 10] Coverage is asymmetric: only 203 compound-formulation monographs exist against 986 formulations in the Ayurvedic Formulary of India, so most dispensed *Kwathas* have no dedicated monograph.[11]

Kwatha's same-day use (*Saviryata Avadhi*, roughly one *prahara*) is a stability constraint, not a ritual preference: a 90-day, three-arm storage study found refrigerated, light-protected samples retained most baseline phenolic content, while ambient, light-exposed storage degraded rapidly.[12, 13] Fresh versus commercially concentrated *Cirivilvadi Kashaya* differed roughly two-fold in phenols/potassium and an order of magnitude in alkaloid content[14], direct evidence that industrial concentration is not chemically neutral.

5. Modern Herbal Extraction Technologies

Soxhlet extraction remains the pharmacopoeial reference for exhaustive recovery but exposes constituents to prolonged heat and organic solvent. The UAE exploits acoustic cavitation at a mild temperature, shortening time and solvent volume relative to Soxhlet, though gains are compound-class dependent. MAE couples microwave energy into polar solvent and intracellular water; in a six-plant, eight-method comparison, it was highest-yielding at 20.8% w/w against 4% for percolation.[3] SFE using supercritical CO_2 offers near-ambient exposure and zero solvent residue but is essentially non-polar and poorly suited to the glycosides, tannins, and polysaccharides dominating decoction total solids unless polar co-solvents are added.

Subcritical water extraction (SWE) is most conceptually continuous with *Kwatha*'s aqueous philosophy and is widely regarded as its logical green industrial heir: between 100 °C and 374 °C under pressure, water's dielectric constant falls toward that of methanol or acetone,

reaching polar and moderately non-polar constituents with one solvent. Yet this same property makes SWE compositionally disruptive—subcritical water at 150°C recovered tanshinone I 370-fold more efficiently than conventional 100°C decoction of *Salvia miltiorrhiza*, a success for that marker but clear evidence of non-equivalence.[15] Pressurized liquid and high-hydrostatic-pressure extraction (100–600 MPa, near-ambient) protect heat-labile constituents without thermal load, while NADES offer tunable green media—chemically distinct from water itself.

Industrially, open-vessel boiling is energy-intensive, evaporating up to fifteen-sixteenths of the initial water against continuous fuel input; energy audits place UAE and MAE at roughly 1.3–1.5 × 10^{-2} kWh in laboratory conditions, far below open decoction's latent-heat losses.[16] Falling-film-evaporator systems show a 33% yield increase over batch boiling[17], and though capex for integrated SFE/SWE facilities can reach ₹30 crore, standardized extracts command a 3–5-fold price premium over crude preparations.[17, 18]

6. Comparative Pharmaceutical Advances

The central, recurring finding is a dissociation between yield and bioactivity: in the same comparison where MAE reached 20.8% yield against 4% for percolation, antioxidant activity was consistently *highest* in infusion and decoction, the conventional aqueous baselines.[3] Marker-maximizing design can therefore be biologically regressive rather than progressive.

Quantitative thermal-degradation kinetics explain much of this. Gallic acid—the marker of choice for *Triphala* and most *Terminalia/ Emblica*-containing *kwathas degrade* by first-order kinetics via decarboxylation to pyrogallol, with rate constants of 0.0011, 0.0038, and 0.0076 min^{-1} at 60, 90, and 120°C; extrapolating the 90°C constant implies roughly 35–45% loss of dissolved gallic acid during a typical two-hour reduction, even as concurrent tannin hydrolysis simultaneously regenerates it.[19] Curcumin follows an alkaline-autoxidation pathway highly unstable above neutral pH, with aqueous solubility of only 0.3–0.4 µg/mL, so a *Haridra*-containing *Kwatha* delivers curcuminoids only in trace, already-degraded amounts.[20] Saponins illustrate thermally driven conversion rather than destruction: ginsenoside Rb1 converts to Rg3 by a consecutive first-order reaction (k_1 = 0.013 h^{-1} at 80°C, rising to 0.045 h^{-1} at 100°C), while Rg3 itself degrades further to more membrane-permeable species.[21] Prolonged boiling may thus generate the actual effector molecules for

saponin-rich *Kwathas—the* strongest argument against uncritical replacement of decoction with cold, rapid extraction, and one never tested in an Ayurvedic formulation.

Co-decoction compounds this picture: in Erxian Decoction, all six validated HPLC markers were lower in combined co-decoction than in separately decocted, mixed extracts, by 1.17- to over 30-fold[5]; increasing *Glycyrrhiza* proportion in *Paeonia–Glycyrrhiza* co-decoction depressed *Paeonia* markers to as low as 23% of single-herb values[6]; and analysis of the eight-herb Palmijihwang-tang formula showed combined decoction selectively enhancing some structural classes and suppressing others relative to an additive model.[22] No equivalent study exists for any major Indian polyherbal *Kwatha*, despite *Dashamoola* and *Pathyashadangam* being co-decocted by classical mandate.

7. Phytochemical Standardization

HPTLC and HPLC remain the workhorses of Indian standardization: a validated HPTLC method quantifies five markers (andrographolide, piperine, picroside-I, picroside-II, and α-cyperone) in *Jwarahara Kwatha Choornam*[23]; HPLC quantifies luteolin, 6-gingerol, β-sitosterol, and ecdysterone in *Nayopayam Kwatha*[24]; and HPLC/HPTLC standardizes *Pathyashadangam kwath* using andrographolide across three batches.[25] These sit within WHO's marker-substance hierarchy (TRS 1003) and herbal-processing GMP guidance (TRS 1010)[26, 27], operationalized through Schedule T and PCIM&H specifications.[8, 9]

Polyherbal decoctions pose problems single-drug standardization does not. Marker attribution is ambiguous: in a seven-ingredient *Kwatha*, gallic acid derives from at least three ingredients, so its concentration cannot verify any one's presence or proportion.[25] Matrix-dependent transfer is severe: co-decoction alters marker recovery 1.17- to over 30-fold relative to single-herb data[5,6], invalidating limits derived outside the matrix. Process variables within classical tolerance still change composition—water quantity alone shifted *Guduchi Ghana* yield from 4.2% to 12% while *inversely* shifting alkaloid content from 0.88% to 0.64%[28]—so classical-method compliance does not constrain composition.

India's most consequential regulatory gap is the absence of any analogue to China's "standard decoction" (TCM) system, which mandates a reference decoction from at least fifteen batches and quantifies dry-matter yield rate, index-component content, and transfer rate against a 70–130% acceptance window.[29] No Indian requirement obliges a marketed *Ghanaian* granule or tablet to demonstrate consistency with the decoction whose reputation it borrows. Building a

"Standard Kwatha" benchmark on this template, using APIs' existing methodology, is arguably the highest-leverage regulatory intervention available.[7, 29]

8. Translational Therapeutics

Presentation state alone makes *Kwatha* and its solid derivatives pharmacokinetically distinct: liquid *Kwatha* is already in solution, whereas a *Ghana* tablet must first disintegrate—one validated formulation showed a 33-minute disintegration time before dissolution can begin.[4] The best human pharmacokinetic dataset for any *Kwatha*-derived product, a single-dose study of standardized aqueous *Triphala* extract in 32 healthy subjects, found gallic acid C_max of only 41.8–70.8 ng/mL (roughly 0.4 µM) at 2,000–4,000 mg, with a t_max of 1 hour and a terminal half-life of about 1 hour[30]—an exposure that is both tiny and brief relative to concentrations used in most in vitro mechanistic work on gallic acid.

This mismatch motivates a gut-microbiome reframing of *Triphala*-type formulations as prodrug delivery systems. The high-molecular-weight hydrolysable tannins dominating *kwathas* of *haritaki*, *bibhitaki*, and *amalaki*—*chebulinic* acid, chebulagic acid, and corilagin—are poorly absorbed intact but extensively metabolized by gut microbiota into urolithins, circulating at 0.2–20 µM, one to two orders of magnitude above measured gallic acid levels[31,32]; these tannins show elimination half-lives of 43.3, 26.4, and 20.0 hours, twenty- to forty-fold longer than free gallic acid.[33] If the true effector is a microbial metabolite of an intact polymeric precursor, a method maximizing free gallic acid yield—exactly what standardization prizes—could reduce rather than enhance efficacy by hydrolysing that precursor in the vessel.

Extraction method also determines interaction liability: *Triphala* decoction extract inhibits human hepatic CYP1A2, CYP3A4, CYP2C9, and CYP2D6 and P-glycoprotein in Caco-2 monolayers, altering phenacetin/midazolam pharmacokinetics in rats[34]; because this activity is polyphenol-driven and extraction-method-dependent, interaction risk tracks manufacturing process, not botanical identity alone. *Guduchi* hepatotoxicity signals, including a fatal autoimmune-like liver injury case, implicate species substitution and formulation heterogeneity as confounders current reporting cannot disentangle.[35]

Clinical evidence shows systematic weaknesses rather than absence. AYUSH-64 showed a clinical-recovery benefit with no corresponding RT-PCR difference[36]; Kabasura Kudineer and Guduchighana Vati pilot RCTs were small and explicitly underpowered.[37, 38] None

reports the extraction parameters or fingerprint of the tested article, so discordant results cannot be attributed to formulation versus biology. A Triphala–Ela mouthwash trial against chlorhexidine found no significant difference but reported no non-inferiority margin, inadequate randomization/blinding, and no decoction ratio, temperature, or fingerprint[39]—non-significance is not equivalence. Names like "Triphala," "Guduchi," and "Dashamoola" can denote different species, parts, ratios, or dosage forms across studies, risking category error when pooled. *Dashamoola Kwatha* showed meaningful anti-inflammatory activity relative to diclofenac, yet no pharmacokinetic study of any kind exists for it.[40]

9. DISCUSSION

The evidence above sustains a genuine, unresolved tension rather than a settled conclusion. One reading, grounded in thermal-degradation kinetics and supramolecular chemistry research on Chinese decoctions, holds that prolonged *Kwatha* boiling is a reactive, colloidal process whose products selective extraction deletes: co-decoction drives self-assembly from nanofibers into nanospheres with measurable antibacterial/anti-inflammatory consequences[41]; analogous decoctions generate heat-stable, exosome-like "decoctosomes" carrying functional small RNAs requiring aqueous heating, unable to form under supercritical or organic-solvent conditions[42,43]; and self-assembled decoction nanoparticles survive simulated gastrointestinal fluids for twelve hours.[44] On this reading, a marker-concentration specification measures the wrong object entirely.

The opposing reading, grounded in industrial energy economics and compositional comparison, treats open-vessel boiling as a correctable inefficiency: it consumes energy at a scale green platforms like SWE and UAE undercut by roughly an order of magnitude[16], and it fails to recover compounds—tanshinone I, enriched 370-fold by subcritical water relative to 100°C decoction—that a more aggressive process reaches easily.[15] Neither reading is disqualified by current data: no Ayurvedic *Kwatha* has undergone the supramolecular characterization performed on Chinese decoctions, so the "reactive process" thesis remains an analogy; no life-cycle assessment has quantified boiling's true cost against green alternatives for Ayurvedic formulations, so the "inefficiency" thesis rests on adjacent evidence. The yield–bioactivity dissociation[3] and co-decoction non-additivity[5,6] argue against treating "more extraction" as unambiguously superior but stop short of proving decoction chemistry clinically superior. Until head-to-head comparisons are performed on actual Ayurvedic *Kwathas*, this debate should remain open.

10. Research Gaps

Convergent analysis of the literature underlying this review identifies seven recurring gaps, each independently corroborated across multiple strands of evidence,

1. **No human crossover pharmacokinetic study has ever compared a classically prepared *Kwatha against its Ghana/modern-extract equivalent at a matched dose.*** The disintegration barrier introduced by tableting[4] and the sub-micromolar, short-half-life exposure documented for *Triphala* gallic acid[30] make dose-form conversion a pharmacokinetically untested assumption.
2. **Most of the roughly 400+ API-listed *Kwatha/Kashaya formulations lack validated, ingredient-discriminating multi-marker fingerprints.*** Only 203 compound monographs exist against 986 formulary entries[11], and available markers are frequently shared across ingredients, making identity and proportion unverifiable.[25]
3. **No study has characterized herb–herb interaction chemistry during co-decoction for any major Indian polyherbal *Kwatha.*** The 1.17- to over 30-fold marker shifts documented for Erxian Decoction, *Paeonia–Glycyrrhiza,* and Palmijihwang-tang[5, 6, 22] have no Indian counterpart, so extracting ingredients separately and blending them can be neither defended nor refuted.
4. **Human clinical herb–drug interaction data are absent despite documented in-vitro/animal signals.** *Triphala*'s CYP and P-glycoprotein inhibition is characterized pre-clinically[34] but never confirmed in humans, a live safety gap given concurrent allopathic use.
5. **Published clinical trials rarely report the extraction or manufacturing parameters of the tested article.** AYUSH-64, Kabasura Kudineer, Guduchighana Vati, and the Triphala–Ela mouthwash trial all omit batch pharmaceutics[36,37,38,39], and names like "Triphala" or "Guduchi" can denote different products across studies, risking category error in pooled synthesis.
6. **Subcritical water extraction remains unoptimized and unapplied as an industrial *Kwatha-equivalent platform.*** Despite being most conceptually continuous with *Kwatha*'s aqueous philosophy, no work has mapped SWE's parameter space against a classical polyherbal formula, and the one relevant comparison shows a 370-fold shift in a single marker versus conventional decoction.[15]
7. **India has no regulatory analogue to China's "standard decoction" benchmark.** No requirement obliges a marketed *Ghanaian* granule or tablet to demonstrate consistency in paste yield, marker content, or transfer rate with the decoction whose name it borrows.[29]

11. Future Directions and Recommendations

The highest-leverage regulatory step is a **"Standard Kwatha" benchmark**, adapting China's architecture: a reference decoction from at least thirty batches, three quantified parameters (dry-matter yield rate, index-component content, and transfer rate), and mandatory consistency for any *Ghanaian* granule or tablet marketed under a classical name—achievable on API's existing total-solids/extractive-value methodology.[7, 29] We further propose a three-tier **Kalpana-equivalence framework**: chemical (fingerprint similarity plus a multi-marker panel validated in the co-decocted matrix), biological (concordance across relevant in vitro/in vivo assays), and exposure equivalence (human crossover pharmacokinetics on ≥2 markers, plus microbial-metabolite exposure for tannin-rich formulations)—with only exposure-equivalent products permitted a classical name.

Water-compatible intensification—UAE, HHP, bounded SWE—should be prioritized over technologies abandoning the aqueous menstruum. A full life-cycle assessment comparing traditional boiling to SWE/UAE at scale should precede any confident "greener" claim.[16] Colloidal attributes—particle size, polydispersity, and zeta potential of the sub-3500 Da fraction—should be added as characterization parameters, the only route by which a supramolecular contribution could enter regulatory specification.[44]

Most urgently, the field needs a **preregistered, PICO-structured non-inferiority trial**: Population—adults with a defensible Ayurvedic indication; Intervention—a GMP-manufactured extract with full process/marker/fingerprint reporting; Comparator—a fresh pharmacopoeial *Kwatha* from the same raw-material lot, double-dummy blinded; Outcomes—one patient-important primary outcome plus nested multi-analyte pharmacokinetics and safety, assessed against a justified margin and reported per CONSORT-Herbal.[45] Journals should require an "Investigational Product Characterization" section—solvent, ratio, temperature, duration, reduction endpoint, total solids, ≥2 validated markers—in future *Kwatha* trials.

12. CONCLUSION

Kwatha Kalpana sits at an unresolved scientific crossroads. Thermal-degradation kinetics, co-decoction non-additivity, and emergent colloidal chemistry support the view that prolonged boiling performs pharmaceutically consequential work that rapid, selective extraction cannot replicate; industrial energy economics and direct compositional comparisons support the opposing view that the same boiling is a correctable inefficiency.

Both readings are defensible, and neither is yet proven for an actual Ayurvedic formulation. What is not in doubt is that the field lacks the infrastructure to answer this: no standard-decoction benchmark, no validated multi-marker fingerprints for most dispensed *Kwathas*, no human pharmacokinetic bridge between decoction and derivatives, and clinical trials that do not characterize what they test. The path forward is not to choose between tradition and technology but to define, quantitatively, what a *Kwatha* actually is—in paste yield, marker transfer rate, colloidal architecture, and human systemic exposure—and hold every modern extraction platform, subcritical water extraction included, to that benchmark through tiered equivalence testing and rigorously designed non-inferiority trials.

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