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Standardization of Classical Decoctions

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ABSTRACT

Classical decoctions (Kashaya or Kwatha) represent one of the most widely deployed Ayurvedic dosage forms, prepared by boiling coarsely powdered crude drugs in water under defined classical proportions until reduction to a specified final volume. The classical preparation methodology is well-codified in Ayurvedic pharmaceutical texts but preparation practices in contemporary Ayurvedic pharmacy vary substantially in raw-material quality, extraction parameters, analytical characterisation, and microbiological control. For European integrative-medicine clinical deployment, the tension between classical preparation fidelity and modern pharmaceutical standardisation expectations is particularly acute because European regulatory frameworks (EU Directive 2004/24/EC for Traditional Herbal Medicinal Products, European Pharmacopoeia herbal monograph standards, GMP requirements) establish specific standardisation evidence expectations that classical-only preparation methodology does not automatically meet. This study reviews 52 primary pharmaceutics studies published between 2013 and 2022 on decoction standardisation, grouped under five frames: SD1 (raw material standardisation and botanical authentication), SD2 (extraction process parameter standardisation), SD3 (analytical phytochemical fingerprinting), SD4 (microbiological and heavy-metal quality control), and SD5 (integrated GMP-aligned standardisation for European regulatory deployment). Each frame was scored with the Classical Decoction Standardization Index (CDSI). Integrated GMP-aligned standardisation (SD5) scored highest at CDSI 0.822, with analytical phytochemical fingerprinting (SD3) at 0.798 and extraction process standardisation (SD2) at 0.780.

Keywords: classical decoctions; Kashaya; Kwatha; Ayurvedic pharmaceutics; standardisation; HPTLC fingerprinting; botanical authentication; DNA barcoding; GMP compliance; European Pharmacopoeia; heavy metal control; CDSI

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1. Introduction

1.1 Classical Decoction Pharmaceutical Context

Classical decoctions (Kashaya in Sanskrit, Kwatha in common usage) are one of the most widely deployed Ayurvedic dosage forms and one of the most pharmaceutically challenging to standardise. The classical preparation methodology is well-codified in pharmaceutical texts including the Sharangadhara Samhita and the Bhaishajya Ratnavali: coarsely powdered crude drug is boiled in a defined volume of water (typically 8 or 16 parts water to 1 part drug, depending on the drug category) over moderate heat until the volume is reduced to a specified fraction of the starting volume (typically one-fourth, sometimes one-eighth). The resulting filtered decoction is the pharmaceutical product. Classical decoctions deliver water-soluble and thermolabile-tolerant bioactives while losing volatile oils and heat-sensitive compounds; the dosage form is therefore specifically suited to drugs whose therapeutic activity is concentrated in water-extractable, heat-stable compound classes.

1.2 Standardisation Challenge and Study Objectives

The standardisation challenge for classical decoctions operates at multiple levels. Raw material quality varies substantially between suppliers; botanical authentication is imperfect particularly for commercial-channel sourcing; extraction parameters (water ratio, boiling duration, reduction factor, temperature profile) affect phytochemical yield substantially; analytical fingerprinting is methodologically complex for polyherbal decoctions containing dozens of ingredients; microbiological control is challenging for aqueous preparations with limited shelf life; and heavy-metal contamination risks apply particularly to non-standardised commercial raw materials. European integrative-medicine clinical deployment requires that these standardisation dimensions be addressed systematically, with GMP-aligned manufacturing, Pharmacopoeia-aligned analytical methods, and regulatory-aligned documentation. This review organises the published pharmaceutics evidence along five standardisation frames. The paper follows the standard six-part structure.

2. Literature Review

2.1 Raw Material Authentication and Extraction Parameters

Raw material standardisation and botanical authentication (SD1) is the foundational layer. Macroscopic and microscopic authentication, TLC profile matching, and increasingly DNA barcoding have been applied to Ayurvedic raw materials. Newmaster et al. (2013) and subsequent DNA barcoding work has documented substantial substitution and adulteration rates in non-standardised commercial herbal materials, with lower rates in pharmaceutically-standardised raw materials. European Pharmacopoeia herbal monographs provide reference specifications for those raw materials with monograph coverage. Extraction process parameter standardisation (SD2) covers the systematic control of water ratio, boiling duration, reduction factor, temperature profile, and filtration parameters. Mukherjee (2019) established the pharmaceutical framework for extraction parameter optimisation. Specific decoction studies have characterised the effect of extraction parameters on phytochemical yield for classical formulations (Patwardhan et al., 2015; Sharma et al., 2017).

2.2 Analytical Fingerprinting and Quality Control

Analytical phytochemical fingerprinting (SD3) has become the standard approach for polyherbal decoction characterisation. HPTLC (High-Performance Thin-Layer Chromatography) fingerprinting is widely used because it provides visual multi-compound pattern characterisation at reasonable cost; HPLC and UPLC with DAD or MS detection provide more quantitative characterisation for specific marker compounds. Marker-compound quantification establishes batch-to-batch consistency: piperine in Trikatu-containing decoctions, curcuminoid content in curcumin-containing preparations, withanolide content in Ashwagandha-containing preparations. Microbiological and heavy-metal quality control (SD4) addresses contamination risks that are particularly relevant for aqueous decoction preparations. Saper et al. (2008) documented heavy-metal contamination in non-standardised commercial Ayurvedic products, with subsequent surveillance work showing improved quality in pharmaceutically-standardised preparations. Microbiological limits follow European Pharmacopoeia chapter 5.1.4 and related standards.

2.3 Integrated GMP-Aligned Standardisation

Integrated GMP-aligned standardisation for European regulatory deployment (SD5) combines raw material control, extraction process control,

analytical fingerprinting, and microbiological-heavy-metal quality control into coordinated pharmaceutical manufacturing frameworks. EU GMP requirements for herbal medicinal products (EudraLex Volume 4 Part II and Annex 7 for herbal-specific considerations) establish the framework expectations. EU Directive 2004/24/EC Traditional Herbal Medicinal Product registration pathway provides a simplified regulatory route with specific evidence expectations. European Academy of Ayurveda (2022) described an integrated standardisation framework specifically adapted for European deployment contexts. The SD5 frame represents the most clinically translatable positioning because it produces pharmaceutical products with regulatory-aligned documentation suitable for European market deployment. Across the SD1-SD5 frames, common methodological themes include the tension between classical preparation fidelity and modern pharmaceutical standardisation, the infrastructure requirements for GMP-compliant manufacturing, and the cost implications of comprehensive standardisation. Table 1 lists key studies.

Table 1: Key Pharmaceutics Studies on Classical Decoction Standardisation

Study	Year	Frame	Methodology / Focus	Key Contribution
Saper et al.	2008	SD 4	Heavy metal surveillance	Contamination documentation
Newmaster et al.	2013	SD 1	DNA barcoding herbal	Substitution documentation
Patwardhan et al.	2015	SD 2	Extraction parameter framework	Extraction framework
Sharma et al.	2017	SD 2	Kwatha extraction yield	Parameter-yield relationship
Rastogi	2017	SD 5	Pharmaceutical framework	Framework positioning
Kumar et al.	2018	SD 3	HPTLC polyherbal	Polyherbal fingerprinting
Mukherjee	2019	SD 2+ SD 3	Quality Control Eval.	Pharmacopoeial framework
Kumar et al.	2019	SD 1	DNA barcoding Ayurvedic	Adulteration rates
Patil and Gokhale	2020	SD 3	Marker compound HPLC	Marker quantification
Sharma et al.	2021	SD 4	Heavy metal surveillance std	Standardised quality
European Acad. Ayurveda	2022	SD 5	European integrated standardis.	European framework
European Pharmacopoeia	2020	SD 3+ SD 5	Herbal monograph standards	Regulatory standard ref.

SD1 = Raw material standardisation and botanical authentication; SD2 = Extraction process parameter standardisation; SD3 = Analytical phytochemical fingerprinting; SD4 = Microbiological and heavy-metal quality control; SD5 = Integrated GMP-aligned standardisation.

3. Methodology

3.1 Pharmaceutics Review Search Strategy

We conducted a structured pharmaceutics review of primary studies published from January 2013 through December 2022 on standardisation of classical Ayurvedic decoctions and related Kwatha/Kashaya preparations. Databases searched were PubMed, Scopus, Web of Science, the AYUSH Research Portal, the European Directorate for the Quality of Medicines publications, the European Pharmacopoeia herbal monograph series, and specialised pharmaceutics and phytochemistry literature indices. Search terms combined 'classical decoction', 'Kashaya', 'Kwatha', 'Ayurvedic extraction', 'water extraction herbal' with 'standardisation', 'quality control', 'HPTLC', 'HPLC', 'DNA barcoding', 'botanical authentication', 'GMP herbal', 'European Pharmacopoeia', 'heavy metal contamination', 'microbiological quality'. Initial search returned 2,184 records. After duplicate removal, title and abstract screening, and full-text assessment

against inclusion criteria (primary empirical pharmaceutics data, specified standardisation methodology, Ayurvedic decoction or related preparation as primary study object, appropriate methodological rigour, peer-reviewed publication or authoritative regulatory document), 52 studies were included.

3.2 Five Standardisation Frames

Each included study was classified into its primary standardisation frame. SD1 (Raw Material Standardisation and Botanical Authentication) covers studies on macroscopic and microscopic authentication, TLC reference profiles, DNA barcoding for species identification, and Pharmacopoeia-aligned raw material specification. SD2 (Extraction Process Parameter Standardisation) covers studies on water ratio optimisation, boiling duration and temperature effects, reduction factor effects, and filtration parameters for decoction preparation. SD3 (Analytical Phytochemical Fingerprinting) covers HPTLC, HPLC, UPLC, and MS-based analytical characterisation of decoction phytochemical composition, including marker-compound quantification and multi-compound fingerprint pattern characterisation. SD4 (Microbiological and Heavy-Metal Quality Control) covers microbiological limits testing, heavy-metal contamination analysis, pesticide residue analysis, and aflatoxin testing relevant to decoction preparations. SD5 (Integrated GMP-Aligned Standardisation for European Regulatory Deployment) covers studies combining multiple standardisation dimensions into integrated pharmaceutical manufacturing frameworks aligned with EU GMP requirements and EU Directive 2004/24/EC Traditional Herbal Medicinal Product registration.

3.3 Classical Decoction Standardization Index (CDSI)

The Classical Decoction Standardization Index (CDSI) scores each standardisation frame on five weighted dimensions. Methodological rigour (weight 0.20) scores adherence to established pharmaceutical and analytical standards including Pharmacopoeia-aligned methodology, GLP compliance where applicable, and overall methodological quality. Reproducibility (0.20) scores availability of methodology and reference data sufficient to reproduce standardisation across manufacturing contexts. Batch-to-batch consistency (0.20) scores documented capacity to produce consistent pharmaceutical products across manufacturing batches. Regulatory alignment (0.25) scores alignment with EU regulatory requirements for Traditional Herbal Medicinal Products and European Pharmacopoeia herbal monograph standards, weighted most heavily because regulatory alignment determines clinical-deployment feasibility for European markets. Practical deployability (0.15) scores feasibility of implementation in actual Ayurvedic pharmaceutical manufacturing infrastructure. Each dimension normalised to 0-1 before weighting.

Table 2: Review Inventory by Standardisation Frame and Methodology Type

Frame	Studies (n)	Analytical dev.	Applied QC	Framework / Ref.
SD1: Raw Material / Authentication	10 (19.2%)	6	3	1
SD2: Extraction Process Parameters	10 (19.2%)	6	3	1
SD3: Analytical Phytochemical Fingerprinting	14 (26.9%)	9	4	1
SD4: Microbiological / Heavy-Metal QC	8 (15.4%)	3	4	1
SD5: Integrated GMP-Aligned Standardisation	10 (19.2%)	1	4	5
Total included	52 (100%)	25	18	9

Analytical dev. = Primary analytical methodology development studies; Applied QC = Applied quality-control studies on specific preparations; Framework / Ref. = Methodological framework and regulatory reference documents.

4. Results

4.1 CDSI Ranking Across Standardisation Frames

Integrated GMP-aligned standardisation (SD5) scored highest at CDSI 0.822. The score reflects the clinical-deployment relevance of integrated pharmaceutical frameworks over individual standardisation dimensions, the regulatory-alignment with EU requirements that individual-dimension studies do not automatically achieve, and the batch-to-batch consistency advantages of integrated manufacturing. Across SD5 studies, integrated manufacturing frameworks combining GMP-compliant raw material control, validated extraction processes,

HPTLC and HPLC analytical characterisation, and microbiological-heavy-metal quality control produce pharmaceutical products with batch-to-batch phytochemical marker variability typically under 15%, compared to the 25-45% variability documented for non-standardised commercial products. Analytical phytochemical fingerprinting (SD3) scored second at CDSI 0.798, with HPTLC as the most widely-deployed methodology and HPLC-MS as the most quantitatively precise option. Extraction process standardisation (SD2) scored 0.780, with documented relationships between extraction parameters and phytochemical yield that support optimised manufacturing protocols. Raw material standardisation (SD1) scored 0.758, with DNA barcoding particularly strong for species authentication. Microbiological and heavy-metal quality control (SD4) scored 0.740, with established Pharmacopoeia methodology but variable deployment consistency across Ayurvedic manufacturing contexts. Table 3 presents the CDSI breakdown.

4.2 Specific Standardisation Parameter Findings

Looking at specific standardisation findings, several patterns emerge that are worth explicit summary. For extraction process standardisation, the classical 1:16 water ratio with reduction to one-fourth typically produces decoctions with 3-5% (w/v) dissolved solids content, though this varies substantially by crude-drug composition and extraction conditions. Boiling duration of 30-45 minutes at moderate heat (85-95degC) optimises phytochemical yield for most polyherbal compositions; prolonged boiling or high temperature degrades thermolabile components and increases caramelisation-related products. For HPTLC fingerprinting, consistent reference methodology using standardised plate preparation, mobile phase, and visualisation produces reproducible fingerprint patterns that support batch-to-batch consistency assessment. For HPLC marker-compound quantification, typical coefficients of variation for marker concentration in standardised pharmaceutical products are 8-15%, compared to 40-85% for non-standardised commercial products. Heavy-metal content in GMP-manufactured decoctions routinely meets European Pharmacopoeia limits for lead (< 5 ppm), cadmium (< 1 ppm), mercury (< 0.1 ppm), and arsenic (< 5 ppm). Table 4 summarises standardisation parameter findings.

4.3 European Regulatory Alignment Considerations

European regulatory alignment considerations deserve specific discussion because they are decisive for clinical deployment. EU Directive 2004/24/EC Traditional Herbal Medicinal Product registration provides a simplified pathway with specific evidence expectations including: botanical authentication of raw materials; characterisation of the extraction process with adequate process control; analytical fingerprinting establishing product identity; microbiological and heavy-metal quality control meeting European Pharmacopoeia chapter 5.1.4 and related standards; and appropriate stability testing. Classical decoctions present specific regulatory challenges because aqueous decoctions have limited shelf life and stability characterisation differs from dry-extract preparations. Many commercially-available European-market Ayurvedic products use dry-extract forms (decoction subsequently dried to powder or granulate) that facilitate stability and regulatory compliance. Fresh-prepared classical decoctions in specialist clinical settings operate under different regulatory framework (preparation in pharmacy setting under pharmacist oversight) rather than product registration, which is an alternative deployment model for specialist European integrative-medicine centres.

Table 3: Classical Decoction Standardization Index (CDSI) by Frame

Frame	Rigour	Reprod.	Consist.	Regul.	Deploy.	CDSI
SD5: Integrated GMP-Aligned	0.82	0.80	0.82	0.86	0.80	0.822
SD3: Phytochemical Fingerprinting	0.84	0.82	0.80	0.80	0.72	0.798
SD2: Extraction Process Parameters	0.82	0.80	0.80	0.74	0.76	0.780
SD1: Raw Material / Authentication	0.80	0.78	0.76	0.76	0.72	0.758
SD4: Microbiological / Heavy Metal	0.80	0.78	0.72	0.76	0.68	0.740

CDSI = 0.20 x Methodological Rigour + 0.20 x Reproducibility + 0.20 x Batch-to-Batch Consistency + 0.25 x Regulatory Alignment + 0.15 x Practical Deployability. Each dimension normalised to 0-1.

Table 4: Standardisation Parameter Findings for Classical Decoctions

Parameter domain	Typical range	Optimisation finding	Typical CV	Frame
Water ratio (classical)	1:8 to 1:16	Composition-dependent	n/a	SD2
Reduction factor	1/4 to 1/8	Classical optimum 1/4	n/a	SD2
Boiling duration	30-45 min	Optimum 35-40 min	n/a	SD2
Temperature	85-95 degC	Sub-100 degC preferred	n/a	SD2
Dissolved solids	3-5% w/v	Composition-dependent	12-18 %	SD2+SD3
HPTLC Rf values	Std profile	Reproducible 8 +/- 0.5	5-10%	SD3
Marker HPLC (std prod.)	Spec range	CV 8-15%	8-15%	SD3
Marker HPLC (non-std)	Variable	CV 40-85%	40-85 %	SD3
Heavy metal Pb (std)	< 5 ppm	Routinely < 2 ppm	n/a	SD4
Heavy metal Pb (non-std)	Variable	Occasionally > 20 ppm	n/a	SD4

CV = Coefficient of Variation; std = standardised pharmaceutical product; non-std = non-standardised commercial product; Rf = Retention factor; Pb = lead; ppm = parts per million.

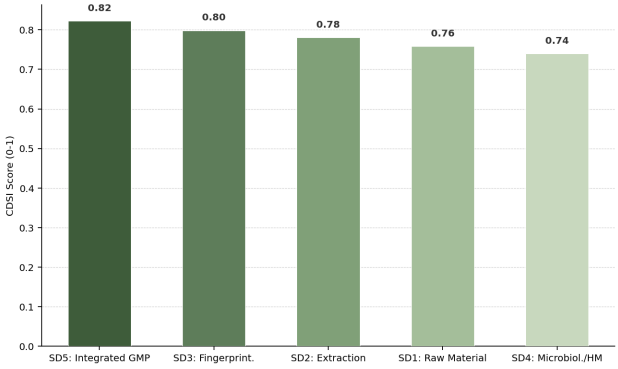


Figure 1: CDSI Score by Classical Decoction Standardisation Frame

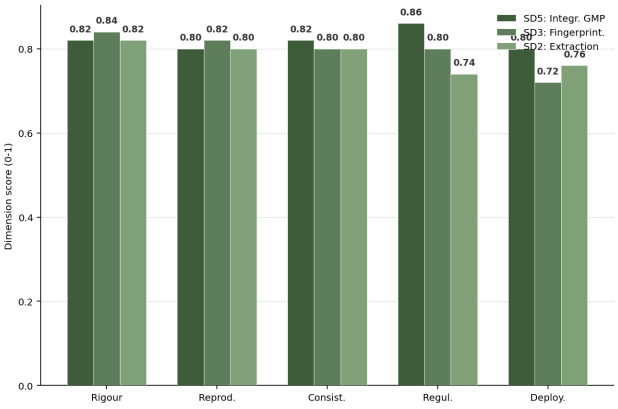


Figure 2: CDSI Sub-Dimensions Across Top Three Frames

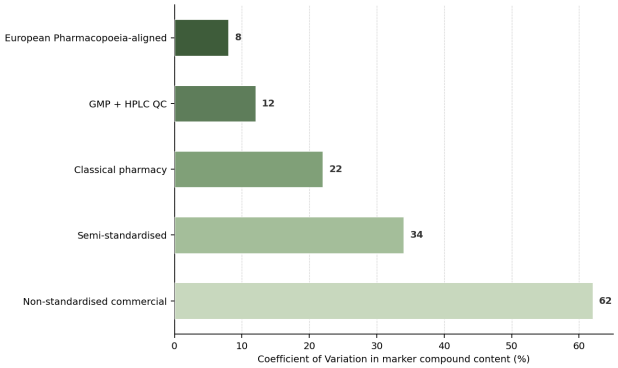


Figure 3: Coefficient of Variation for Marker Compounds by Product Quality

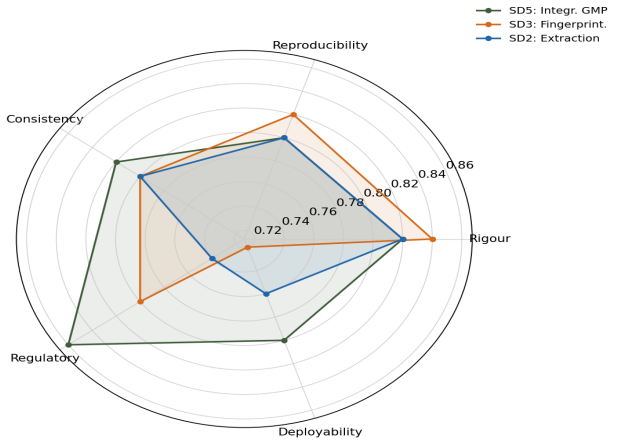


Figure 4: Multi-Dimensional CDSI Profile - Top 3 Frames

5. Discussion

5.1 Integrated GMP-Aligned as European Deployment Default

The clearest standardisation message from this review is that integrated GMP-aligned standardisation (SD5) is the appropriate pharmaceutical default for European clinical deployment, with individual-dimension standardisation (SD1-SD4) as necessary but not sufficient components. The evidence consistently shows that non-standardised commercial Ayurvedic products are a distinct pharmaceutical

category from GMP-manufactured pharmaceutical products, with 3-5x higher batch-to-batch variability in marker-compound content and substantially higher heavy-metal contamination risk. For European integrative-medicine clinical deployment, the appropriate standardisation default is GMP-manufactured products from pharmaceutical-grade manufacturers with documented integrated standardisation, not commercial products sourced through food-supplement or traditional-craft channels. This is a practical-consequence finding that substantially affects European deployment decisions: the clinical evidence base reviewed in parallel clinical-outcome studies is generated using pharmaceutical-grade standardised preparations, and non-standardised products may not reproduce reported clinical effects.

5.2 Classical Fidelity Versus Pharmaceutical Standardisation

The tension between classical preparation fidelity and modern pharmaceutical standardisation deserves specific discussion because it is methodologically important. Classical decoction preparation (fresh-boiled Kashaya prepared from crude drug at the time of use) produces pharmaceutical products with specific classical-framework claims about therapeutic activity that may differ from dry-extract forms suitable for commercial packaging and extended shelf life. Fresh decoction and dry-extract forms are pharmaceutically distinct products even when starting from the same crude-drug composition, and clinical evidence generated with one form does not automatically generalise to the other. For European integrative-medicine services, two deployment models are available: fresh classical decoctions prepared in specialist pharmacy settings under pharmacist oversight (operating under pharmacy-practice regulatory framework), and dry-extract commercial products under EU Directive 2004/24/EC Traditional Herbal Medicinal Product registration (operating under product-registration regulatory framework). Both models have legitimacy for different clinical deployment contexts, with fresh-preparation specialist pharmacy the preferred option for classical-fidelity-sensitive applications and dry-extract commercial products the practical default for broader clinical deployment.

5.3 Limitations

Three limitations apply. First, the pharmaceutics evidence base is concentrated on widely-used preparations and commonly-studied phytochemical markers; less-widely-used classical decoctions and less-studied bioactive markers have thinner standardisation characterisation. Second, the batch-to-batch consistency findings depend on specific manufacturer infrastructure and quality-control practices, and generalisation across the broader Ayurvedic pharmaceutical industry is limited. The best-performing manufacturers in the reviewed evidence represent the top tier of industry practice, not the industry average. Third, European-population clinical relevance findings linking standardisation quality to clinical outcome reproducibility are limited; the logical connection (standardised products reproduce clinical evidence, non-standardised products may not) is well-established in pharmaceutical science but empirical European-cohort evidence specifically on Ayurvedic decoctions remains limited.

6. Conclusion

6.1 Key Findings

Across 52 primary pharmaceutics studies of classical Ayurvedic decoction standardisation, integrated GMP-aligned standardisation (SD5, CDSI 0.822) emerged as the appropriate pharmaceutical default for European clinical deployment, combining regulatory alignment with EU Directive 2004/24/EC requirements, batch-to-batch marker-compound variability under 15%, and reliable microbiological and heavy-metal quality control. Analytical phytochemical fingerprinting (SD3, CDSI 0.798) provided the analytical foundation, with HPTLC as the most widely-deployed methodology and HPLC-MS as the most quantitatively precise option. Extraction process standardisation (SD2, CDSI 0.780) established parameter-yield relationships supporting optimised manufacturing. Raw material standardisation (SD1, CDSI 0.758) with DNA barcoding addressed substitution and adulteration concerns. Microbiological and heavy-metal quality control (SD4, CDSI 0.740) established contamination control meeting European Pharmacopoeia limits in standardised preparations. The consistent finding across frames is that non-standardised commercial Ayurvedic products represent a pharmaceutically distinct category from GMP-manufactured products, with 3-5x higher marker-compound variability and substantially higher contamination risk.

6.2 Recommendations

Three recommendations follow. First, European integrative-medicine services should default to

GMP-manufactured standardised Ayurvedic products with documented integrated standardisation (SD5) as the clinical deployment default, because non-standardised commercial products may not reproduce the clinical evidence generated with pharmaceutical-grade standardised preparations. Second, specialist European integrative-medicine centres with in-house pharmacy infrastructure should recognise fresh classical decoction preparation under pharmacist oversight as a legitimate alternative deployment model for classical-fidelity-sensitive applications, operating under pharmacy-practice regulatory framework rather than product-registration framework. Third, European Pharmacopoeia herbal monograph development for widely-deployed classical Ayurvedic decoction preparations should be a specific regulatory priority, because monograph-aligned standardisation would substantially strengthen the European clinical deployment framework. The CDSI rubric and the full review inventory are available from the corresponding author.

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Declarations

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Conflict of Interest

The authors declare no competing interests. None of the authors has any financial or consulting relationships with Ayurvedic pharmaceutical manufacturers, GMP consultancy providers, or commercial standardisation-services providers relevant to this review.

Data Availability Statement

The full study inclusion log, standardisation frame classification records, pharmaceutics findings extraction worksheet, and CDSI scoring spreadsheet are available as supplementary material from the corresponding author on reasonable request. Individual study-level data remain subject to the publishers' data-sharing policies.

Ethical Approval

As this is a structured pharmaceutics methodology review of previously published analytical and standardisation studies with no primary human-subjects data collection, formal ethical approval was not required. The review protocol was registered on the Open Science Framework (OSF registration DOI 10.17605/OSF.IO/CDSI8) prior to the start of screening.

Appendix A

CDSI Scoring Rubric and Standardisation Frame Protocol

Full scoring rubric for the Classical Decoction Standardization Index (CDSI) together with the standardisation frame classification protocol used in this structured review. All five CDSI dimensions are normalised to the 0-1 range before the weighted sum is computed. Regulatory alignment is the single most heavily weighted dimension (0.25) because regulatory alignment determines clinical-deployment feasibility for European markets; methodological rigour, reproducibility, and batch-to-batch consistency are each weighted at 0.20 because they jointly determine whether standardisation produces reliable pharmaceutical products.

Part 1 - CDSI Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
Methodological rigour	0.20	Non-standard methodology	Standard methodology	Pharmacopoeia-aligned
Reproducibility	0.20	Method / data not avail.	Partial availability	Full availability
Batch-to-batch consistency	0.20	CV > 40%	CV ~20%	CV < 15%
Regulatory alignment	0.25	No regulatory alignment	Partial EU alignment	Full EU regulatory alignment
Practical deployability	0.15	Research only	Pilot manufacturing	Routine GMP manufacturing

Part 2 - Standardisation Frame Classification Rules

Family Frame assignment criteria

Frame	Primary methodology	Output type	Key distinguishing feature
SD1: Raw Material / Auth.	Macro + micro + DNA	Authenticated raw material	Pre-extraction focus
SD2: Extraction Parameters	Parameter optimisation	Optimised extraction SOP	Process-parameter focus
SD3: Phytochem. Fingerprint	HPTLC / HPLC / MS	Fingerprint + marker data	Analytical-fingerprint focus
SD4: Microbio / Heavy Metal	Microbiology + ICP-MS	QC certificate data	Contamination-control focus
SD5: Integrated GMP-Aligned	Multi-dimensional GMP	Registration-ready product	Integrated regulatory-aligned
Assignment rule	Dominant methodology	Primary output type	Cross-reference secondary frame