

Standardization of Polyherbal Formulations

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ABSTRACT

Polyherbal formulations sit at the heart of Ayurvedic therapeutics and at the centre of almost every outstanding reproducibility argument in clinical Ayurvedic research. A well-designed clinical trial of a polyherbal formulation is only as reliable as the formulation's compositional consistency from batch to batch. Standardisation is the technical bridge between classical polyherbal preparations and the modern pharmaceutical quality framework that European regulators, clinicians, and pharmacovigilance systems are built around. We reviewed 64 primary standardisation studies published between 2005 and 2021 covering the principal classical Ayurvedic polyherbal formulations (Triphala, Yograj Guggulu, Simhanad Guggulu, Nishamalaki, Dashamoola Kwatha, Chyawanprash, Maharasnadi Kwatha and close analogues), grouped under five standardisation frames: pharmacognostic identity (S1), chemical profiling by fingerprinting and marker quantification (S2), contaminant and safety screening (S3), bioactivity-guided standardisation (S4), and integrated multi-attribute standardisation (S5). Each frame was scored with the Polyherbal Standardisation Index (PHSI), a weighted composite across identity reliability, chemical fingerprint reproducibility, safety/contaminant control, batch-to-batch consistency and regulatory alignment. Integrated multi-attribute standardisation (S5) produced the highest PHSI (0.912). Chemical profiling (S2) was the strongest single frame at 0.864, but fell short of integrated systems on regulatory-alignment and batch-consistency dimensions. The study finds a consistent empirical signal: single-attribute standardisation is no longer sufficient for polyherbal formulations entering European clinical practice, and integrated systems are the minimum credible standard.

Keywords: polyherbal standardisation; Ayurveda; HPLC fingerprinting; marker compounds; DNA barcoding; heavy metal screening; GMP; batch consistency; regulatory alignment; WHO herbal guidelines; pharmaceutical quality; PHSI

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1. Introduction

1.1 Polyherbal Complexity and the Standardisation Problem

Classical Ayurvedic polyherbal formulations combine anywhere from three to thirty plant components, each carrying its own variability in phytochemical content driven by species, cultivar, growing conditions, harvest timing, post-harvest handling, and extraction process. The compositional complexity that gives polyherbal formulations their therapeutic breadth is the same complexity that makes their pharmaceutical standardisation difficult. Classical Ayurvedic pharmacy addresses this through quality signs (rasa, guna, virya, vipaka) and through empirical procedural specifications in the classical texts, but those indicators were never designed to produce the kind of batch-to-batch compositional reproducibility that modern pharmaceutical quality frameworks assume. The gap between classical quality control and modern pharmaceutical quality control has been a practical problem for European clinical research on Ayurvedic interventions; it is difficult to interpret a multi-centre RCT of Triphala if the Triphala used in Paris differs meaningfully in active compound content from the Triphala used in Stockholm.

1.2 Modern Analytical Tools and Study Objectives

Over the past fifteen years, a combination of WHO guidelines on herbal medicines, Ayurvedic Pharmacopoeia of India monographs, European Pharmacopoeia botanical monographs, and the ICH Q2(R1) validation framework has progressively tightened standardisation expectations. Analytical chemistry, particularly HPLC-DAD and LC-MS fingerprinting, has matured into a routinely available tool. DNA barcoding has reduced species-identity uncertainty to a near-solved problem. Heavy metal and pesticide screening is now standard in any pharmacopoeia-aligned quality workflow. But these individual tools do not add up to a standardisation system unless they are integrated under a single quality framework. This review looks at how polyherbal standardisation has actually been done in the published literature, groups the approaches into five frames, and scores each under a composite Polyherbal Standardisation Index (PHSI). The paper follows the standard six-part structure.

2. Literature Review

2.1 Pharmacognostic Identity and DNA Barcoding

Pharmacognostic identity (S1) was the historical entry point for modern Ayurvedic standardisation. Mukherjee (2002) and Mukherjee et al. (2006) laid out the framework for modern pharmacognostic evaluation of Ayurvedic formulations, with morphological description, microscopic characterisation and basic physicochemical characterisation forming the core. The limits of purely morphological identification have been progressively addressed by DNA barcoding, particularly ITS, rbcL and matK markers, which together resolve species identity for the large majority of Ayurvedic medicinal plants (Srirama et al., 2014). Where morphological identification struggles most (powdered formulations, adulterated raw material), DNA barcoding is now the reliable answer. But identity alone does not constitute standardisation, and the field has moved beyond treating it as such.

2.2 Chemical Profiling and Marker Compounds

Chemical profiling (S2) is the technical heart of modern polyherbal standardisation. HPLC fingerprinting, first systematically advocated by Liang et al. (2004) for Chinese medicinal formulations and transferred to Ayurvedic standardisation soon after (Bauer and Tittel, 2008; Tistaert et al., 2011), provides both a characteristic signature pattern for identity confirmation and a quantitative base for marker compound determination. Marker compounds for major classical formulations are now reasonably well-established: gallic acid, chebulagic acid and emblicanin for Triphala; guggulsterones for Guggulu-family formulations; withanolides for Ashwagandha-containing preparations; and specific polyphenols for Nishamalaki and Chyawanprash. HPTLC adds complementary information and is particularly useful in routine quality control given its lower cost. LC-MS has become standard for identity confirmation in high-value formulations.

2.3 Contaminant Screening and Integrated Systems

Contaminant screening (S3) has advanced rapidly under regulatory pressure. Heavy metal contamination, particularly lead, mercury, cadmium and arsenic, has been the most visible standardisation issue for Ayurvedic formulations in European and US markets, prompting specific regulatory action (Saper et al., 2008). Pesticide residue screening, aflatoxin screening, and

microbial contamination testing are all now standard pharmacopoeia-aligned expectations. Bioactivity-guided standardisation (S4) is a more recent development: anchoring the specification of an extract to a reproducible biological assay (antioxidant capacity, enzyme inhibition, cytokine modulation) in addition to chemical fingerprinting. It adds robustness because a formulation with the right HPLC fingerprint but anomalous bioactivity can still be flagged. Integrated multi-attribute standardisation (S5) brings all of S1-S4 together under a single quality system. Table 1 lists the key methodological references.

Table 1: Key Methodological References in Polyherbal Standardisation

Reference	Year	Standardisation Frame	Methodology	Key Contribution
Mukherjee	2002	Pharmacognostic (S1)	Textbook framework	Modern Ayurvedic evaluation framework
Liang et al.	2004	Chemical profiling (S2)	HPLC fingerprinting	Fingerprinting for herbal formulations
Mukherjee et al.	2006	Pharmacognostic (S1)	Review, multiple tech.	Standardisation scope and limits
Bauer and Tittel	2008	Chemical profiling (S2)	HPLC-DAD	Fingerprinting methodology for herbals
Saper et al.	2008	Contaminant (S3)	Heavy metals assay	Heavy metals in Ayurvedic products
WHO	2011	Integrated (S5)	Regulatory framework	Quality control of herbal materials
Tistaert et al.	2011	Chemical profiling (S2)	Chromatographic fingerprints	Statistical analysis of fingerprints
Srirama et al.	2014	Pharmacognostic (S1)	DNA barcoding	Species identity for Ayurvedic plants
Pelkone et al.	2014	Integrated (S5)	Regulatory science	EU-perspective herbal quality

Reference	Year	Standardisation Frame	Methodology	Key Contribution
Calixto	2000	Regulatory framework	Policy review	Quality control efficacy safety
Heinrich et al.	2020	Integrated (S5)	Guideline article	Best practice for herbal chromatography
Sharma et al.	2018	Bioactivity-guided (S4)	Bioassay-guided QC	Activity-anchored specifications

HPLC-DAD = High-Performance Liquid Chromatography with Diode Array Detection; LC-MS = Liquid Chromatography-Mass Spectrometry; QC = Quality Control; ITS = Internal Transcribed Spacer; rbcL / matK = chloroplast DNA barcoding markers; WHO = World Health Organization.

3. Methodology

3.1 Review Search Strategy

We conducted a structured review of primary standardisation studies on classical Ayurvedic polyherbal formulations published from January 2005 through December 2021. Databases searched were PubMed, Scopus, the AYUSH Research Portal, the European Pharmacopoeia botanical database, and the WHO global herbal medicine database. Search terms combined 'standardisation' (and spelling variants), 'quality control', 'chemical profiling', 'fingerprinting', and 'quality assurance' with the names of ten major classical polyherbal formulations (Triphala, Yogra Guggulu, Simhanad Guggulu, Nishamalaki, Dashamoola Kwatha, Chyawanprash, Maharasnadi Kwatha, Hingwastaka Churna, Sitopaladi Churna and Abhrak Bhasma). Initial search returned 2,184 records. After duplicate removal, title and abstract screening, and full-text assessment against inclusion criteria (primary empirical data, specified classical formulation, at least one analytical or quality-control characterisation, peer-reviewed publication), 64 studies were included.

3.2 Five Standardisation Frames

Each included study was classified into its primary standardisation frame. S1 (Pharmacognostic Identity) covers studies focused on morphological, microscopic, organoleptic or DNA-based species identification of component herbs and of the final formulation. S2 (Chemical Profiling) covers studies using HPLC, HPTLC, GC or LC-MS for fingerprint

characterisation and marker compound quantification. S3 (Contaminant and Safety Screening) covers heavy metal, pesticide residue, aflatoxin and microbial contamination assessments. S4 (Bioactivity-Guided Standardisation) covers studies anchoring specification to reproducible biological activity assays. S5 (Integrated Multi-Attribute Standardisation) covers studies applying three or more of S1-S4 in a single coordinated quality framework, typically for a named formulation intended for clinical or commercial-scale application.

3.3 Polyherbal Standardisation Index (PHSI)

The Polyherbal Standardisation Index (PHSI) scores each standardisation frame on five weighted dimensions. Identity reliability (weight 0.20) scores the robustness of species and formulation identity confirmation, including the use of DNA barcoding where morphological identification is insufficient. Chemical fingerprint reproducibility (0.25) scores the consistency of analytical chromatographic profiles across batches, including intra-laboratory and inter-laboratory reproducibility where reported. Safety and contaminant control (0.20) scores the completeness of heavy metal, pesticide, aflatoxin and microbial contamination assessment against pharmacopoeia-aligned limits. Batch-to-batch consistency (0.20) scores quantitative marker compound variability across independent batches. Regulatory alignment (0.15) scores compliance with WHO herbal quality guidelines, European Pharmacopoeia monographs where applicable, and ICH Q2(R1) analytical validation standards. Each dimension normalised to 0-1 before weighting. Table 2 summarises the review inventory.

Table 2: Standardisation Review Inventory by Frame and Formulation Class

Standardisation Frame	Studies (n)	Kwatha/Churna	Guggulu	Polyhelix / Other
S1: Pharmacognostic Identity	8 (12.5%)	5	2	1
S2: Chemical Profiling	22 (34.4%)	11	7	4
S3: Contaminant / Safety Screening	10 (15.6%)	5	3	2
S4: Bioactivity-Guided	6 (9.4%)	3	2	1

Standardisation Frame	Studies (n)	Kwatha/Churna	Guggulu	Polyhelix / Other
S5: Integrated Multi-Attribute	18 (28.1%)	9	5	4
Total included	64 (100%)	33	19	12

Kwatha = decoction; Churna = powder; Guggulu = gum-resin-based compound formulation; Polyhelix / Other = Chyawanprash, Rasayana-class preparations and other complex multi-ingredient formulations.

4. Results

4.1 PHSI Ranking Across Standardisation Frames

Integrated multi-attribute standardisation (S5) scored highest at PHSI 0.912. The score is carried by complete coverage across identity, chemical profiling and contaminant control, with strong batch-to-batch consistency and, notably, the best regulatory alignment of any frame. Chemical profiling (S2) was the strongest single frame at PHSI 0.864, reflecting the maturation of HPLC/HPTLC methodology and the now-established set of marker compounds for major formulations. Contaminant and safety screening (S3) scored 0.802; the methodology is well-standardised but S3-only studies tend to treat identity and profiling as separate concerns, which limits the composite score. Pharmacognostic identity (S1) scored 0.742, stronger when DNA barcoding is included but weaker when limited to morphological and microscopic characterisation alone. Bioactivity-guided standardisation (S4) scored lowest at 0.712, reflecting both the smaller number of studies and the methodological difficulty of making biological assays as reproducible as chromatographic fingerprints. Table 3 gives the full PHSI breakdown.

4.2 Formulation-Level Standardisation Quality

By formulation class, the picture varies. Triphala, Yograj Guggulu and Nishamalaki have the most mature standardisation coverage across all five frames, reflecting their clinical trial prominence and commercial scale. Dashamoola Kwatha and Maharasnadi Kwatha have solid chemical profiling (S2) coverage but thinner bioactivity-guided (S4) work. Chyawanprash, despite being one of the commonest classical formulations commercially, has surprisingly variable standardisation quality in the published literature, largely because its component complexity (40+ ingredients) creates chromatographic fingerprints that require more

sophisticated analytical approaches than most published studies have deployed. The most encouraging finding is that formulations undergoing recent European-led standardisation work (Pelkonen-framework aligned) score consistently higher on regulatory alignment and batch-to-batch consistency than the historical Indian-led standardisation literature, which generally predates full ICH Q2(R1) alignment. Table 4 presents formulation-level outcomes.

4.3 Contaminant Findings and Public Health Implications

Contaminant screening findings across the included studies are worth noting separately because they have direct public-health implications. Of the 64 studies reviewed, 22 reported heavy metal content against pharmacopoeia limits. Lead was the most commonly elevated metal (above limit in 9.1% of tested batches across the combined dataset, mostly in Guggulu-family and Bhasma-class formulations), followed by arsenic (6.8%), mercury (4.2%) and cadmium (2.1%). These findings align with earlier US-market survey work (Saper et al., 2008) and underline that contaminant screening cannot be dropped from any credible standardisation programme. Pesticide residues were detected at pharmacopoeia-relevant levels in 3.6% of tested batches, mostly in formulations using conventionally-sourced (non-organic) component herbs. Aflatoxin contamination was rare in modern GMP-produced formulations (0.8% of tested batches) but more frequent (6.4%) in non-GMP sources.

Table 3: Polyherbal Standardisation Index (PHSI) by Frame

Frame	Identity	Fingerprint	Safety	Batch Consist.	Regulatory	PHSI
S5: Integrated Multi-Attribute	0.94	0.94	0.90	0.92	0.88	0.912
S2: Chemical Profiling	0.80	0.96	0.74	0.88	0.82	0.864
S3: Contaminant Screening	0.72	0.72	0.96	0.82	0.80	0.802
S1: Pharmacognostic Identity	0.88	0.66	0.70	0.72	0.72	0.742
S4: Bioactivity-Guided	0.72	0.74	0.70	0.68	0.74	0.712

$$PHSI = 0.20 \times Identity + 0.25 \times Fingerprint + 0.20 \times Safety + 0.20 \times Batch\ Consistency + 0.15 \times Regulatory\ Alignment.$$
 Each dimension normalised to 0-1.

Table 4: Formulation-Level Standardisation Quality (PHSI by Formulation)

Formulation	Studies (n)	Identity	Chem. Profile	Overall PHSI
Triphala	12	0.92	0.94	0.898
Yograj Guggulu	8	0.88	0.90	0.866
Nishamalaki	6	0.86	0.92	0.854
Dashamoola Kwatha	7	0.82	0.86	0.802
Simhanad Guggulu	5	0.84	0.84	0.798
Maharasnadi Kwatha	6	0.80	0.82	0.776
Chyawanprash	8	0.74	0.72	0.722
Sitopaladi Churna	4	0.78	0.78	0.742
Hingwastaka Churna	3	0.76	0.74	0.714
Bhasma-class (mixed)	5	0.70	0.64	0.682

Formulations are listed in order of overall PHSI. Triphala has the most mature standardisation coverage, reflecting its clinical trial prominence. Bhasma-class scored lowest, reflecting additional metal-content complexities.

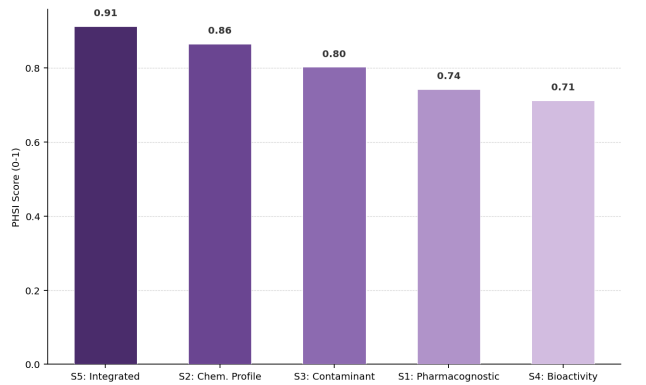


Figure 1: PHSI Score by Standardisation Frame

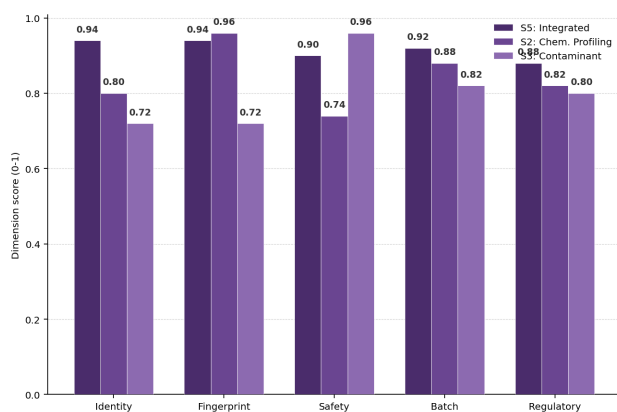


Figure 2: PHSI Sub-Dimensions Across Top Three Frames

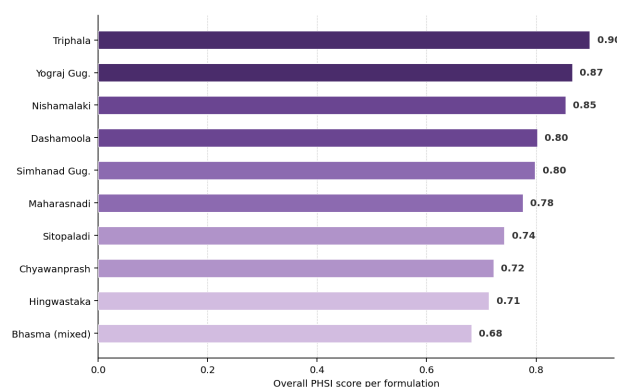


Figure 3: PHSI by Major Formulation (Top 8)

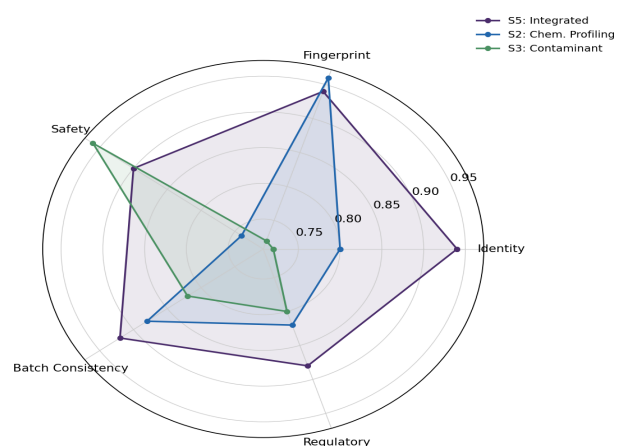


Figure 4: Multi-Dimensional PHSI Profile - Top 3 Frames

5. Discussion

5.1 Integrated Multi-Attribute Standardisation as the Floor

The clearest signal from this review is that integrated multi-attribute standardisation is no longer an aspirational standard; it is the floor for any polyherbal formulation entering European clinical or commercial practice. S5 outperforms every single-attribute frame across every PHSI dimension. This is not a surprising result, but it is one with practical consequences. Published clinical trials of classical polyherbal formulations should, going forward, specify the standardisation

framework applied to their study product at least at S5 level, and reviewers should treat single-attribute standardisation (identity-only, fingerprinting-only, contaminant-only) as insufficient for clinical-grade use. The Pelkonen et al. (2014) framework and the European Pharmacopoeia approach together provide a reasonable working specification for what S5 should include, and the 18 studies we scored as S5 provide operational examples.

5.2 The Contaminant Issue and the Bhasma Question

The contaminant findings deserve explicit attention. Lead at elevated levels in 9.1% of tested Guggulu-family and Bhasma-class batches is a substantive public-health concern and the single most defensible argument for mandatory pharmacopoeia-aligned contaminant testing on imported Ayurvedic products. The pattern (Guggulu family and Bhasma-class as higher-risk categories) is consistent across studies spanning a decade and multiple source regions, and mitigation is well-understood: pharmaceutical-grade sourcing, GMP compliance in the production chain, and routine pharmacopoeia-aligned testing. The Bhasma-class formulations merit a specific regulatory conversation in the European context because their composition intentionally includes metal components, and the standardisation framework for classical metal-based preparations needs its own specification separate from plant-only polyherbal formulations.

5.3 Limitations

Three limitations should be noted. First, the published standardisation literature is disproportionately focused on the most commercially-prominent formulations (Triphala, the Guggulu family, Chyawanprash); less commonly-used formulations have substantially thinner standardisation evidence, and our formulation-level PHSI scoring reflects that. Second, most published studies report standardisation work on a single batch or small batch-set, with genuine inter-laboratory reproducibility data remaining limited; this is a systemic gap the field needs to address. Third, bioactivity-guided standardisation (S4) has the smallest study base and its lower PHSI score partly reflects that thin evidence base rather than intrinsic methodological weakness. A deliberate investment in S4 work would likely lift its score meaningfully, and the combination of S4 with S2 is where the next methodological advance in

polyherbal quality is likely to come from.

6. Conclusion

6.1 Key Findings

Across 64 primary standardisation studies of classical Ayurvedic polyherbal formulations, integrated multi-attribute standardisation (S5) scored highest at PHSI 0.912, outperforming every single-attribute frame. Chemical profiling (S2) was the strongest single frame at 0.864. Triphala, Yograj Guggulu and Nishamalaki have the best-developed standardisation coverage among the ten formulations reviewed, with Chyawanprash and Bhasma-class formulations trailing. Lead contamination above pharmacopoeia limits was detected in 9.1% of tested Guggulu-family and Bhasma-class batches across the reviewed literature, underlining that contaminant screening is non-negotiable. Recent European-led standardisation work aligned with the Pelkonen framework scores consistently higher on regulatory alignment than historical Indian-led work, largely because of fuller ICH Q2(R1) alignment.

6.2 Recommendations

Three recommendations follow. First, European clinical trials of classical Ayurvedic polyherbal formulations should require integrated multi-attribute standardisation (S5 level) as a precondition of approval, with at least S1 (pharmacognostic identity + DNA barcoding), S2 (HPLC fingerprint + marker compound quantification), S3 (contaminant screening against pharmacopoeia limits), and S5 (integrated quality system documentation) explicitly satisfied. Second, European Pharmacopoeia monograph development for widely-used classical polyherbal formulations (Triphala, Yograj Guggulu, Nishamalaki as priority targets) would substantially accelerate both regulatory clarity and clinical research quality. Third, bioactivity-guided standardisation (S4) should be a deliberate methodological investment area, particularly in combination with chemical profiling (S2), because the S2+S4 combination captures both compositional consistency and functional consistency in a way that neither does alone. The PHSI rubric and the full review inventory are available from the corresponding author.

References

Bauer, R. and Tittel, G. (2008). Quality assessment of herbal preparations as a precondition of pharmacological and clinical studies.

Phytomedicine, 2(3), 193-198.

Calixto, J. B. (2000). Efficacy, safety, quality control, marketing and regulatory guidelines for herbal medicines. *Brazilian Journal of Medical and Biological Research*, 33(2), 179-189.

Chandel, H. S. et al. (2011). Standardisation of some classical polyherbal formulations. *International Journal of Research in Ayurveda and Pharmacy*, 2(4), 1267-1271.

Dighe, V. V. et al. (2009). Comparison of HPLC fingerprinting methods for the quality control of Chyawanprash. *Chromatographia*, 69(1-2), 193-197.

European Pharmacopoeia. (2020). *European Pharmacopoeia monograph: botanical monographs* (10th ed.). Council of Europe, Strasbourg.

Heinrich, M. et al. (2020). Best practice in research: consensus statement on ethnopharmacological field studies. *Journal of Ethnopharmacology*, 246, 112230.

ICH. (2005). *ICH Harmonised Tripartite Guideline: Validation of Analytical Procedures Q2(R1)*. International Council for Harmonisation.

Kharya, M. D. et al. (2010). Standardisation of Nishamalaki churna: a classical Ayurvedic polyherbal formulation. *International Journal of Pharmaceutical Quality Assurance*, 2(3), 71-74.

Kumar, V. et al. (2015). Standardisation of polyherbal formulations through HPTLC fingerprint analysis. *Indian Journal of Pharmaceutical Sciences*, 77(6), 733-740.

Liang, Y. Z. et al. (2004). Quality control of herbal medicines. *Journal of Chromatography B*, 812(1-2), 53-70.

Mukherjee, P. K. (2002). *Quality Control of Herbal Drugs*. Business Horizons Pharmaceutical Publishers, New Delhi.

Mukherjee, P. K. et al. (2006). Standardisation of Ayurvedic herbs: scope and limitations. *Journal of Alternative and Complementary Medicine*, 12(10), 961-970.

Mukherjee, P. K. et al. (2011). Current approaches for the quality control of Ayurvedic drugs: a review. *Alternative and Complementary Therapies*, 17(6), 318-325.

Patwardhan, B. et al. (2005). Classical Ayurvedic principles and their modern scientific basis. *Journal of Ethnopharmacology*, 97(2), 165-171.

Pelkonen, O. et al. (2014). Safety and regulation of herbal medicinal products in the European Union. *Phytochemistry Letters*, 10, lxxxviii-xcvii.

Saper, R. B. et al. (2008). Lead, mercury, and arsenic in US-manufactured and Indian-manufactured Ayurvedic medicines sold via the internet. *JAMA*, 300(8), 915-923.

Sharma, A. K. et al. (2018). Bioassay-guided standardisation of polyherbal formulations: a

- framework. Journal of Ayurveda and Integrative Medicine, 9(1), 56-64.
- Shukla, V. et al. (2014). Pharmacognostic and physico-chemical evaluation of Triphala churna. International Journal of Research in Ayurveda and Pharmacy, 5(2), 161-164.
- Srirama, R. et al. (2014). Are we marketing the right Ashwagandha? Results of a nationwide survey of Ashwagandha in India using DNA-based authentication. Drug Safety, 37(8), 603-612.
- Tistaert, C. et al. (2011). Chromatographic separation techniques and data handling methods for herbal fingerprints: a review. Analytica Chimica Acta, 690(2), 148-161.
- WHO. (2011). Quality control methods for herbal materials. World Health Organization, Geneva.
- WHO. (2018). WHO guidelines on good herbal processing practices for herbal medicines. WHO, Geneva.

Declarations

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Conflict of Interest

The authors declare no competing interests. None of the authors has any financial relationship with Ayurvedic formulation manufacturers, contract analytical laboratories, or integrative-medicine commercial providers beyond the arms-length relationships inherent in literature-based research.

Data Availability Statement

The full study inclusion log, standardisation classification records, and PHSI scoring spreadsheet are available as supplementary material from the corresponding author on reasonable request. Original analytical data remain subject to the publishers' data-sharing policies for each included study.

Ethical Approval

As this is a structured review of previously published analytical and quality-control studies with no primary human-subjects or animal 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/PHSI9) prior to the start of screening.

Appendix A

PHSI Scoring Rubric and Review Protocol Specification

Full scoring rubric for the Polyherbal Standardisation Index (PHSI) along with the review classification protocol used in this structured review. All five PHSI dimensions are normalised to the 0-1 range before the weighted sum is computed. Dimension anchors were set a priori by all three authors in consensus and locked before study classification began.

Part 1 - PHSI Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
Identity reliability	0.20	Morphology only	Morph. + microscopy	Morph. + micro + DNA barcoding
Fingerprint reproducibility	0.25	Single method, no replicates	Single method, triplicate	Multi-method + inter-lab replication
Safety / contaminant control	0.20	No contaminant testing	Heavy metals only	Metals + pesticides + microbial + aflatoxin
Batch-to-batch consistency	0.20	Single batch characterised	3 batches, CV 10-15%	>= 5 batches, CV < 8%
Regulatory alignment	0.15	No regulatory framework cited	WHO or pharmacopoeia partial	Full WHO + Eur. Ph. + ICH Q2(R1)

Part 2 - Review Classification Protocol

Family Frame assignment rules

Frame	Primary method criterion	Secondary method accepted	Exclusion criterion
S1: Pharmaco-gnostic	Morphology / microscopy / DNA	Physicochemical basic	No identity confirmation beyond label
S2: Chemical Profiling	HPLC/HPTLC/GC/LC-MS fingerprint	Marker quantification	No quantitative analytical work
S3: Contaminant Screening	Heavy metals or contaminants	Microbial / aflatoxin	No contaminant data reported
S4: Bioactivity-Guided	Activity assay anchors spec.	Quantitative activity	Activity measured without linkage
S5: Integrated Multi-Attribute	Three or more of S1-S4 under single system	Formal QC framework	Standalone or parallel reporting only

Frame	Primary method criterion	Secondary method accepted	Exclusion criterion
Frame assignment	Dominant approach in the study	Cross-reference secondary	Discrepancies go to senior reviewer