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PHYTOPREPARATIONS AND MODERN TECHNOLOGIES

Usmonova Malikakhon Komiljon kizi
Acting Associate Professor (PhD),
Department of Pharmaceuticals and Chemistry,
Alfraganus University, Tashkent, Uzbekistan
e-mail: m.usmonova@afu.uz
Orcid: https//orcid.org/0009-0008-0644-4426

Abstract

This article examines how modern technologies reshape the development, standardization, and clinical translation of phytopreparations used in contemporary healthcare. The aim is to synthesize technological solutions that improve reproducibility, efficacy, and safety of plant-derived medicines while preserving their multicomponent therapeutic nature. A structured review-design methodology was applied, combining comparative analysis of quality control approaches, technology readiness assessment, and a conceptual mapping of the phytopharmaceutical value chain from cultivation to finished dosage forms. The scientific novelty lies in an integrated framework that links phytochemical fingerprinting, process analytical technologies, and advanced delivery systems into a unified quality-by-design logic tailored to phytopreparations. The practical significance is demonstrated through technologized pathways for reducing batch-to-batch variability and controlling contaminants, with emphasis on scalable extraction, chromatographic standardization, and digital traceability. The findings support evidence-oriented modernization without reducing phytopreparations to single-marker products.

Keywords: (English) phytopreparations; standardization; modern technologies; chromatographic fingerprinting; nanoencapsulation; quality by design; digital traceability.

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Introduction

Phytopreparations can be defined as medicinal products whose therapeutic activity is derived from biologically active constituents of plants, typically present as complex mixtures rather than isolated single molecules. The central mechanism that makes them clinically attractive is the synergistic and additive interaction of multiple phytochemical classes, including phenolics, terpenoids, alkaloids, and polysaccharides, which can modulate several biochemical targets simultaneously. For example, extracts of Hypericum perforatum combine naphthodianthrones and flavonoids that influence neurotransmitter reuptake and oxidative stress pathways, illustrating why many phytopreparations occupy a niche between traditional remedies and conventional drugs. At the same time, the global herbal medicines market has been estimated at roughly USD 170–200 billion in the early 2020s, while inter-batch variability in marker compounds of commercial products frequently exceeds 20–30 percent, which undermines reproducibility and confidence. From a scientific perspective, this tension indicates that phytopreparations require modernization not by abandoning complexity but by controlling it through robust technology, metrology, and clinically anchored specifications consistent with contemporary regulatory science [1; 2].

Modern technologies in this context can be defined as advanced analytical, manufacturing, and digital tools that quantify, control, and document critical attributes along the phytopharmaceutical value chain. The mechanism by which these technologies improve outcomes is by converting botanical variability, processing uncertainty, and storage instability into measurable parameters that can be managed using standardized workflows and feedback control. For instance, high-performance liquid chromatography coupled with diode-array detection or mass spectrometry allows multi-component fingerprinting, while near-infrared spectroscopy can provide rapid in-line estimation of moisture and key constituents during drying and blending. Empirically, pharmacopeial monographs increasingly incorporate chromatographic identity tests, and industrial adoption of process analytical technology has been associated with measurable reductions in out-of-specification batches, sometimes by 30–50

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percent when properly integrated with statistical process control. Scientifically, these developments align with the quality-by-design paradigm, where product performance is linked to critical quality attributes and critical process parameters rather than end-product testing alone, a shift that is particularly consequential for multicomponent botanical products [3].

The present study addresses the problem that phytopreparations often enter practice with incomplete standardization strategies that rely on one or two marker compounds, despite evidence that therapeutic activity can depend on broader chemical space. The mechanism underlying this gap is historical: traditional quality control favored simple assays, while modern regulatory and clinical expectations demand reproducible pharmacology, contaminant control, and traceability across globalized supply chains. A representative example is a ginkgo extract standardized only to total flavone glycosides and terpene lactones, which may still vary significantly in minor constituents that influence bioavailability or safety, such as ginkgolic acids. In measurable terms, differences in extraction solvents and plant provenance can yield two- to fivefold changes in selected minor compounds even when headline markers meet specification. Scientifically, the gap suggests that phytopreparation modernization should integrate holistic fingerprinting, mechanistic bioassays, and advanced formulation technologies to ensure that "sameness" reflects clinically meaningful attributes rather than convenient surrogates [4; 5]. Accordingly, the aim of this article is to develop an integrated IMRAD-structured synthesis of technological solutions for phytopreparations, with objectives to map key technological nodes, propose a QbD-oriented framework, and identify measurable indicators for improved reproducibility and safety, thereby providing scientific novelty in the form of an end-to-end modernization logic and practical relevance for manufacturing and regulation.

Materials and Methods

The research design can be defined as a structured narrative review with an explicit analytical framework, oriented toward technology integration rather than exhaustive bibliometric enumeration. The mechanism of this approach is to

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combine comparative analysis, conceptual modeling, and technology readiness reasoning to generate a coherent set of recommendations that can be operationalized in phytopharmaceutical development. As an example, analytical platforms were grouped into identity, purity, potency, and stability domains, while manufacturing technologies were grouped into extraction, concentration, drying, and formulation domains, enabling cross-linking between process parameters and quality attributes. Quantitatively, the framework emphasized measurable endpoints such as chromatographic similarity indices, acceptance ranges for marker ratios, contaminant thresholds aligned with pharmacopeial expectations, and stability-indicating degradation rates expressed as percentage loss per month under accelerated conditions. Scientifically, this method is appropriate because phytopreparations are systems-level products where technological value emerges from integration, and thus interpretive synthesis can be more informative than isolated comparisons of individual instruments or unit operations [6].

The data sources can be defined as international regulatory and pharmacopeial concepts, peer-reviewed research on botanical analytics and delivery systems, and methodological literature on QbD and process analytical technology. The mechanism for ensuring rigor was triangulation: claims about analytical or manufacturing impact were included only when consistent across multiple strands of evidence, such as alignment between regulatory expectations and independent laboratory demonstrations. For instance, the conceptual model required that any proposed critical quality attribute be measurable by at least one validated technique, such as LC-MS fingerprinting, GC-MS residual solvent profiling, ICP-MS elemental impurity analysis, or qPCR-based authentication for selected taxa. Numerically, the synthesis prioritized technologies that can reach limits of detection relevant for safety, including heavy metals in the low parts-per-million range and pesticide residues in the parts-per-billion range, because these thresholds often determine real-world compliance. Scientifically, this emphasis reflects the reality that phytopreparations are frequently challenged not only by potency variability but also by contaminant risk driven by agricultural and environmental factors [2; 6].

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Analytical and conceptual procedures were defined as three sequential steps: value-chain mapping, identification of critical sources of variability, and selection of modern technology interventions with measurable performance indicators. The mechanism of value-chain mapping is to represent how raw material decisions propagate into finished product attributes, making causal pathways explicit and testable. For example, variability in drying temperature can shift the ratio of glycosides to aglycones via hydrolysis, which then affects dissolution profiles and potentially pharmacokinetics, illustrating the need for in-process monitoring. Quantitatively, the article uses indicative metrics such as relative standard deviation for marker content, similarity coefficients for fingerprints, extraction yield in percent mass/mass, and encapsulation efficiency for delivery systems, because these are the parameters that can be incorporated into specifications and control strategies. Scientifically, the procedure is consistent with QbD, where understanding and control of variability is foundational, and it is particularly suitable for phytopreparations because botanical heterogeneity is inherent and cannot be eliminated, only managed within justified boundaries [3; 7].

Results

Phytochemical standardization is defined here as ensuring consistent chemical identity and composition within justified limits that correlate with therapeutic function and safety. The mechanism enabling modern standardization is multi-dimensional fingerprinting combined with chemometrics, where a product is characterized by a pattern of peaks or spectral features rather than one marker. For example, LC-DAD or LC-MS fingerprints can be processed using principal component analysis to cluster authentic batches and detect adulteration or process drift, while quantitative NMR can provide orthogonal quantification without reference standards for every compound. In practical terms, studies across several botanical matrices have reported that chemometric fingerprinting can classify origin or detect adulteration with accuracies often exceeding 90 percent when adequate training sets are used, and similarity thresholds such as correlation coefficients above 0.95 have been proposed for routine conformity decisions. Scientifically, these results support the view that “identity” for phytopreparations

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should be operationalized as a multivariate space, enabling tighter control of complex mixtures while acknowledging that therapeutic action may be distributed across many constituents [1; 4].

Modern extraction and processing technologies can be defined as unit operations that improve selectivity, scalability, and stability of plant extracts by controlling solvent composition, temperature, pressure, and residence time. The mechanism by which these technologies improve phytopreparations is the reduction of thermal and oxidative degradation while enhancing mass transfer, thereby preserving labile constituents and stabilizing target ratios. A representative example is supercritical CO_2 extraction, which can selectively recover lipophilic terpenes with minimal residual solvents, while ultrasound-assisted extraction can shorten extraction times and reduce solvent consumption for polyphenol-rich extracts. Quantitatively, reported process intensification often yields 1.2- to 2-fold improvements in extraction efficiency or comparable yields with 30–60 percent shorter times, and residual solvent levels can be reduced to below pharmacopeial limits when appropriate downstream drying is applied. Scientifically, these process results demonstrate that modernization is not only analytical but also manufacturing-centered, because the chemical profile is a function of process history, and reproducibility requires controlling the transformation pathways occurring during extraction and concentration [3; 6].

Advanced delivery systems are defined as formulation technologies that modulate solubility, permeability, stability, and release kinetics of phytochemical constituents, particularly those with poor aqueous solubility or low oral bioavailability. The mechanism is encapsulation or complexation, such as nanoemulsions, liposomes, polymeric nanoparticles, or cyclodextrin inclusion complexes, which increase apparent solubility and protect against degradation. For example, curcumin, a polyphenolic compound with low intrinsic bioavailability, has been formulated into nanoemulsions and phospholipid complexes to improve absorption, offering a technologically relevant template for other phytoconstituents with similar constraints. Numerically, published formulations frequently report several-fold increases in dissolution rate and two- to tenfold increases in pharmacokinetic exposure measures under controlled

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conditions, although variability is high and depends on composition and dosing context. Scientifically, these results imply that phytopreparation modernization should treat formulation as a critical determinant of clinical performance, and that chemical standardization alone may be insufficient if delivery constraints prevent consistent systemic exposure [5; 7].

Digital traceability and authenticity assurance are defined as technology-enabled documentation and verification of identity, origin, and handling of botanical raw materials and intermediates. The mechanism is the integration of electronic batch records, supplier qualification data, barcoding or serialization, and, where relevant, genomic or chemical authentication results into a coherent provenance narrative. For instance, DNA barcoding or targeted qPCR assays can identify species substitution in powdered materials where morphological inspection fails, while stable isotope ratios can support geographic provenance claims in high-value botanicals. Quantitatively, targeted genetic assays can achieve high sensitivity for detecting adulterant species at low percentage levels in mixtures, and digital systems can reduce documentation errors and improve recall readiness, with some industries reporting double-digit percentage improvements in deviation closure times after digitization. Scientifically, these findings underscore that modernization includes governance of information, because phytopreparations are vulnerable to economically motivated adulteration and supply chain complexity, and robust technological traceability supports both safety and scientific reproducibility [2; 6].

A consolidated view of technology-to-attribute mapping can be expressed as a structured table, defined as a matrix linking critical attributes to measurement technologies and control points. The mechanism of such a matrix is to make control strategy explicit, ensuring that each critical quality attribute is paired with a feasible measurement and a decision rule. For example, identity can be paired with LC-MS fingerprint similarity, purity with ICP-MS and pesticide panels, potency with multi-marker quantification and bioassays, and stability with accelerated degradation kinetics. Quantitatively, decision rules can be parameterized as acceptance ranges, such as marker ratios within plus or minus 10 percent of a reference, fingerprint similarity above 0.95, heavy metals below

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specified ppm limits, and moisture below 5–8 percent depending on dosage form requirements. Scientifically, a matrix approach operationalizes QbD for phytopreparations by translating complexity into measurable controls that can be validated and audited.

Discussion

Technological modernization for phytopreparations can be defined as a shift from artisanal or marker-minimal production toward data-rich, mechanism-informed, and clinically oriented control strategies. The mechanism explaining why this shift is necessary is that plant materials exhibit natural heterogeneity driven by genotype, environment, and post-harvest handling, and this heterogeneity propagates into extract composition and dosage form performance unless actively managed. For example, two batches harvested in different seasons can differ in secondary metabolite profiles due to stress physiology, leading to different fingerprint clusters even when total extract yield appears similar. Numerically, agricultural studies commonly show seasonal or geographic effects leading to 15–50 percent changes in selected metabolite classes, which is large relative to typical pharmaceutical acceptance ranges and therefore cannot be ignored. Scientifically, this supports the argument advanced by contemporary regulatory science that botanical products require enhanced control strategies and, where feasible, clinically justified specifications that connect chemical space to pharmacological function [1; 3].

Limitations of the present synthesis should be defined in terms of scope and evidence heterogeneity rather than methodological weakness, because phytopreparation technologies span diverse plants, indications, and regulatory contexts. The mechanism generating uncertainty is that improvements reported for one botanical matrix or one delivery system may not translate directly to another due to differing chemistry, matrix effects, and use patterns. For example, fingerprint similarity thresholds may require product-specific calibration, and bioavailability gains reported for a single compound such as curcumin cannot be assumed for all polyphenols or terpenoids without dedicated pharmacokinetic validation. Quantitatively, the variance in reported enhancement factors for

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nanoformulations, ranging from modest to order-of-magnitude changes, illustrates that technology performance is context-dependent and sensitive to formulation composition. Scientifically, future research should prioritize standardized reporting, shared reference materials, and clinically anchored endpoints that allow cross-study comparability and facilitate meta-analytical synthesis, thereby strengthening the evidence base for regulatory and clinical decisions [2; 5].

Conclusion

Phytopreparations are complex medicinal products whose therapeutic value is linked to multicomponent chemical systems, and modernization requires controlling complexity rather than eliminating it. The study synthesizes an integrated framework that connects fingerprint-based standardization, process analytical technologies, advanced extraction, and modern delivery systems within a quality-by-design logic tailored to botanical products. The results indicate that multi-dimensional identity and composition control, combined with contaminant management and digital traceability, can reduce batch variability and strengthen safety assurance across supply chains. The discussion demonstrates that formulation technologies are critical for translating chemical consistency into consistent bioperformance, especially for poorly soluble phytochemicals. Overall, the article provides an end-to-end modernization pathway that is compatible with contemporary regulatory expectations and supports evidence-oriented phytopharmaceutical development. Continued progress depends on standardized reporting, validated multivariate specifications, and closer linkage between analytical fingerprints, mechanistic bioassays, and clinically meaningful outcomes.

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