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Review Article

Shelf-Life Assessment and Stability Testing Methods for Herbal Medicinal Products: A Systematic Review

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ABSTRACT

HMPs (Herbal Medicinal Products) are popular because of their potential therapeutic benefits and safety; but preservation of shelf-life and stability is a major issue that needs to be addressed in regulation and science. The aim of this systematic review is to explore existing methods for assessing stability and shelf-life of HMPs, to discuss the lack of standardisation in existing methodologies and to highlight the emerging trends in the field. The interaction of physicochemical degradation pathways, environmental parameters and analytical method with relation to best practices for stability testing is analyzed. The review gathers data from a variety of research and combines traditional and modern methods to be able to predict the correct shelf-life. The key findings showed that accelerated stability testing and chromatographic methods are the predominantly used approaches. There is increasing interest in the techniques that are non-destructive and multivariate modelling for better prediction. There are considerable differences in regulation between regions, and there is a need for harmonised international guidelines, packaging innovation, advanced delivery systems and digital technologies in preserving HMP stability are discussed in this review. Future perspectives such as machine learning, metabolomics, and quality by design approaches are also highlighted. This review will serve as a comprehensive reference for researchers, regulators and industry interested in finding science-based approaches to herbal product shelf-life assessment that are robust.

Keywords: Accelerated testing, Chromatography, Herbal medicinal products, Metabolomics, Regulatory harmonisation, Shelf-life, Stability testing.

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INTRODUCTION

Herbal Medicinal Products (HMPs) have always played an important role in traditional and conventional medicine, and are considered to be safe and effective (Balkrishna *et al.*, 2024). In the last few decades, the global market for herbal medicines has grown exponentially owing to the growing demand of the consumers for natural and holistic medicines for their health, growing prevalence of chronic diseases, and the rising awareness about preventive health care (Bhattacharjee *et al.*, 2023). However, there are ongoing concerns about the authenticity of these products and their potential for adulteration, as well as about the variability in therapeutic efficacy. Without quality control standards that have been universally agreed upon, these problems are compounded and consumer safety is compromised (Srivastava and Misra, 2018).

There is a basic difference between HMPs and traditional synthetic drugs, that is, the complexity of the composition. As opposed to single-component pharmaceuticals, HMPs are complex mixtures of bioactive constituents, and determining their stability and shelf life is more complex (Srivastava and Misra, 2018). HMPs can degrade through a number of parallel routes over time, such as oxidation, hydrolysis, photolysis, and enzymatic degradation, all of which may alter the pharmacological properties over time. Although progress has been made in analytical chemistry, there are still serious shortcomings in the harmonisation of stability testing procedures. For example, the EMA (European Medicines Agency) and the US-FDA (Food and Drug Administration) have different requirements for stability testing, which makes it hard to trade in products from different countries (Reddy and Koushik, 2025). The lack of standardized accelerated stability testing models adds to the challenges and ultimately impacts consumer safety and efficacy (Kim *et al.*, 2019).

The urgent demand for robust and evidence-based quality assurance systems drive the present review. We hope to determine

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best practice and emerging trends in analytical development for stability testing by synthesizing existing knowledge and identifying gaps between traditional practice and modern scientific validation (Rahi and Pandit, 2026; Prajapati *et al.*, 2023).

METHODOLOGY

A thorough literature search was carried out to look for relevant publications on the shelf-life assessment and stability testing of Herbal Medicinal Products (HMPs) (Figure 1). Peer-reviewed research papers, review papers, pharmacopoeial monographs, and regulatory guidance papers on the stability of herbal formulations, analytical method, shelf-life determination, packaging methods and predictive stability approach were included in the search.

The literature was retrieved from the major scientific databases such as PubMed, Scopus, Web of Science, Google Scholar, and ScienceDirect with the combinations of the keywords used: Herbal medicinal products, Stability testing, Shelf-life, Stability studies, Analytical techniques, Herbal formulations, Accelerated stability testing, Regulatory guidelines, Predictive stability models. In addition, regulatory documents issued by World Health Organization (WHO), European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), Ministry of AYUSH, National Medical Products Administration (NMPA) and Pharmaceuticals and Medical Devices Agency (PMDA) were also reviewed.

The following types of studies were considered for inclusion: those that describe stability testing methodologies, analytical techniques, regulatory frameworks, packaging innovations and computational or predictive approaches, to herbal medicinal products. Different dosage forms of herbal formulations such as solid, liquid, injectable, biopharmaceutical and advanced nanoformulations were covered in the review. The studies retrieved were filtered according to their relevance and then critically assessed according to the methodological quality, scientific validity, regulatory relevance and applicability to various climatic zones. The final review included publications that included significant evidence for stability evaluation and shelf-life determination of herbal medicinal products.

Aspects of Shelf-Life in Herbal Medicinal Products

Storage or shelf life is the time that a product will retain a microbiological load and physicochemical stability that are acceptable and at least 90% of the labelled content of active ingredient(s). The shelf life of HMPs can be predicted by controlled stability testing or prediction models validated by sound scientific data to ensure the product's safety, efficacy and quality over its useful life (Kumadoh *et al.*, 2020). The key parameters measured for shelf-life testing are summarised (Table 1). The fundamental methods used to determine product shelf life are still stability testing and shelf-life modelling.

Factors Governing Shelf Life

The stability of HMPs is governed by a combination of intrinsic and extrinsic factors (Figure 2) (Irudaya *et al.*, 2023). Intrinsic factors refer to the inherent physicochemical properties of the herbal material, such as the species of the plants, phytochemical composition and moisture content, while extrinsic factors include environmental and processing factors such as temperature, humidity, exposure to light, and access to oxygen, which, in turn, can act independently or in combination to increase the degradation.

It is important to be familiar with the interactions of these variables in order to optimize storage conditions and to design stability studies and predict shelf life. In Table 2, detailed information about both factor types and mitigation measures are provided.

The breakdown of herbal drugs is a complex and simultaneous process involving oxidation, hydrolysis and enzyme mediated degradation which can significantly impact the pharmacological properties of the drug. Conventional shelf-life testing methods like sensory and organoleptic evaluation are insufficient for application at the desired precision level for current regulatory requirements (Swarnalata and Aishwarya, 2025).

Stability Testing and Shelf-Life Assessment of Pharmaceutical and Herbal Medicinal Products

One of the most important parts of a drug development process, stability testing, ensures that a drug maintains the desirable properties during its period of storage. Stability data provide information for decisions on expiration dates, labelling, package selection, and recommended storage conditions. The main types of stability testing are summarized below (Figure 3).

Approaches to Shelf-Life Estimation

The shelf-life estimation should be based on scientifically valid methods, relevant to the regulations, using validated analytical procedures and be representative of the actual storage environment. Herbal medicine is a complex medicine and requires evidence-based effective strategies. These models incorporate empirical data, physicochemical laws, and degradation trends. Statistical tools including regression analysis, Analysis of Variance (ANOVA), confidence intervals, and trend analysis are used to interpret stability data, detect deviations, and characterise degradation profiles over time (Pujitha *et al.*, 2025). The major estimation approaches empirical, kinetic, and accelerated stability modelling are summarised in Table 3, organised by dosage form.

Stability Testing Methodology

As demonstrated in Figure 4, Stability evaluation involves physical, chemical, microbiological, therapeutic and packaging parameters (Figure 4A) which are supported by a sound protocol design, a validated analytical method and an appropriate

container-closure system (Figure 4B). ICH-recommended climatic zone related storage conditions and protocols for long, intermediate and accelerated stability testing for shelf-life determination are provided in Figures 4C and 4D. Standardized documentation and reporting is emphasized in Figure 4E and the regulatory framework, such as ICH, WHO, FDA, EMA, CDSCO, PMDA, and NMPA guidelines, are summarized in Figure 4F for ensuring the quality, safety and efficacy of herbal medicinal products over their shelf life (Welankiwar and Jambhe, 2025; ICH Q1AR[2]; ICH Guidelines: Drug Stability Testing Essentials). For HMPs, harmonized global stability frameworks are critical to ensure consistent quality throughout the labelled shelf life (Kim *et al.*, 2019). Shelf-life estimation is primarily supported by three modelling strategies. Empirical models derive stability projections by fitting linear or nonlinear regression functions to observed degradation data. Kinetic models, based on chemical reaction theory, describe degradation behaviour by assuming a defined reaction order and rate law. Accelerated stability approaches subject products to elevated stress conditions and employ the Arrhenius equation to extrapolate degradation rates under recommended storage conditions (Waterman and Adami, 2005).

Of these, first order kinetic models, and Arrhenius-based accelerated methods are most widely used in pharmaceuticals shelf-life prediction and widely used in regulatory submissions (Fan and Zhang, 2015). The regulatory emphasis on traditional kinetic analysis methods persists, despite the increasing demand for non-isothermal kinetic analyses and machine learning predictive methods, because traditional kinetic approaches are mechanistic, and the methods have been well validated. The Arrhenius equation is a useful tool to correlate degradation kinetic with temperature and extrapolate the shelf life from short-term accelerated studies (González-González *et al.*, 2022). But it is limited by some internal factors. Specifically, it simplifies complex degradation pathways into a single rate-determining

Table 1: Parameters monitored during stability testing of herbal medicinal products (Kunle *et al.*, 2012; Yadav *et al.*, 2023; Chaudhary and Kumari, 2022).

Category	Parameter	Methods	Significance
Physical	Colour, odour, texture, viscosity	Visual, sensory, Brookfield viscometer	Detects organoleptic degradation
Chemical	Active constituent content	HPLC, HPTLC, GC-MS, UV spectrophotometry	Monitors potency and chemical stability
Moisture content	Residual water	Karl Fischer titration, loss on drying	Indicates hygroscopicity and microbial risk
Micro-biological	Total aerobic count, pathogens	Plate count, culture, PCR	Ensures microbial safety and compliance
Physico-chemical	pH, total solids, ash value	pH meter, gravimetric methods	Assesses formulation consistency

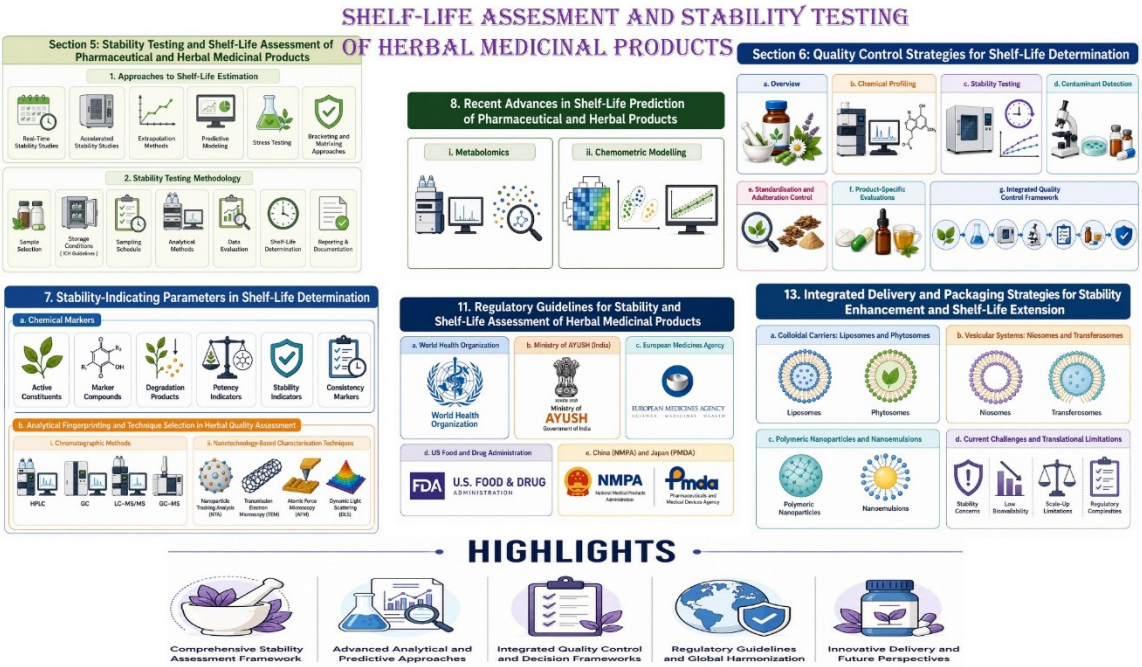


Figure 1: Conceptual Framework for Shelf-Life Assessment and Stability Evaluation of Herbal Medicinal Product.

Table 2: Intrinsic and extrinsic factors influencing herbal drug shelf life (Kashinath *et al.*, 2024; Tembhare *et al.*, 2019).

Factor Type	Specific Factor	Impact on Shelf Life	Mitigation Strategy
Intrinsic	Plant species/part	Varying chemical profiles; stability differs by species	Use standardised extracts
Intrinsic	Phytochemical nature	Varying stability to heat, light, and pH	Antioxidants; pH adjustment
Intrinsic	Moisture content	Promotes hydrolysis and microbial growth	Desiccants; low-humidity storage
Intrinsic	Excipients	Interactions with actives may accelerate degradation	Inert/stable excipients
Extrinsic	Temperature	Accelerates chemical reaction rates	Refrigerated or controlled room temperature
Extrinsic	Humidity	Increases moisture uptake and microbial risk	Sealed containers; moisture barriers
Extrinsic	Light	Photodegradation of sensitive compounds	Amber/opaque packaging
Extrinsic	Oxygen	Oxidative degradation of actives	Vacuum sealing; nitrogen flushing

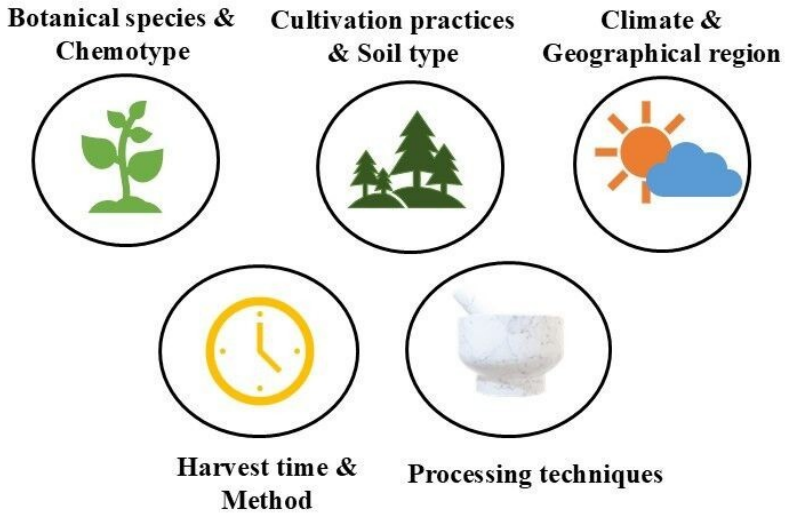


Figure 2: Pre- and post-harvest factors which influenced the herbal drug stability.

process, which may not adequately represent multicomponent systems such as HMPs, and it does not incorporate the influence of non-thermal stressors, including humidity, light, and oxidative conditions. These limitations highlight the need for integrated or complementary modelling strategies when addressing chemically complex matrices.

Quality Control Strategies for Shelf-Life Determination

Overview

Quality assessment of HMPs requires a multifaceted approach that integrates chemical profiling, stability testing, contaminant detection, botanical standardisation, and product-specific evaluations. The compositional complexity of HMPs complex mixtures of phytochemicals, many of which act synergistically makes the selection of appropriate quality and stability indicators inherently challenging. Chromatographic and spectroscopic methods are particularly prominent in this context, and their principal applications are summarised in Table 4.

Chemical Profiling

Chemical profiling is a fundamental aspect of the quality control of HMP (Jing *et al.*, 2015). HPLC-DAD (Diode array detection) has been extensively used for fingerprinting herbal extracts, such as chemical fingerprinting of *Cinnamomum tamala* by geographical origin (Champati *et al.*, 2024). CE (Capillary electrophoresis) has also shown to be complementary in the quantification of total β-escin in herbal products (Dutra *et al.*, 2013). FTIR spectroscopy, coupled with chemometrics, can be used to rapidly discriminate commercial herbal products (Umar *et al.*, 2023).

Stability Testing

Stability testing plays an important role in long-term therapeutic efficacy and as the basis for the empirical data supporting shelf-life assignments. *Lamiaceae* family tinctures have been evaluated for degradation markers by HPLC and spectrophotometry over a long storage time. New technologies are promising to ensure real-time quality consistency assessments, though additional standardization needs to be undertaken before their use (Pujitha *et al.*, 2025; Sik *et al.*, 2021).

Table 3: Shelf-life estimation approaches for different dosage forms.

Dosage form	Major degradation pathways	Estimation/modeling approach	Key assumptions	Limitations	Stabilization strategies	References
Solid dosage forms	Hydrolysis (if hygroscopic); oxidation; Maillard reaction	First-order kinetic models; accelerated stability testing (ICH); moisture sorption modelling; empirical regression models	Degradation follows predictable kinetic/ empirical trends under controlled conditions	Limited extrapolation beyond study conditions; complex reactions may deviate from first-order behavior	Desiccants; protective packaging (e.g., blister packs); stable excipients	(Waterman and Adami, 2005)
Liquid products	Hydrolysis; oxidation; photolysis	Zero- or first-order kinetics; real-time and accelerated testing; oxidative stress testing; Arrhenius-based accelerated models	Degradation under stress reflects real-time conditions; consistent environmental parameters	Arrhenius limitations in multi-mechanism degradation; environmental variability impacts accuracy	Antioxidants; inert atmosphere; amber containers	(Kim *et al.*, 2019)
Injectables	Hydrolysis; oxidation; pH instability	pH monitoring; clarity/ turbidity testing; potency assays under ICH conditions; kinetic modeling approaches	Stability influenced by controlled pH and sterility conditions; reaction kinetics remain consistent	Sensitivity to minor environmental changes; complex formulations may not follow simple kinetics	Nitrogen flushing; chelators (e.g., EDTA); buffer optimization	(Sirohiya and Kumar, 2025)

Footnotes: QbD: Quality by Design; EDTA: Ethylenediaminetetraacetic acid; ICH: International Council for Harmonisation guidelines for stability testing; Arrhenius equation assumes temperature-dependent reaction kinetics under accelerated conditions; $p<0.05$ considered statistically significant where applicable in stability studies.

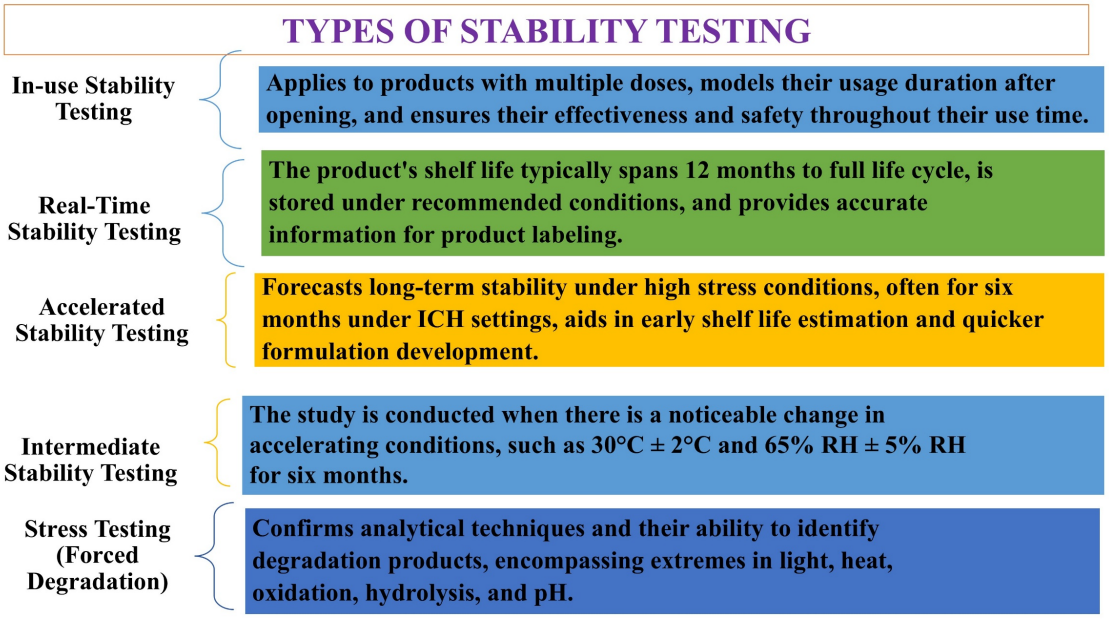


Figure 3: Types of stability testing.

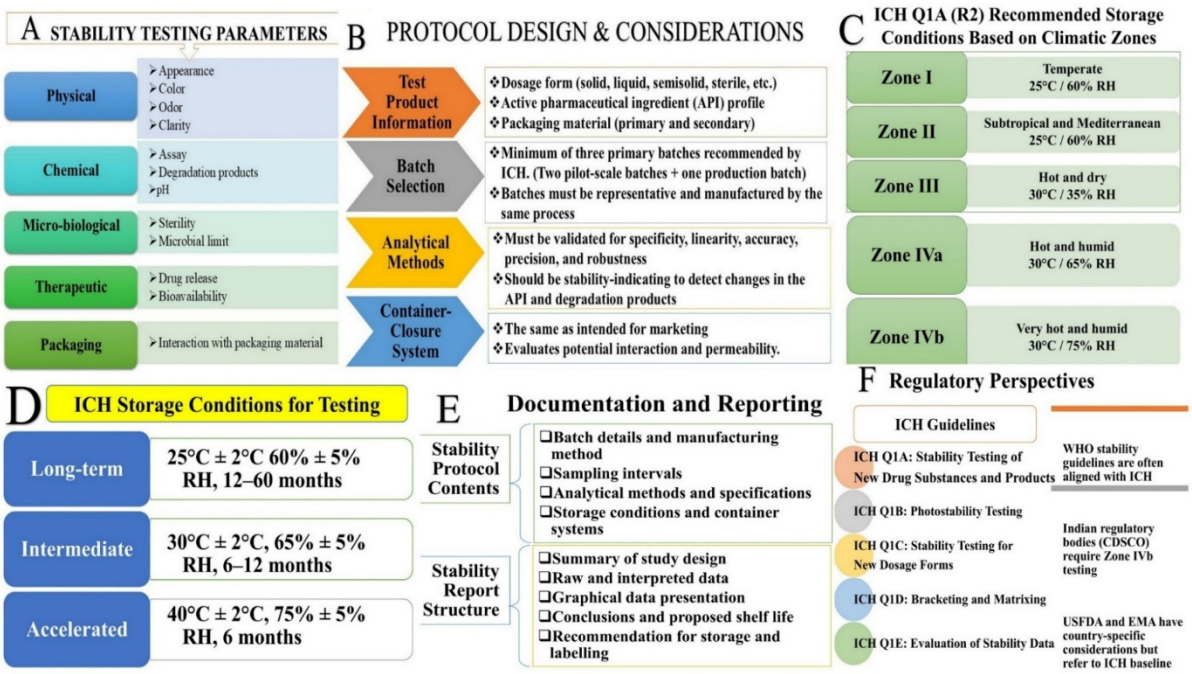


Figure 4: A brief consortium of stability testing: A) Stability testing parameters; B) Protocol design and considerations; C) Recommended storage conditions based on climatic zones as per ICH; D) ICH storage conditions for testing; E) Documentation and reporting; F) Regulatory perspectives.

Table 4: Taxonomy of quality assessment and control methods for herbal medicines, with reference to their roles in shelf-life determination.

Dimension	Method/Technique	Application	References
Chemical profiling	HPLC-DAD; Capillary Electrophoresis (CE); FTIR-chemometrics; multicomponent analysis	Fingerprinting; quantification; origin discrimination	(Li *et al.*, 2018)
Stability testing	HPLC; UV-vis spectrophotometry; novel real-time technologies	Long-term and real-time quality consistency assessment	(Li *et al.*, 2020; Wu *et al.*, 2025)
Contaminant detection	Mycotoxin assays; microbiological culture; PCR	Safety screening throughout shelf life	(Zhang *et al.*, 2018)
Standardisation	Regulatory compliance review; botanical authentication; DNA barcoding	EU market entry; adulteration detection	(Ichim, 2019)
Product-specific QC	Preparation-specific HPTLC, GC-MS, organoleptic evaluation	Sage, thyme, and ginger formulation quality assessment	(Feng *et al.*, 2014; Gad *et al.*, 2013)

Contaminant Detection

In some areas of the world with less tough regulations, contaminant detection, especially mycotoxin analysis is also important for product safety. The microbial stability should be kept within prescribed limits during the declared shelf life, as microbial growth may facilitate phytochemical degradation.

Standardisation and Adulteration Control

Regulatory differences between jurisdictions and the continued threat of purposeful adulteration make standardisation efforts difficult. For meaningful monitoring of its stability, botanical authentication, whether by morphological means, by chromatography or by molecule sequencing is necessary as adulterated or misidentified material can have degradation kinetics that differ significantly from the authentic species (Balekundri and Mannur, 2020).

Product-Specific Evaluations

Product-specific evaluations highlight the necessity for a product-specific quality control approach that takes into consideration the different physicochemical properties and degradation pathways of each herbal formulation. The results indicate that general-purpose methods are often not adequate to describe the stability behaviour of individual herbal matrices, highlighting the importance of selecting an indicator for the formulation and validating the method (Muyumba *et al.*, 2021).

Integrated Quality Control Framework

A seamless approach to integration of chemical profiling, stability testing, and contaminant monitoring throughout the product lifecycle, in addition to botanical standardisation, is required to assure the safety, efficacy, and consistency of HMP products across their product shelf life. The main obstacle to global harmonisation is still the lack of analytical rigor and different regulations in different markets, which will only be overcome through collaborative methodological work and regulatory harmonisation.

Stability-Indicating Parameters in Shelf-Life determination

Stability indicators have two main uses: To determine chemical degradation that occurs with time and to ensure chemical batch-to-batch consistency throughout the product life cycle (Wang *et al.*, 2023). Two of the main types of stability-indicating parameters (chemical markers and analytical fingerprinting techniques) and the validated methods of their application are addressed in the following subsections.

Chemical Markers

The most common tools for monitoring active ingredients during the shelf life of a product are chemical markers. They are defined as chemically characterised constituents used for identity testing, quantitative analysis, quality assurance and stability monitoring. Effective markers should be stable in normal storage conditions, representative of the plant material, and susceptible to validated analytical procedures (Yadav *et al.*, 2023).

For polyherbal products, selection of candidate markers is difficult due to the fact that either the marker can be volatile, or it may not be directly associated with the therapeutic action. While there are no standards in Ayurvedic, Siddha or Unani systems. Both WHO and the Ministry of AYUSH have suggested the use of multiple markers or composite index to improve the credibility of quality assessment (Table 5).

Analytical Fingerprinting and Technique Selection in Herbal Quality Assessment

Assessing the quality, stability and therapeutic effectiveness of HMPs requires a suite of complementary analytical methods to tackle each compound of interest and the overall chemical profile of each formulation. Analytical fingerprinting is not restricted to quantitative determination of a single marker but rather provides a profile of all phytochemicals, which can identify any differences between batches and indicate degradation that would not be apparent from targeted assays. This description is especially invaluable for formulations that involve complex or incompletely characterised ingredients, where none of the single ingredients can fully describe the stability of the whole formulation. Thus, fingerprinting techniques coupled with metabolomics and chemometrics processes in total strengthens the long-term quality assessment and facilitate regulatory compliance (Sree *et al.*, 2025). The introduction of new chromatographic techniques, nanotechnology-based characterization, and traditional methods from specific areas have been added to the analytical arsenal for evaluating herbal preparations. This will significantly improve the precision and reliability of the evaluation. The different methods and uses are compared in Table 6.

Chromatographic Methods

Phytochemical fingerprinting and quantification are still based on chromatographic techniques. HPLC has been extensively validated for the detection and quantification of specific marker compounds in a wide variety of herbal matrices. For example, quantification of Rosmarinic acid in a polyherbal syrup, where extensive method validation (linearity, precision and percentage recovery) is performed, is proof of the analytical rigor necessary for regulatory submission (Shukla *et al.*, 2021; Zakerin *et al.*, 2020). At higher resolution LC-MS/MS and GC-MS can identify the unknown degradation products, and the monitoring of complex chemical changes like conversion of polar forms of ginsenosides to less-polar aglycones during storage which cannot be identified by HPLC. These combined chromatographic tools can be used to cover the entire range of marker monitoring to detailed understanding of degradation pathways and play a pivotal role in

Table 5: Examples of common marker compound.

Plant Source	Marker Compound	Therapeutic Class	Analytical Method	References
Curcuma longa (Turmeric)	Curcumin	Anti-inflammatory, antioxidant	HPLC (High-Performance Liquid Chromatography), UV, LC-MS	(Jayaprakasha *et al.*, 2002)
Andrographis paniculata	Andrographolide	Immunomodulatory, hepatoprotective	HPTLC, HPLC	(Akowuah *et al.*, 2006)
Bacopa monnieri	Bacosides	Neuroprotective, nootropic	HPTLC, HPLC	(Deepak *et al.*, 2005)
Glycyrrhiza glabra (Licorice)	Glycyrrhizin	Demulcent, anti-ulcer	UV-Vis, HPLC	(Sabbioni *et al.*, 2006)
Panax ginseng	Ginsenosides	Adaptogenic, anti-stress	LC-MS/MS, HPLC	(Ji *et al.*, 2001)

Table 6: Comparison of fingerprinting methods.

Method	Resolution	Quantitative	Applications	References
HPTLC	Moderate	Semi-quantitative	Routine QC (Quality Control), visual tracking of major components	(Nicoletti, 2011)
NMR	High	Yes	Comprehensive profiling of multiple constituents	(Kumar *et al.*, 2016)
LC-MS/ GC-MS	Very High	Yes	Identifying unknown degradation products and pathways	(Xiaohui *et al.*, 2006)

the science-based approach to shelf-life determination (Jagdale *et al.*, 2023).

Nanotechnology-Based Characterisation Techniques

With the increasing emergence of nanoformulations in herbal product development, the analytical methods based on nanotechnology have also gained importance in stability assessment. DLS (Dynamic light scattering) and SEM (Scanning Electron Microscopy) are the principal methods for characterising the physicochemical properties of herbal nanocarriers, providing quantitative data on particle size distribution, surface morphology, and zeta potential parameters that directly determine colloidal stability and *in vivo* performance (Bonifácio *et al.*, 2014). Chitosan nanoparticles loaded with nettle essential oil and *Citrus limonum* essential oil-based nanoemulsions have both demonstrated significantly enhanced antioxidant activity and improved stability relative to their non-encapsulated counterparts, confirming that nano-encapsulation can meaningfully extend the functional shelf life of labile herbal bioactives (Kaur *et al.*, 2020). Rigorous and standardised reporting of these characterisation parameters across studies is essential for enabling meaningful cross-study comparisons and building the evidence base required for regulatory acceptance of nano-herbal formulations.

Recent Advances in Shelf-Life Prediction of Pharmaceutical and Herbal Products

Metabolomics

Metabolomics provides a global perspective on the chemical events occurring during storage (Table 7). Techniques such as GC-MS, LC-MS, and NMR (Nuclear magnetic resonance) enable real-time monitoring of metabolomic changes and the early identification of degradation markers associated with potency loss (Figure 5). Advances in untargeted metabolomics reveal unexpected degradation pathways, while chemometric tools identify patterns within large datasets. Integration with proteomics and other omics platforms supports the construction of detailed stability profiles (Lee *et al.*, 2017).

Chemometric Modelling

Chemometrics combines multivariate statistical tools with analytical data and storage variables to predict shelf life (Figure 6). Commonly employed techniques include PCA (Principal Component Analysis), PLS (Partial Least Squares) regression, and HCA (Hierarchical Cluster Analysis). They are used to model degradation trends, identify stability-determining factors, and generate real-time shelf-life predictions without the need for prolonged stability studies (Banerjee *et al.*, 2025).

Herbal Shelf-Life Assessment Pipeline

A systematic approach to stability and durability evaluation of herbal products is provided by the HSAP (Herbal Shelf-Life Assessment Pipeline). The process entails standardized extraction, formulation, stability testing, shelf-life modeling, regulatory compliance, and agricultural quality control (Figure 7).

The pipeline ensures the same quality is maintained and performance is certified. The processing conditions are also mentioned as controlled in addition to the phytochemical fingerprinting. Identity, potency, and purity are confirmed through analytical testing. HSAP is the link connecting the manufacturing and regulatory requirements with the agricultural practices. The method helps in the establishment of right shelf life through the mention of evidence and thus also the reliability of the product is increased (Mukherjee, 2019). Apart from this, it also helps in increasing the regulatory and customer trust in herbal medications which are sold globally (Table 8).

Decision tree/selection matrix for choosing stability indicators, analytical methods, and shelf-life models

The decision tree can be useful to organize the selection of the stability indicators, method of analysis and shelf-life models when assessing herbal products (Table 9).

The initial process is to determine the stability indicators, that is, phytochemical markers, bioactivity features, or even microbiological features, depending on the product nature and degradation mechanisms. The selection of that option then dictates the most suitable methods of analysis, like chromatographic profiling, bioassays, or spectroscopic analyses, which allows quality tracking with high specificity through time. Lastly, the decision matrix anticipates the product expiration and guarantees compliance with the regulations by correlating analytical findings with appropriate shelf-life models: zero-order, first-order, or complex kinetic modelling

Regulatory Guidelines for Stability and Shelf-Life Assessment of Herbal Medicinal Products

These range from technical barriers to market integration challenges and require attention to, or protection of, intellectual property, and vary according to region in terms of rigor and approach to analysis and regulation.

The world is still divided on how to regulate HMPs. The lack of standardized stability testing procedures is a significant hurdle, especially for products with more than one bioactive compound with different degradation rates. This lack of standardisation makes it difficult for manufacturers to gain access to international markets. Different agencies have different requirements like EMA, FDA, and WHO. This difficulty is compounded by technical problems associated with scaling up traditional preparations to the pharmaceutical-grade production process (Jain *et al.*, 2011). A comparative analysis of the major regulatory frameworks is presented in Table 10.

World Health Organization

WHO recommends the implementation of chemical markers to guide the quality and consistency assessment of herbal preparations and pharmacopoeial procedures to detect microbial contamination during the shelf life. The normal procedures for real-time stability testing and storage condition impact documentation are also recommended. The principle WHO reference documents are Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues (2007) and Quality Control Methods for Herbal Materials (2005). There is a recognized lack of complete information on protocol formats and/or precise and dosage-specific storage time guidelines, leading to regulatory imbalance and varied use of national interpretations (WHO, Quality Control Methods for Herbal Materials 2011; WHO, GMP for Herbal Medicines 2007).

Table 7: Analytical techniques and marker-based approaches for quality assessment and stability monitoring of herbal medicinal products.

Analytical focus	Technique/ Method	Resolution	Quantitative capability	Application in herbal analysis and stability assessment	Representative marker compounds / examples	References
Chromatographic analysis	HPLC	High	Yes	Quantification of marker compounds; routine quality control	Curcumin (*Curcuma longa*); andrographolide (*Andrographis paniculata*); bacosides (*Bacopa monnieri*)	(Wichitnithad *et al.*, 2009)
Nanotechnology-based analysis	DLS; SEM	Moderate-High	Semi-quantitative	Nanoparticle characterization; antioxidant/antibacterial activity; stability profiling	Nanoformulated phytoconstituents (e.g., curcumin nanoparticles)	(Yallapu *et al.*, 2012)
Nanoemulsion characterization	Droplet size analysis; zeta potential	Moderate	Yes	Evaluation of emulsion stability; assessment of antioxidant stability enhancement	Nanoemulsion-based herbal actives	(Liu *et al.*, 2022)
Nanocapsule analysis	Encapsulation efficiency assays	Moderate	Yes	Determination of encapsulation efficiency; oxidative stability evaluation	Encapsulated phytoconstituents (e.g., polyphenols)	(Almasi *et al.*, 2016)
Historical and regional methods	Traditional/complex analytical approaches	Variable	Limited	Medicinal plant analysis; ethnopharmacological and contextual quality control	Whole plant extracts (multi-component systems)	(Kunle *et al.*, 2012)
Fingerprinting methods	HPTLC	Moderate	Semi-quantitative	Routine QC; visual profiling of phytoconstituents	Andrographolide; bacosides	(Jain *et al.*, 2010)
	NMR	High	Yes	Comprehensive profiling of multiple constituents in complex matrices	Ginsenosides (*Panax ginseng*)	(Yang *et al.*, 2012)
	LC-MS/GC-MS	Very high	Yes	Identification of degradation products; pathway elucidation	Glycyrrhizin (*Glycyrrhiza glabra*); curcumin degradation products	(Huang *et al.*, 2019)
Marker-based stability monitoring	HPLC; LC-MS; UV-Vis; HPTLC	High	Yes	Targeted monitoring of stability-indicating compounds in herbal products	Curcumin; andrographolide; bacosides; glycyrrhizin; ginsenosides	(Zhao *et al.*, 2016)

Abbreviations: HPLC: High-performance liquid chromatography; HPTLC: High-performance thin-layer chromatography; DLS: Dynamic light scattering; SEM: Scanning electron microscopy; NMR: Nuclear magnetic resonance; LC-MS: Liquid chromatography-mass spectrometry; GC-MS: Gas chromatography-mass spectrometry.

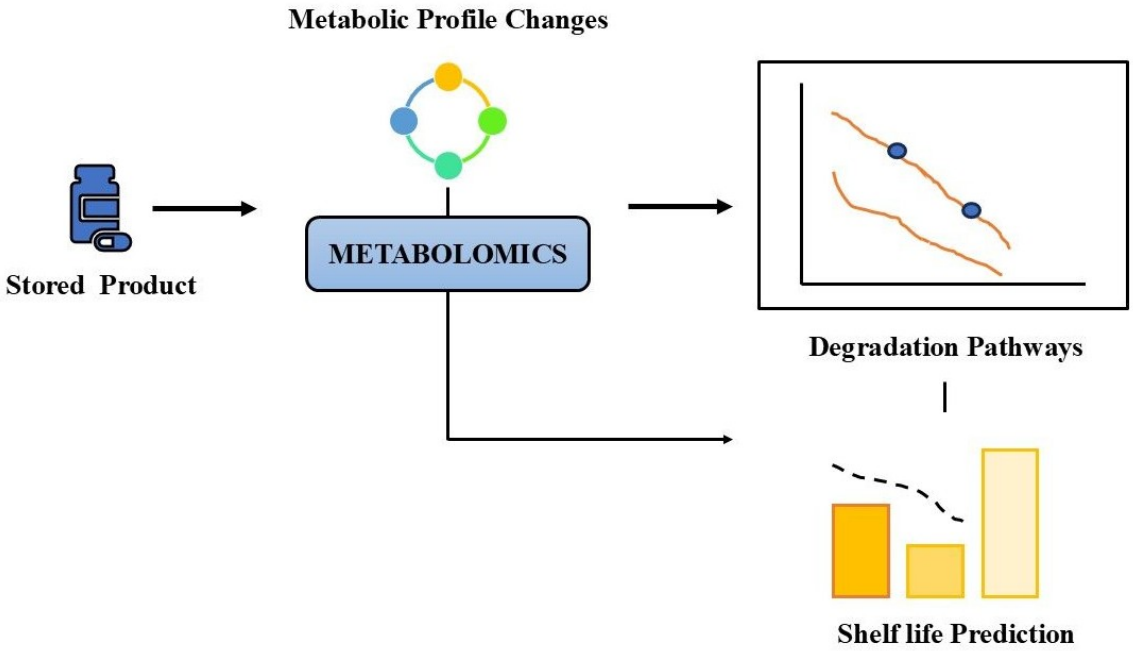


Figure 5: Conceptual outline of metabolomics guided shelf-life prediction.

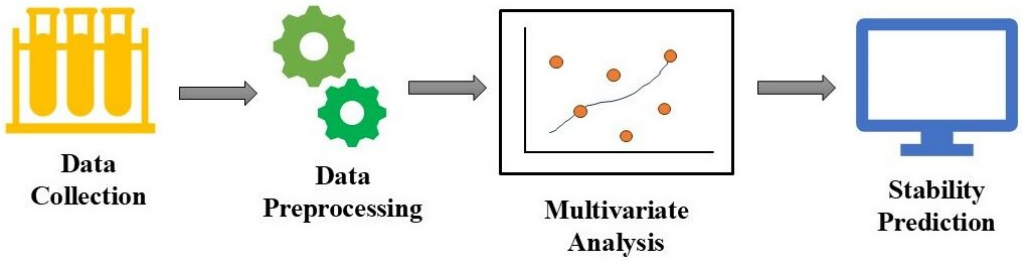


Figure 6: Chemometric modeling approach for herbal drug stability prediction.

Ministry of AYUSH (India)

In India, traditional and herbal medicines are regulated by the Ministry of Ayurveda, Yoga, Unani, Siddha and Homeopathy, which has laid down shelf-life criteria in Drugs and Cosmetics Rules 1945 (Rules 161-B and 161-C). Prescribed shelf life of various dosage forms such as Churna (2-3 years), Kwatha (6 months-1 year) and Asava/arishta (up to 10 years) are mentioned in Table 11. In the present scenario there are no standardised procedures for conduct of stability studies according to AYUSH pharmacopoeias and the use of modern scientific instruments for degradation profiling is limited, and in many instances, the shelf life is derived from organoleptic analysis or classical textual prescriptions. The proposal to do accelerated and real-time stability testing of Ayurvedic patent medicines has not been implemented (AYUSH GMP Guidelines).

European Medicines Agency

Herbal medicinal goods are regulated in the EU by Directive 2004/24/EC (amending Directive 2001/83/EC). The Committee on Herbal Medicinal Products (HMPC) of the EMA establishes specific requirements such as shelf-life data which is compliant with ICH Q1A(R^2) requirements, long term and accelerated data, accepted analytical methods and monitoring of active markers. The EMA Guideline on Stability Testing of Herbal Medicinal Products (2008), Directive 2004/24/EC and the European Pharmacopoeia 10.0 apply to this. EMA Monographs include shelf-life considerations, packaging compatibility, degradation and quality testing. The stability data continue to be required for the products registered under Traditional Use Registration but are not required as strenuously as for other products (EMA, Traditional Herbal Medicinal Products) (EMA, Guideline on Stability Testing of Herbal Medicinal Products) (EMA, Committee on Herbal Medicinal Products) (EMA Quality Guidance for Herbal Medicinal Products) (EMA Herbal Monographs and List Entries).

US Food and Drug Administration

Herbal products are regulated in the United States by FDA via two avenues: botanical drug products and dietary supplements. Botanical drug products are regulated under 21 CFR Part 312 and

shall meet the ICH stability requirements (Q1A(R^2), Q1B, Q1E). They must have analytical methods that have been validated, expiration dates and a Chemistry, Manufacturing, and Controls (CMC) dossier. By contrast, most OTC herbal products sold in the U.S. are sold as dietary supplements and fall under the regulation of the Dietary Supplement Health and Education Act (DSHEA). Expiration dating is required to be based on stability data, but is not required to be filed with FDA, and the manufacturer is responsible for demonstrating product safety. The result is that the shelf life and quality of commercial herbal products differ from those of pharmaceutical-grade botanical medicines due to this regulatory branching (USFDA Botanical Drug Development Guidance, USFDA 21 CFR Part 312 Investigational New Drug Application, Dietary Supplement Health and Education Act 1994; ICH Q1A(R^2) Stability Guideline, ICH Q1B Photostability Guideline, ICH Q1E Evaluation of Stability Data).

China (NMPA) and Japan (PMDA)

Two additional large markets, China and Japan, have put in place a structured regulatory system for herbal medicines. The approval and quality control of Traditional Chinese Medicine (TCM) in China is currently managed by the National Medical Products Administration (NMPA), which focuses on Good Manufacturing Practices (GMP) and regulatory science and the Chinese Pharmacopoeia acts as the guide. Kampo medicines are regulated by the Pharmaceuticals and Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare in Japan. A large number of Kampo composition products are covered by national health insurance, allowing a uniform use throughout the country. Products must comply with the Japanese Pharmacopoeia standards, and the determination of the shelf-life is assisted by stability data, as well as traditional use data (National Medical Products Administration, China) (Pharmaceuticals and Medical Devices Agency (Japan). These frameworks are examples of how traditional and modern regulatory science can work together and provide a glimpse of the variation in herbal medicine regulations around the world.

Linking Predictive Models to Regulatory Acceptance

Different regulatory bodies like WHO, EMA, FDA and AYUSH have increasingly appreciated the potential of chemometric and machine learning models in predicting the shelf life, stability and quality parameters. For these models to be submitted to regulators they must meet the following criteria: (i) the model must be based on comprehensive experimental datasets from long-term and accelerated stability study conducted under the ICH conditions; (ii) the statistical aspects of the model, such as assumptions, regression methods, error modelling and confidence intervals, must be clearly documented as required by ICH Q1E; (iii) model generalisability, freedom from overfitting, must be confirmed by external validation on independent stability batches; and (iv) predictive estimates must be comparable to the conventional real-time stability results conducted by ICH and the model requirements should be satisfied by ICH Q1A(R^2), Q1D and Q1E.

I. Comprehensiveness of experimental data: predictive models should be based on adequate experimental data. Such data sets should include long-term and accelerated stability testing conducted under ICH conditions. This will ensure that the model inputs will be within the regulatory range of environment, tests and analysis parameters (Taofeek *et al.*, 2026).

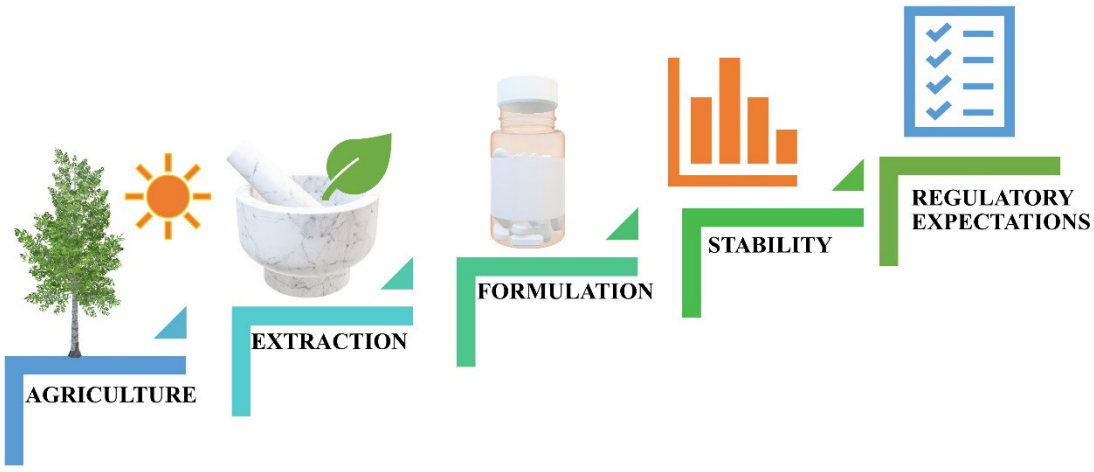


Figure 7: Herbal shelf-life assessment pipeline.

Table 8: Herbal shelf-life assessment pipeline.

Pipeline Stage	Detailed Activities/Consideration	References
Agriculture	Selection of superior varieties of plants in accordance with Good Agricultural and Collection Practices (GACP). Management of soil condition, pesticide application, harvest time, and crop maturity. Proper post-harvest drying, storage, and contamination avoidance. Traceability and documenting of plant identification and provenance.	(WHO GACP 2003)
Extraction	Selection of appropriate extraction techniques (maceration, percolation, Soxhlet extraction, ultrasonic extraction, supercritical CO_2 extraction). Selection of solvents dependent on polarity, safety, and regulatory compliance. Optimization of temperature, duration, and solvent-to-plant ratio. Elimination of contaminants, concentration, desiccation, and standardization of the extract.	(WHO, Good Herbal Processing Practices for Herbal Medicines)
Formulation	Selection of dosage form (like tablets, capsules, syrups, tinctures, etc.). Compatibility between herbal actives and excipients; interaction studies. Packaging material compatibility (moisture barrier, light protection). Use of stabilizers, preservatives, antioxidants, and bioavailability enhancers.	(Borse *et al.*, 2019)
Stability	Chemical stability: marker compounds, fingerprint profile, degradation pathways. Biological stability: preservation of bioactivity and pharmacological potency. Physical stability: color, odor, moisture, viscosity, phase separation. Microbial stability: total viable count, pathogens, fungal contamination. Study conditions: accelerated (40°C/75% RH), long-term (25°C/60% RH).	(Kumadoh & Ofori-Kwakye 2017; Thakur *et al.* , 2011)
Regulatory Guidelines	Compliance with AYUSH, WHO, ICH Q1A(R^2) stability guidelines. Establishment of shelf-life using statistical models (Arrhenius, Q10, regression). Comprehensive documentation: batch manufacturing record, Certificate of Analysis (CoA), stability protocol. Label claim justification, product specifications, and quality assurance audits.	(Singh and Shukla, 2021; Vishwakarma and Pandey, 2025)

II. Model is to be statistically justified: Comprehensible Statistical justification: Such a justification should explicitly state the assumptions, regression methods, error models, and confidence intervals. The documentable reasons for selection of parameters, treatment of data and the structure of the models used in the evaluation of the data of stability (Etaware *et al.*, 2025) in accordance with the criterion of ICH Q1E is required by regulators.

III. Separate Stability Batch External Validation: External validation should be done using independent stability batches. This validation features the prediction and makes sure that the model is not over fitting. It affirms that the model can be useful in predicting the degradation rates, changes in the potency and changes in the quality attributes of the manufacturing batches accurately. The emphasis of the regulators on reproducibility and batch-to-batch consistency can be backed up by external validation (Dadhaniya *et al.*, 2025).

IV. Demonstrated Comparability to Stability Results of ICH: Model results must be comparable to the traditional ICH stability results. The predictive estimates based on kinetic and chemometric models as well as ML (Machine learning) shall give projections of shelf-life that are comparable to those results obtained from traditional real-time stability test. ICH Q1A(R^2), Q1D and Q1E data requirements will be demonstrated to the regulators to be met by the model. So, the model could also be used as an appropriate supplemental or complementary part of a regulatory application (Pujitha *et al.*, 2025).

Integrated Delivery and Packaging Strategies for Stability Enhancement and Shelf-Life Extension

However, the unique characteristics of HMPs like stability and bioavailability have inspired the development of sophisticated drug delivery systems as solutions to these limitations. Recent studies have focused on colloidal and vesicular platforms with improved therapeutic potential via targeted delivery and controlled release mechanisms. Herbal formulations are unique in having two related problems: (1) many active constituents are poorly soluble in water and (2) many are prone to degradation during storage and passage through physiological barriers. A brief summary of the various systems, their operation and their constraints is provided in Table 12.

Colloidal Carriers: Liposomes and Phytosomes

Liposomes and phytosomes are two advanced delivery systems that are especially efficient when it comes to increasing the bioavailability of plant-derived compounds, due to their poor aqueous solubility (Doroshenko and Shevchenko, 2026). The oral bioavailability of curcuminoids loaded in lipidosomes has been reported to be 20-fold higher than that of the free curcuminoid (Tsai *et al.*, 2011) due to gastrointestinal protection of the active ingredient and to improved membrane permeability. The principle of phytosome technology is to create a stoichiometric molecular complex between phytoconstituents and phospholipids which closely resemble the cell membrane architecture. In the context of therapeutic applications such as oncology and hepatoprotection, where the bioavailability at the level of the tissues is crucial, this structural homology enables the transcellular transport of bioactive saponins and flavonoids across intestinal and hepatic barriers (Anju *et al.*, 2026).

Vesicular Systems: Niosomes and Transferosomes

Vesicular systems provide complementary and route-specific benefits to expand labile herbal bioactives delivery options. Transferosomes are characterised by the presence of extremely deformable lipid bilayers. They are designed for transdermal administration and are able to pass through the channels in the skin that are smaller than the diameter of the transferosomes. They release thermolabile anti-inflammatory terpenoids, which are not able to survive conventional sterilisation procedures (Chen *et al.*, 2022).

Polymeric Nanoparticles and Nanoemulsions

Polymeric nanoparticles and nanoemulsions are another promising horizon in the field of delivery of herbals, where the benefits are related to the stability of the formulation and prolonged residence time. Chitosan-based nanoparticles take advantage of the mucoadhesive properties of chitosan to stay longer in the gastrointestinal mucus layer and therefore increase the luminal absorption of catechins encapsulated in them (Imam *et al.*, 2021). Nanoemulsions fall between the sizes of 20-200 nm and have oil-in-water interfaces with kinetically stable droplet sizes, which prevents the volatile EO (essential oil) from undergoing oxidation on the shelf and at the same time enhances its aqueous dispersion, thus overcoming both shelf-life and bioavailability issues (https://www.sciencedirect.com/author/54882170900/ranjit-k-harwansh *et al.*, 2019). These two systems can also be tailored to allow for stimuli-controlled release, with the drug released in response to a physiological change-like a change

Table 9: Decision tree and selection matrix for stability assessment.

Component	Purpose	References
Stability Indicators	Select degradation indicators such as phytochemicals, bioactivity and microbial quality based on product type and risk level.	(Himanshu *et al.*, 2025)
Phytochemicals	Marker compounds or fingerprints track chemical stability and degradation pathways.	(Kushwaha *et al.*, 2010)
Bioactivity	Mimics the efficacy of therapy with *in vitro* / *in vivo* bioassays.	(Agarwal *et al.*, 2014)
Microbial Stability	Assures microbial safety through checking total viable count, pathogens and the risk of contamination.	(Munukuntla *et al.*, 2024)
Analytical Method Selection	Identifies appropriate analytical tools depending on indicators that have been selected in order to measure changes in the process of stability studies.	(Dadhaniya *et al.*, 2025)
Chromatographic Methods (e.g., HPLC)	Phytochemical profiling, quantification, and degradation analysis.	(Chaudhary and Verma, 2022)
Spectroscopic Methods	Fingerprinting, rapid screening and detection of physical/chemical changes are appropriate.	(Shen *et al.*, 2026)
Bioassays	Determine biological potency change with time, which is associated with product efficacy.	(Sabotic *et al.*, 2024)
Shelf-Life Model Selection	Determines product expiry based on mathematical models that are in line with stability data.	(Anzar *et al.*, 2019)
Zero-Order Model	The degradation rate is assumed to be constant; used when the concentration is decreasing linearly with time.	(Bhangare *et al.*, 2022)
First-Order Model	Makes the assumption that degradation is a function of residual concentration; usually applied to herbal constituents.	(Bhangare *et al.*, 2022)
Arrhenius/Q10 Models	Applied to accelerated research to regulate actual shelf-life by temperature-dependent kinetics.	(Bhangare *et al.*, 2022)

Table 10: Comparative analysis of global regulatory frameworks for HMP shelf-life assessment.

Regulatory Aspect	WHO	AYUSH	EMA	FDA	DSHEA
Scientific Basis for Shelf-Life Determination	Depends on ICH stability requirements; employs climatic zone modeling to guide long-term and accelerated investigations.	May depend on conventional textual references; empirical stability testing criteria are developing and not matched with ICH.	Fully depends on ICH stability guidelines and needs established analytical methods, degradation kinetics, and robust stress testing.	Based on ICH stability requirements, it demands a lot of long-term and accelerated stability data.	There is no requirement for mandatory pre-market stability data; it is not aligned with ICH guidelines; manufacturers establish their own testing protocols.
Primary Focus	Global harmonization and guidance.	Traditional and classical formulations.	Evidence-based pharmaceutical quality.	Safety and efficacy of drugs.	Dietary supplements; minimal oversight.
Analytical Rigor	Moderate; general recommendations.	Variable; expedited for classical forms.	High; ICH-compliant protocols required.	High; comprehensive testing.	Minimal; manufacturer responsibility.
Stability Testing	Recommended; not mandatory.	Expedited or waived for traditional.	Mandatory; accelerated and real-time data.	Mandatory; ICH guidelines.	Optional; self-regulation.
Enforcement Mechanism	Voluntary adoption by member states.	National; variable compliance.	Stringent; regular inspections and surveillance.	Strict; FDA inspections and enforcement.	Weak; post-market only after adverse events.
Post-Market Surveillance	Advisory; inconsistent implementation.	Limited resources; variable monitoring.	Robust pharmacovigilance systems.	Systematic; MedWatch program.	Minimal; burden on consumers/ FDA.
Scientific Standardization	Moderate; lacks specificity.	Limited; evolving standards.	Comprehensive and harmonized.	Comprehensive and standardized.	Minimal; no pre-market review.
Key Strength	Global consensus and flexibility.	Traditional knowledge integration.	Analytical rigor and safety assurance.	Rigorous safety and efficacy data.	Accessibility and consumer choice.
Key Weakness	Lacks enforcement power.	Inconsistent scientific standards.	High regulatory burden and cost.	Lengthy approval timelines.	Inadequate pre-market oversight.
Countries Following	194 WHO member states (advisory).	India; select Asian countries.	EU (27 member states) + UK, Switzerland, Norway.	United States (primary) + Canada, Japan.	United States (primary regulatory framework).
Reference/Guideline	WHO Guidelines on Herbal Medicine Quality.	AYUSH Ministry Monographs and Standards	EMA Guideline CPMP/QWP [66]; ICH Q1A-Q1F.	FDA CDER Guidance; 21 CFR Parts 320-314.	Dietary Supplement Health and Education Act (DSHEA), 1994; 21 USC §321(ff).

in pH or the action of enzymes-in the body that targets the tissue it needs to reach, such as the inflamed colon.

Current Challenges and Translational Limitations

Although these cutting-edge delivery systems have good therapeutic potential, there are some translational hurdles that prevent the current clinical and commercial use of these systems.

Rigorous physicochemical characterisation, including particle size distribution, zeta-potential, polydispersity index, and encapsulation efficiency, is required for reproducibility among batches and *in vivo* performance, yet is often not fully reported or measured in published studies. Laboratory to industrial scale up of lipid based and polymeric systems also has some engineering challenges particularly for liposomal or polymeric systems that need to be processed under high-pressure conditions such as homogenisation, microfluidisation or processing under an inert atmosphere. In most countries, the regulatory categorisation of nano-herbal products is not clear, since traditional herbal medicine legislation was written for conventional dosage forms which fails to capture the different pharmacokinetic and safety characteristics that are expected from products containing nanoscale carriers (Teja *et al.*, 2022). Standardized characterisation procedures, reporting guidelines, and specific regulatory pathways will play a key role in moving research findings to clinically viable herbal products.

Future Perspectives in Stability Assessment and Shelf-Life Prediction of Pharmaceutical and Herbal Products

Future Directions for Regulatory Alignment

Although substantial efforts have been made at an individual level by some jurisdictions, the regulatory systems related to the shelf-life assessment of Herbal Medicinal Products (HMPs) are still not unified worldwide. Popular systems often depend on historical shelf-life claims and newer economies may not have the analytical system in place to apply state-of-the-art stability protocols. The use of AI-based modelling, chemometrics and advanced characterisation tools is not uniform, resulting in a lack of uniformity in product quality assurance. Meaningful regulatory harmonisation will take concerted action in international bodies, regional agencies and national authorities.

Towards a WHO-Led Global Harmonisation Framework

The most important near-term action would be for the World Health Organization (WHO) to lead the development of standardised global guidelines on HMP stability (as similar to ICH as possible) in terms of scope and function. A dedicated global herbal stability database should be developed to scientifically validate traditional shelf-life claims of herbal medicinal products. Such a database should include information on degradation pathways, chemical markers, and validated stability data across different climatic zones and dosage forms (WHO Guidelines on Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products) (ICH Quality Guidelines (Stability Testing Framework) - EMA, EMA Reflection Paper on Stability Testing of Herbal Medicinal Products and Traditional Herbal Medicinal Products) (WHO Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines, WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues). This infrastructure should include predictive modelling and artificial intelligence tools to assist in shelf-life prediction under different environmental storage conditions and to expand the capacity of regulatory studies to be carried out under conditions where long-term real-time studies may not be feasible (Jaiswal *et al.*, 2025).

Integrating Lessons from Established Regional Frameworks

In China, the National Medical Products Administration (NMPA) has introduced regulation of Traditional Chinese Medicine (TCM) products that includes the Good Manufacturing Practice (GMP) requirements as well as the analytical requirements of the Chinese Pharmacopoeia. The shelf-life determinations are based on the stability testing of chemical markers for various dosage forms and are also supported by large amounts of historical use data, which include traditional data, but require validation by modern scientific methods (Leong *et al.*, 2020). The integrated approach seen in Japan for Kampo medicines is the regulation by the Japanese Pharmacopoeia and the current stability assessment requirements by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), and the involvement of historical knowledge about Kampo medicines in safety evaluations by the Ministry of Health, Labour and Welfare (MHLW), which creates a tiered system (Arai and Kawahara, 2018). Many Kampo formulations are also included in the national health insurance scheme, increasing the incentive to ensure standardised quality compliance at national level and thus a successful example of the regulatory integration of traditional medicines at scale.

Priority Actions for Global Regulatory Harmonisation

Based on the lessons learned from the above-mentioned frameworks, the future regulatory alignment should aim at three priority actions: drawn from the WHO, NMPA, PMDA, EMA, FDA and AYUSH. Harmonisation should not just be a repetition of the resource requirements for high-income regulatory environments and therefore a tiered stability testing standard based on product complexity, analytical tools available and climatic zone should be established (Kim *et al.*, 2019). Second,

Table 11: AYUSH shelf-life notifications for traditional dosage forms (GSR 788 (E), 2016).

Dosage Form	Prescribed Shelf Life
Churna (powders)	2-3 years
Kwatha (decoctions)	6 months-1 year
Asava/Arishta (fermented liquids)	Up to 10 years
Ghrita (medicated ghee)	2-3 years
Taila (medicated oils)	2-3 years

Table 12: Advanced delivery systems and packaging technologies for stability enhancement and shelf-life extension of herbal products.

Category	System/ Technology	Type/Composition	Mechanism/ Description	Key advantages	Impact on shelf life	References
Drug delivery systems	Colloidal carriers	Liposomes; phytosomes	Encapsulation of bioactives within lipid-based carriers	Improved solubility; enhanced membrane permeability	Increased chemical stability and bioavailability; reduced degradation	(Barani *et al.*, 2021)
	Vesicular systems	Niosomes; transferosomes	Flexible vesicles enabling enhanced transport across biological barriers	Prolonged circulation; enhanced skin penetration	Improved stability in topical/ transdermal formulations	(Sergazy *et al.*, 2026)
	Polymeric nanoparticles	Chitosan-based systems	Mucoadhesive polymeric matrix enabling controlled release	Gastrointestinal retention; protection from enzymatic degradation	Sustained release; enhanced stability in GI environment	(Imam *et al.*, 2021)
	Innovative formulations	Nanoemulsions	Nanoscale emulsified systems with high surface area	Thermodynamic stability; protection against oxidation	Reduced oxidative degradation; extended shelf life	(Harwansh *et al.*, 2019)
Packaging technologies	Modified atmosphere packaging	Gas composition control	Alters internal package atmosphere (e.g., reduced O_2, increased CO_2)	Minimizes oxidative reactions and spoilage	Prolongs shelf life by reducing oxidation and microbial growth	(Caleb *et al.*, 2013)
	Vacuum packaging	Air removal	Eliminates oxygen from packaging environment	Inhibits aerobic microbial growth	Extends shelf life by reducing oxidation and contamination	(Farber, 1991)
	Edible coatings	Biopolymer-based coatings	Forms protective consumable barrier on product surface	Barrier to moisture and gases	Reduces moisture loss and oxidative degradation	(Jung and Han, 2014)
	Active packaging	Antimicrobial/ antioxidant incorporated systems	Releases active compounds into packaging environment	Controls microbial growth; prevents oxidation	Enhances shelf life through continuous protection	(Dobrucka & Cierpiszewski, 2014)

there should be an agreement on mutual recognition of stability data obtained under similar analytical conditions between the major regulatory agencies, which would minimise the duplication of testing that hinders access to international markets (Chegu and Nagabhushanam, 2021). These measures, when applied collectively, would help close the governance gap that currently enables very different levels of quality assurance on the herbal medicine shelf as a result of its manufacture and sale location, and facilitate the establishment of a science-based, global approach to the shelf-life regulation of herbal medicines.

Development of Standardized Stability Testing Protocols Tailored to Herbal Products

Herbal products are complex and variable which necessitate stability testing procedures specific to products. Traditional drug approaches are narrowly targeted at individual active ingredients and may not reflect the multi-dimensionality of herbal medicines. Appropriate methods to monitor organoleptic attributes, degradation products and marker compounds need to be validated. Other stresses relevant to herbal matrices that should be included in stability studies include the effect of temperature on the volatility of oils and the effect of moisture on the action of polysaccharides (Thakur *et al.*, 2011).

Promotion of Good Agricultural and Collection Practices (GACP)

Good Agricultural and Collection Practices (GACP) are designed to facilitate standard methods of growth, harvest and processing of plant materials to minimize contamination and chemical variability. Other essential factors are proper botanical identification, cultivation within proper agroclimatic zone, standard harvest time, quick post-harvest processing and

complete traceability. GACP would have more consistency of materials if more people around the world used it, and there would be a way of predicting how long they would last (WHO, GACP 2003; EMA, GACP).

Creation of Herbal-specific Pharmacopeial Monographs with Shelf-Life Criteria

Although herbal medicines are increasingly used, most pharmacopeias do not contain shelf-life criteria derived from stability data. Production of monographs, which establish shelf-life requirements, markers for degradation, packaging requirements, and storage requirements, would help to build quality assurance and facilitate regulatory assessments (Patil *et al.*, 2023).

Incorporation of Machine Learning for Predictive Shelf-Life Modeling

Traditional stability studies require time, money and on-site observation. Machine Learning (ML) can be used to aid predictive shelf-life models by connecting environmental factors and stability trends from the past. Computational methods like the neural network, random forest and partial least squares regression have the potential to be used to predict degradation kinetics. Future directions involve the establishment of integrated herbal stability databases, integration of ML into pharmaceutical quality systems, and the development of hybrid models of combining empirical data and mechanistic degradation pathways (Salman *et al.*, 2025).

Case Study 1: Prediction of Shelf Life of product from HPTLC Fingerprints by CNN.

Rationale

Chemical fingerprints of herbal formulations is a commonly used technique in HPTLC but small changes during storage may not be noticed during manual evaluation. Predicting shelf life using data is possible with Convolutional Neural Networks (CNNs) that can read the fingerprint patterns with a large number of dimensions.

Workflow

Formulations are fingerprinted using the HPTLC at specified time intervals and the resulting data are saved in TIFF and JPEG files. A CNN architecture is used for training fingerprint changes with degradation patterns and predicted shelf life. The prediction is compared to the actual stability outcomes in real-time, including sensitivity, accuracy and RMSE (Root Mean Square Error). Comparators used are the traditional regression models. The anticipated gains will be a decrease in long-term studies required and better understanding of the interpretation of fingerprint information, along with earlier recognition of stability concerns (https://www.tandfonline.com/author/Bhope%2C+Shrinivas+G *et al.*, 2011).

This case study follows the same organization, but focuses on linking environmental stressors with degradation of phytomarkers (Case Study 2: Hybrid Model Linking Environmental Stressors with Degradation of Phytomarkers).

Rationale

Degradation behavior can be described by mechanistic kinetic models, such as Arrhenius and ASAP (Accelerated Stability Assessment Program), but these models may not account for complex interactions occurring in herbal matrices. Machine-learning models discover empirical nonlinear patterns; they might not be interpretable. Hybrid approach gives enhanced predictive power and mechanistic relevance.

Experimental Workflow

Marker compounds of syrups, tablets and extracts are evaluated by physical evaluation, impurity profiling, HPTLC imaging, assay values, packaging characteristics, presence of desiccant and headspace oxygen. The kinetic parameters are determined at a controlled temperature and humidity and then correlated with the accelerated degradation data. The kinetic parameters, formulation descriptors, environmental parameters and packaging parameters are used to build an ML dataset. The output variables are label-claim retention, impurity limits and shelf-life classification.

Approaches to Hybrid Architectures are residual-learning models, parameter-modifier hybrids and ensemble meta-models. The combination of the kinetic predictions and Random Forest residual correction is referred to as residual-learning models. For parameter-modifier models, the formulation factors are used to enhance the kinetic parameters using ML. Ensemble meta-models combine several ML and kinetic predictions to provide better prediction accuracy. The framework also includes ways in which the data can be calibrated, uncertainty assessed, and compared to the ICH-compliant real-time stability data (Gandhi *et al.*, 2024).

Structured Route for Future Directions

The proposed routes provided in the analysis can be categorized as short-, medium- and long-term goals. In the short term, tasks will include the alignment of regulatory requirements, the establishment of herbal-specific stability measures, and the improvement of the uniformity of raw materials with GACP standards. Medium-term priorities aim at pharmacopeial monographs that will have stability criteria, and the innovation of the analytical methods already established for degradation kinetics, and coexistence of databases with a quantitative stability track. Advanced machine learning, as well as hybrid kinetic-statistical and digital regulatory systems are used in long-term plans to predict shelf life for various herbal formulations (Jadhav *et al.*, 2025).

DISCUSSION/REVIEW OF LITERATURE

The literature available suggests that the assessment of the shelf-life and stability of Herbal Medicinal Products (HMPs) is still a difficult field due to the complex and variable composition of the herbal materials. In contrast, HMPs have several bioactive components which could be degraded through various pathways depending on temperature, humidity, light, oxygen etc. HMPs have several bioactive components that may be degraded through different pathways depending on environmental factors, such as temperature, humidity, light, oxygen etc. This complexity poses special importance to the choice of appropriate stability-indicating parameters and analytical methods.

The most widely-used method for foreseeing shelf life of HMPs is accelerated stability testing, which delivers quick data on product stability in controlled stress situations. But there are several studies that suggest that the accelerated studies may not fully represent the long-term stability of complex herbal formulations. Hence, real-time stability testing is still necessary to ensure stability of the product in real storage conditions, especially in the case of polyherbal products and new herbal dosage forms.

HPLC, HPTLC, GC-MS and LC-MS/MS are still the most popular analytical techniques used for stability testing because they can be used to detect, quantify and identify marker substances with high sensitivity and specificity. However, recent research indicates that chromatographic fingerprinting, metabolomics and other non-destructive analytical methods can offer a more complete analysis of herbal products, which can assess multiple constituents at once. The combination of multivariate statistical analysis and machine learning has further improved prediction of degradation patterns and better shed light on the estimation of shelf-life.

Moreover, there are significant differences among the various authorities regarding regulations such as WHO, EMA, FDA, AYUSH, NMPA, PMDA etc. While all the regulatory agencies share a common focus on product quality, safety and efficacy, there are difficulties in the world market of HMPs due to the differences in the stability testing protocols, climatic zone considerations and the acceptance criteria. Regulatory harmonisation at an international level would help to ensure uniformity in the quality assessment and the acceptance of regulations in various regions.

Increased attention has been given to packaging technologies and advanced drug delivery systems as important factors that affect product stability. These methods are especially useful in preparations which contain chemically unstable or highly sensitive herb ingredients.

Although there has been some progress, there are still challenges to be faced. Standardized stability-indicating markers are still not available, herbal raw materials are not standardized, and there are limited long-term stability data, which are still in need of validation of predictive models. Further research is recommended to address the incorporation of traditional knowledge into modern analytical tools, long-term stability studies under practical storage conditions and the establishment of harmonised and science-based regulatory frameworks. New techniques like metabolomics, machine learning, quality-by-design or predictive stability modelling are anticipated to increase the accuracy, reliability and acceptance of the stability testing of HMPs worldwide.

CONCLUSION

The shelf-life estimation of herbal medicinal products still poses a problem due to the complexity and variability of such products. It is very important to standardize the stability tests, use an appropriate analytical technique, and implement scientifically sound regulatory procedures for a product to maintain its quality, safety, and efficacy throughout the intended shelf life. While accelerated stability studies and chromatographic approaches are common, new technologies like metabolomics, machine learning and predictive modelling hold promise for advancing the shelf-life prediction. In addition to improved regulatory guidance, which will help to harmonize the approach to stability assessment of HMPs, there will be further developments in packaging and quality-by-design methods to enhance stability assessment. In summary, this review offers a holistic perspective on the existing methods and future prospects for enhancing the stability evaluation of herbal drugs, which can help researchers, regulators, and the herbal pharmaceutical industry create more science- and evidence-driven methods.

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ABBREVIATIONS

HMPs: Herbal Medicinal Products; **EMA:** European Medicines Agency; **FDA:** Food and Drug Administration; **QbD:** Quality by Design; **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **HPLC:** High-Performance Liquid Chromatography; **HPTLC:** High-Performance Thin-Layer Chromatography; **GC-MS:** Gas Chromatography-Mass Spectrometry; **PCR:** Polymerase Chain Reaction; **ANOVA:** Analysis of Variance; **HPLC-DAD:** High-Performance Liquid Chromatography with Diode Array Detection; **CE:** Capillary Electrophoresis; **FTIR:** Fourier Transform Infrared Spectroscopy; **DLS:** Dynamic Light Scattering; **SEM:** Scanning Electron Microscopy; **PCA:** Principal Component Analysis; **PLS:** Partial Least Squares; **HCA:** Hierarchical Cluster Analysis; **HSAP:** Herbal Shelf-Life Assessment Pipeline; **GACP:** Good Agricultural and Collection Practices; **TCM:** Traditional

Chinese Medicine; **NMPA:** National Medical Products Administration (China); **PMDA:** Pharmaceuticals and Medical Devices Agency (Japan); **GMP:** Good Manufacturing Practices; **ML:** Machine Learning; **CMC:** Chemistry, Manufacturing, and Controls; **DSHEA:** Dietary Supplement Health and Education Act; **CNN:** Convolutional Neural Network; **ASAP:** Accelerated Stability Assessment Program; **WHO:** World Health Organization; **AYUSH:** Ayurveda, Yoga, Unani, Siddha, and Homoeopathy; **EDTA:** Ethylenediaminetetraacetic Acid; **MVDA:** Multivariate Data Analysis; **CoA:** Certificate of Analysis; **NMR:** Nuclear Magnetic Resonance; **EO:** Essential Oil; **MHLW:** Ministry of Health, Labour and Welfare (Japan); **RMSE:** Root Mean Square Error.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTION

SP: Contributed to the research concept and study design. **AJ:** Was responsible for the collection and assembly of data. **PA:** Contributed to writing the original draft of the manuscript. **KP:** Critically revised the manuscript for important intellectual content. **SJ:** Reviewed and provided the final approval of the manuscript for publication. All authors have read and approved the final version of the manuscript.

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