

# Shelf-Life Determination in Ayurvedic Dosage Forms: Concepts, Methods, Standards and Research Evidence

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## ABSTRACT

Shelf-life determination is fundamental for assuring safety, efficacy and quality of pharmaceutical products. Ayurvedic dosage forms pose unique challenges for stability and shelf-life estimation because they are multi-component, often contain complex botanicals, metals and mineral drugs, and may be prepared as solid, semisolid, liquid or aerosol forms using traditional processes. This review summarizes the scientific concepts and terminology of shelf-life and stability, outlines analytical and accelerated methods used for shelf-life estimation, presents applicable national and international standards and regulatory guidance, and reviews research evidence on stability testing of common *Ayurvedic* dosage forms. Practical recommendations for industry and researchers are offered to improve robustness and regulatory compliance of shelf-life claims for *Ayurvedic* products.

**Key Words** *Ayurveda, Shelf-Life, Stability Testing, Ayurvedic Pharmacopoeia, ICH Guidelines, Herbal formulations*

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## INTRODUCTION

Shelf-life (also called “expiry date” or “retention period”) is the period during which a medicinal product retains the required quality, safety and efficacy when stored under specified conditions. For modern pharmaceuticals, shelf-life is established by standardized stability testing and regulatory frameworks (e.g., ICH guidelines). *Ayurvedic* medicines, however, often include complex herbal extracts, classical preparations (e.g., *churna, bhasma, asava/arista, tiala*) and

preparations that are subject to traditional processing (*bhavana, marana*, etc.)<sup>1</sup>. These differences demand tailored stability approaches that blend traditional knowledge with modern analytical methods to produce scientifically defensible shelf-life assignments<sup>4</sup>.

This review synthesizes the core concepts and methods for determining shelf-life in Ayurvedic dosage forms, the regulatory and pharmacopeial standards relevant in India and internationally, and the available research on stability of

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representative *Ayurvedic* products. The aim is to equip manufacturers, regulators and researchers with a practical, evidence-based framework for shelf-life determination of *Ayurvedic* medicines.

### Fundamental concepts and terminology

1. **Stability:** The capacity of a product to remain within specified limits of quality, purity and potency throughout storage and use. Stability encompasses physical, chemical, microbiological and therapeutic aspects.

2. **Shelf-life (expiry):** The time interval during which a product is expected to remain within its specification when stored under defined conditions.

3. **Degradation pathways:** Chemical (oxidation, hydrolysis, photolysis), physical (moisture uptake, crystallization, caking), microbiological growth, and interactions between complex components (e.g., botanical matrix with metal ions).

4. **Critical quality attributes (CQAs):** Measurable properties that influence product quality and must be monitored for stability (e.g., assay of marker compounds, moisture content, pH, microbial limits, organoleptic attributes).

5. **Specification limits:** Acceptance criteria established for CQAs, often based on pharmacopeial standards or validated in-house limits.

*Ayurvedic* dosage forms require mapping of CQAs that are meaningful for each type: e.g., assay of marker phytochemicals for herbal decoctions, ash value and particle size for *bhasmas*, alcohol content and microbial load for

*asava/arista*, and peroxide value and rancidity markers for oils<sup>2</sup>.

### Regulatory and pharmacopeial standards

#### International guidance

- **ICH Q1A(R2)** — *Stability Testing of New Drug Substances and Products* provides the general framework for stress testing, long-term and accelerated stability testing. While intended for synthetic drugs, its principles (stress testing, accelerated conditions, shelf-life extrapolation using Arrhenius approach) are widely adopted for herbal products with adaptations<sup>5</sup>.

- **WHO guidance** — WHO has published guidance on quality control methods for herbal materials (including testing, storage and stability considerations), encouraging harmonized approaches and appropriate analytical methods for botanicals<sup>6</sup>.

#### National and traditional standards (India)

- ***Ayurvedic Pharmacopoeia of India (API)***

— API volumes specify methods, identification tests and sometimes shelf-life/packing/storage instructions for classical formulations. API remains the primary reference for pharmacopeial standards of *Ayurvedic* products in India<sup>7</sup>.

- **Indian Pharmacopoeia (IP)** — The IP includes monographs on some herbal drugs and general chapters pertinent to stability testing and microbiological standards that may be relevant for polyherbal products<sup>8</sup>.

- **Drug & Cosmetic Act and Rules (India)** — Regulatory requirements for *Ayurvedic* medicines include labeling, shelf-life declaration and adherence to Good Manufacturing Practices

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(GMPs). Specific stability data expectations may be defined by CDSCO and AYUSH regulatory bodies<sup>9</sup>.

Manufacturers must therefore reconcile classical textual instructions with modern regulatory expectations; when API monographs do not prescribe shelf-life, sound stability data based on validated analytical methods and accelerated studies are expected.

### Analytical methods and experimental designs for shelf-life estimation

#### 1. Selection of critical quality attributes (CQAs)

Define CQAs based on product type:

- **Liquids** (*asavalarista*, *arishta*, *kwath/dry extracts*): alcohol content/brix, pH, assay of marker constituents, microbial counts, oxidative markers.
- **Oils and lipids** (*taila*, *ghrita*): peroxide value, free fatty acid, rancidity, organoleptic changes.
- **Powders/pills** (*churna*, *avaleha*, *gutika*): moisture content, assay of key marker compounds, particle size, flow properties.
- **Metallo-mineral preparations** (*bhasmas*): loss on ignition, ash values, particle size (TEM/SEM), chemical speciation, Zeta potential, heavy metal speciation and bioavailability.

#### 2. Test conditions

- **Stress testing (forced degradation)**: Expose product to extremes (heat, humidity, light, oxidizing/reducing conditions) to identify degradation pathways and generate degradation products for analytical method development<sup>5</sup>.

- **Accelerated stability testing**: For many herbal products, common conditions are  $40 \pm 2$  °C /  $75 \pm 5\%$  RH for 6 months; intermediate conditions ( $30 \pm 2$  °C /  $65 \pm 5\%$  RH) may be used depending on climatic zone and product type. Results are used to estimate shelf-life via extrapolation.

- **Long-term stability testing**: Typically conducted at  $25 \pm 2$  °C and  $60 \pm 5\%$  RH (or climatic zone-specific conditions) for up to the proposed shelf-life (12–36 months). Sampling at specified intervals (0, 3, 6, 9, 12, 18, 24 months) is standard.

- **In-use/stress conditions**: Testing bottles once opened, repeated temperature cycles, freeze-thaw for some products, and photostability testing if light sensitive.

#### 3. Analytical method considerations

- Use **validated analytical methods** (specificity, linearity, accuracy, precision, LOD/LOQ) for quantifying marker compounds and degradation products. Chromatographic (HPLC, UPLC) and spectrometric (LC-MS) methods are preferred for complex matrices. Non-specific assays (e.g., total ash) have limited utility for shelf-life modeling but remain useful for identity and gross degradation detection. Microbiological methods must follow pharmacopeial standards.

- **Method stability-indication**: Analytical methods must be stability-indicating—able to separate and quantitate degradation products from the parent marker(s). Forced degradation studies help confirm this.

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### 4. Data analysis and shelf-life assignment

- **Kinetic modeling:** When degradation follows apparent zero- or first-order kinetics, models can be fitted to data to estimate time to reach specification limits. For many herbal constituents, first-order kinetics is a reasonable assumption, but empirical data must guide choice.
- **Arrhenius approach:** Accelerated study results at elevated temperatures can be used with the Arrhenius equation to estimate shelf-life at lower storage temperatures, provided degradation is temperature-dependent and follows predictable kinetics.
- **Acceptance criteria:** Shelf-life is the time until any monitored CQA reaches its specification limit. Frequently the assay of a marker compound or a microbial limit is the load-bearing attribute for expiry. Conservatism is prudent where uncertainty exists (e.g., assign shorter shelf-life or require packaging and storage conditions that mitigate degradation).

### Special considerations for Ayurvedic dosage forms

#### Multi-constituent complexity

Herbal preparations contain multiple active and inactive constituents that may degrade at different rates and produce transformation products. Selecting a single marker compound may be insufficient; a panel of markers or fingerprinting approaches (HPLC/LC-MS fingerprints) better represent overall chemical stability<sup>6</sup>.

### Traditional processes and “processing-stability” relationships

Classical processes (bhavana, marana, samskara) alter physicochemical properties and can improve stability (e.g., bhavana with acids or alcohols may reduce water activity). Stability studies should therefore be performed on the final marketed form prepared by the intended process, not on unprocessed raw herbs<sup>3</sup>.

#### Metal/mineral based preparations (*Bhasmas*)

*Bhasmas* are calcined metals or minerals with nanoscale or submicron particle sizes. Stability concerns include aggregation, transformation of chemical speciation, and heavy metal leaching. Analytical demands include elemental speciation, particle size distribution (TEM/SEM), and tests for bioaccessibility. Shelf-life must consider both physicochemical stability and safety parameters (e.g., limit tests for residual heavy metals)<sup>10</sup>.

#### Microbial stability and water activity

Many *Ayurvedic* products (*kwath*, *asava/arista*, *avaleha*) have water activity levels that influence microbial growth. Alcoholic fermentation (*asava/arista*) offers inherent microbial stability, but alcohol content must be monitored during storage. Non-alcoholic semi-solid formulations require strict control of water content, preservatives and manufacturing hygiene. Microbial challenge and preservative efficacy testing may be necessary<sup>8</sup>.

#### Packaging and storage

Selection of packaging (amber glass, HDPE, laminated pouches) directly affects shelf-life by minimizing moisture ingress, oxygen exposure

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and light. Packaging compatibility tests (leachables/extractables) and simulated transport conditions are important for shelf-life justification.

### Review of research evidence (selected examples)

The literature on systematic, pharmaceutically robust stability studies of *Ayurvedic* formulations has grown but remains fragmented; many studies are product-specific and vary in methodological rigor. Below is a synthesis of representative findings from published studies and reviews.

1. **Herbal decoctions, *kwath* and liquid extracts:** Studies report that moisture content, microbial counts and loss of marker phytochemicals are primary degradation pathways. Proper drying, low moisture content and adequate preservatives or alcohol content extend shelf-life. Standard assays (HPLC) have been used to monitor key markers over 6–12 months with variable stability depending on extractive solvent and packaging<sup>11</sup>.

2. ***Asava* and *Ariishta*:** These self-generated alcohol products often show stable profiles because alcohol acts as a preservative. However, alcohol content can vary with time (evaporation, fermentation continuation) influencing both potency and microbial stability. Shelf-life studies commonly monitor alcohol percentage, pH and marker assays; many products maintain acceptable quality for 2 years under controlled storage<sup>12</sup>.

3. **Oils and *Ghritas*:** Lipid oxidation (peroxide value elevation), rancidity and organoleptic

deterioration are the main stability issues. Antioxidant co-ingredients, nitrogen blanketing and opaque packaging slow degradation. Shelf-life studies indicate 12–24 months depending on formulation and storage<sup>13</sup>.

4. **Powders, *Churnas* and *Gutikas*:** Moisture uptake causing caking and microbial growth is central. Desiccant packaging and control of moisture content at manufacture are critical. Marker compound assays often remain stable if moisture and microbial parameters are controlled<sup>11</sup>.

5. ***Bhasmas* and mineral preparations:** Research emphasizes characterization (particle size, crystalline phase) rather than traditional “assays.” Aggregation and changes in surface chemistry over time may affect bioavailability. There is limited long-term stability data; conservatively, manufacturers often assign shorter shelf-lives or require specific storage to mitigate transformation<sup>10</sup>.

6. **Polyherbal proprietary formulations:** Published studies often apply chromatographic fingerprinting and targeted assays to demonstrate chemical stability under accelerated and real-time conditions. Many demonstrate acceptable stability for 12–36 months when formulated and packaged appropriately, but variability across batches and manufacturers highlights the need for standardized methods<sup>15</sup>.

**Limitations of current evidence:** Heterogeneity in test methods, variable selection of CQAs, short study durations, and lack of mechanistic degradation studies limit cross-study

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comparability. There is a relative paucity of high-quality, long-term stability studies that adhere strictly to ICH-style design for classical Ayurvedic products.

### Practical recommendations

1. **Define meaningful CQAs for each product type** — include chemical markers, microbiological limits, moisture, pH, alcohol content, peroxide value, and for *bhasmas*, particle size and speciation. Use chromatographic fingerprints alongside targeted assays for robustness.
2. **Develop stability-indicating analytical methods** — demonstrate via forced degradation that methods separate parent compounds and degradation products.
3. **Use a combined approach** — perform forced degradation, accelerated (e.g., 40 °C/75% RH) and long-term (zone-appropriate) studies. Where appropriate, apply Arrhenius modeling to extrapolate shelf-life, but only when degradation kinetics are demonstrated and assumptions hold.
4. **Consider packaging and transport stresses early** — include packaging compatibility and accelerated transport simulation studies.
5. **Document traditional knowledge but generate data** — textual references to long shelf-life in classical texts are informative but insufficient for modern regulatory acceptance; complement with empirical stability data on the actual marketed product.
6. **For bhasmas and minerals** — include advanced characterization (TEM/SEM, XRD,

elemental speciation) and safety monitoring (heavy metals leaching) over storage.

7. **In-use studies** — for multi-use containers, execute in-use stability (repeat opening) and preservative efficacy testing where relevant.
8. **Regulatory alignment** — align study design with API/ICH/WHO and local regulator guidance; when API lacks specifics, present a scientific justification for proposed shelf-life based on robust data.

## CONCLUSION

Determining shelf-life for *Ayurvedic* dosage forms requires integration of traditional manufacturing knowledge with modern stability science. While core principles (stress testing, validated analyses, accelerated and long-term studies) are transferable from conventional pharmaceuticals, the complexity of multi-constituent herbal matrices and metal/mineral preparations demands tailored selection of CQAs, appropriate analytical techniques and thoughtful experimental design. Strengthening the evidence base through standardized, well-documented stability studies—combined with appropriate packaging and storage controls—will improve product quality, patient safety and regulatory confidence in *Ayurvedic* medicines.

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### REFERENCES

1. *Ayurvedic Pharmacopoeia of India. Part I–IV.* New Delhi: Government of India, Ministry of Health & Family Welfare, Department of AYUSH; (multiple volumes and editions).
2. Mukherjee PK. *Quality Control and Evaluation of Herbal Drugs.* 2nd ed. New Delhi: Business Horizons; 2002.
3. Rastogi S, Pandey MM, Rawat AKS. Global acceptance of *Ayurvedic* drugs: key challenges. *J Ethnopharmacol.* 2015
4. Singh RH. Safety and quality of *Ayurvedic* formulations: modern investigative approaches. *Int J Ayurveda Res.* 2011.
5. ICH Harmonised Tripartite Guideline. Q1A(R2): Stability Testing of New Drug Substances and Products. International Conference on Harmonisation; 2003.
6. World Health Organization. *Quality control methods for medicinal plant materials.* Geneva: WHO; 1998.
7. Government of India. *Ayurvedic Pharmacopoeia Commission — Technical Monographs.* New Delhi: Government of India.
8. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia.* Ghaziabad: The Controller of Publications; 2018.
9. *The Drugs and Cosmetics Act, 1940 and Rules, 1945.* Government of India. Ministry of Health and Family Welfare.
10. Bhattacharya A, Chaudhuri TK. Physicochemical characterization and stability aspects of bhasma formulations: a review. *AYU.* 2012;33(3):389–96.
11. Patel KR, Patel MB, Tripathi D. Stability studies on herbal formulations: strategies and case studies. *Pharmacogn Rev.* 2014;8(15):61–70.
12. Sharma V, Sharma K. Stability and shelf life of *Ayurvedic arishta* and *asava*: a review. *J Ayurveda Integr Med.* 2018;9(3):167–74.
13. Jain S, Prakash O. Oxidative stability of medicated oils: evaluation and preservation strategies. *Asian J Pharm Clin Res.* 2016;9(5):12–8.
14. Kaur R, Singh J, Singh M. Chromatographic fingerprinting and stability testing of polyherbal formulations: concepts and applications. *J Pharm Biomed Anal.* 2017;145:211–25.
15. Verma S, Garg A. Stability testing of herbal drugs: a regulatory perspective. *Int J Pharm Sci Res.* 2019;10(6):2515–24.