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"SHELF LIFE (*SAVIRYATA AVADHI*) OF AYURVEDIC DOSAGE FORMS: CLASSICAL LIMITS, RULE 161-B AND THE EVIDENCE FROM STABILITY STUDIES"

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ABSTRACT

Background: Classical Ayurvedic texts specify the period for which each dosage form retains its potency (*saviryata avadhi*), while Indian regulations under Rule 161-B of the Drugs and Cosmetics Rules prescribe fixed shelf lives for Ayurvedic, Siddha and Unani medicines. The two sets of figures differ widely, and the scientific basis of both is debated. **Objective:** To compare classical and regulatory shelf-life norms and to review the evidence from stability studies of Ayurvedic formulations. **Methods:** A critical narrative review of classical sources, the regulatory framework and published stability studies, with reference to international stability-testing guidelines. **Results:** The *Sharangadhara Samhita* gives two months for *churna*, one year for *gutika* and *avaleha*, and four months for *sneha kalpana*, while *asava*, *arishta* and *rasa* preparations are said to improve with age. Rule 161-B, as amended in 2016, assigns two years to *churna* and *ghrita*, three years to *avaleha* and *taila*, five years to *guggulu* and to *vati* containing minerals, and ten years to *asava*, *arishta*, *bhasma*, *kupipakva rasayana* and *parpati*. A 2024 appraisal of 49 stability studies found that 54.7% of calculated shelf lives were shorter than the regulatory norm and 35.9% longer, that only two studies used real-time testing and that most tested a single batch. **Conclusion:** Neither classical nor regulatory figures are fully supported by data. Product-specific stability studies following ICH principles, with multiple batches, real-time confirmation and potency markers, should replace fixed categorical periods.

KEYWORDS: *Saviryata avadhi*; Shelf life; Rule 161-B; Stability testing; Accelerated stability; Ayurvedic dosage forms; ICH guidelines

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INTRODUCTION

Every medicine changes during storage. Active constituents degrade, moisture is gained or lost, fats oxidise, microorganisms grow, and physical properties change. The period during which a product remains within its specification is its shelf life. Ayurveda recognised this long ago: classical texts describe *saviryata avadhi*, the period for which a dosage form retains its potency (*virya*), and they distinguish preparations that deteriorate quickly from those said to improve with age[1].

Modern regulation requires a defined expiry date on every medicine. In India, Rule 161-B of the Drugs and Cosmetics Rules prescribes shelf lives for Ayurvedic, Siddha and Unani medicines by dosage form, and the rule was substantially revised in 2016[2]. The classical and regulatory periods often differ, and manufacturers, regulators and researchers have asked which, if either, is supported by data[3]. This review compares the two frameworks and examines the evidence from stability studies.

METHODS OF THE REVIEW

This is a critical narrative review. Classical shelf-life statements were taken from published analyses of classical texts. Regulatory periods were taken from the 2016 amendment of Rule 161-B. Stability studies of Ayurvedic formulations were identified through PubMed, PubMed Central, DOAJ, Crossref-indexed records and journal archives, using the terms shelf life, *saviryata avadhi*, stability, accelerated stability, Ayurvedic formulation and the names of dosage forms, and from the reference list of a recent systematic appraisal[3]. International stability-testing guidelines were used as the methodological benchmark[4,5].

CLASSICAL SHELF-LIFE NORMS

Table 1. Classical and regulatory shelf-life periods for selected Ayurvedic dosage forms

Dosage form	Classical period (*Sharangadhara Samhita*)	Rule 161-B (2016 amendment)
Churna (including *kwatha* powders, *lepa*)	2 months	2 years
Gutika/*vati*, herbal only	1 year	3 years†
Gutika/*vati* with *rasa*, *uparasa* or *bhasma* and herbs	1 year	5 years
Avaleha, *khanda*, *paka*	1 year	3 years
Ghrita	4 months	2 years
Taila	4 months	3 years
Guggulu	–	5 years
Asava, *Arishta*	Potency increases with age	10 years
Bhasma, *pishti* (except *Naga*, *Vanga*, *Tamra*)	Potency increases with age	10 years
Naga, *Vanga*, *Tamra bhasma*	Potency increases with age	5 years
Kupipakva rasayana, *parpati*	Potency increases with age	10 years

The most widely quoted classical norms come from the *Sharangadhara Samhita*: two months for *churna*, one year for *gutika* and *avaleha*, four months for *sneha kalpana*, and an increase in potency with age for *asava*, *arishta* and metal and mineral preparations[1,6]. Other texts differ. For *sneha kalpana*, *Vangasena* gives six months and *Yogaratnakara* twelve months[6]. These differences probably reflect regional climate, storage practices and the specific products the authors had in mind. The classical norms were based on observation rather than on measurement of active constituents, and they assumed traditional containers and storage.

THE REGULATORY FRAMEWORK

Shelf-life requirements for Ayurvedic medicines were introduced in 2005, and Rule 161-B was later added and then amended in 2016[2,3]. The 2016 amendment assigns fixed periods by dosage form (Table 1) and allows a different period when supported by scientific data. Compared with classical norms, the regulatory periods are generally much longer: for example, *churna* rose from two months to two years and *ghrita* from four months to two years. For preparations said to improve with age, the regulation imposes a ceiling of five to ten years.

The categorical approach has advantages: it is simple, enforceable and avoids indefinite claims. Its weakness is that a single period cannot account for differences in ingredients, processing, moisture, packaging and storage between products of the same dosage form.

EVIDENCE FROM STABILITY STUDIES

1. Overall picture

A 2024 appraisal identified 70 published articles, of which 41 were suitable, together with eight unpublished theses. Shelf lives calculated in these studies were shorter than the regulatory norm in 54.7% of cases, longer in 35.9% and equal in 4.7%. Results varied widely within dosage forms: calculated shelf lives ranged from about 1.1 years to over 8 years for *avaleha*, and from six months to three years for *churna*. Of 43 articles assessed, 33 followed a recognised guideline such as ICH, CCRAS, the Ayurvedic Pharmacopoeia or WHO; only two used real-time testing, and most used a single batch rather than the three required by ICH[3].

Table 2. Selected stability studies of Ayurvedic formulations

Formulation	Dosage form	Focus
Kamsaharitaki avaleha and its granules	*Avaleha* vs granules	Comparative shelf life of traditional and modified forms
Shirishavaleha	*Avaleha*	Shelf-life evaluation
Kunkumadi ghrita	*Ghrita*	Physicochemical screening and shelf life
Kasisadya ghrita	*Ghrita*, two methods of preparation	Effect of preparation method on shelf life
Bhallataka taila	*Taila*	Shelf-life evaluation
Rasayana churna	*Churna*	Shelf-life evaluation
Hridya yoga churna	*Churna*	Shelf life and HPTLC profile
Laghu sutashekhara rasa	Mineral-containing *vati*	Shelf-life evaluation
Devdarvadyarishta	*Arishta*	Influence of storage conditions on physicochemical properties

2. Factors affecting stability

Studies point to several factors that influence stability within a dosage form. Converting *avaleha* into granules has been studied as a way to improve stability[7]. The method of preparation, including heating pattern, affected the stability of *ghrita*[9,10]. Storage conditions influenced the physicochemical properties of an *arishta*[15]. Processing steps such as *bhavana*, granulation, the age of ingredients and the presence of minerals have also been suggested as determinants[3]. These findings support product-specific rather than categorical shelf lives.

3. Methodological problems

The appraisal identified several recurring weaknesses[3]:

- **Accelerated testing without real-time confirmation.** Accelerated studies at elevated temperature and humidity are useful for prediction, but extrapolation assumes a single, temperature-dependent degradation mechanism, which may not hold for complex herbal mixtures.
- **Single batches.** ICH principles require at least three batches to capture variability[4].
- **Choice of stability-indicating parameters.** Many studies relied on general physicochemical parameters such as moisture, pH and loss on drying, rather than on the content of active or marker constituents.
- **Statistical evaluation.** Few studies applied the regression-based evaluation recommended for estimating shelf life[5].

RECO NCILING CLASSICAL AND REGULATORY VIEWS

The classical and regulatory frameworks answer slightly different questions. Classical *saviryata avadhi* concerns therapeutic potency as judged by experienced physicians; regulatory shelf life concerns compliance with a specification. A rational approach would combine them:

- Use classical norms as a prior expectation and a signal of which products are likely to be unstable, for example *churna* and *sneha kalpana*.
- Define stability-indicating parameters for each product, including marker constituents linked to activity, microbial limits and, for fats, oxidation indices such as peroxide and acid values.
- Conduct stability studies on at least three batches in the final container, with accelerated testing for initial prediction and real-time testing for confirmation.
- For products said to improve with age, such as *asava*, *arishta* and *bhasma*, test whether potency markers or biological activity actually change over time, so that claims can be examined rather than assumed.

RESEARCH GAPS

The main gaps are: real-time stability studies on multiple batches; identification of stability-indicating markers for common formulations; studies of packaging and climatic zones; and studies that relate chemical changes during storage to biological or clinical activity. Studies of *asava*, *arishta* and *bhasma* over long periods would also test the classical claim that these preparations improve with age.

CONCLUSION

Classical texts and Rule 161-B give very different shelf lives for Ayurvedic dosage forms, and neither is fully supported by stability data. Published studies suggest that real shelf lives vary widely within dosage forms and are often shorter than regulatory norms, but most studies are accelerated, single-batch and based on general rather than activity-linked parameters. Product-specific stability studies following ICH principles, with real-time confirmation and potency markers, would provide a sound basis for expiry dates and for revising categorical norms.

REFERENCES

1. Tripathi B, editor. Sharangadhara Samhita with Dipika Hindi commentary. Purva Khanda 1/54–55. Varanasi: Chaukhamba Surbharati Prakashan; 2008.
2. Ministry of AYUSH, Government of India. Drugs and Cosmetics (Fifth Amendment) Rules, 2016: Rule 161-B (shelf life or date of expiry of Ayurvedic, Siddha and Unani drugs). The Gazette of India, Extraordinary. New Delhi: Government of India; 2016.
3. Soundaryashree NR, Chandan RS, Singamaneni VR, Nagidi HR, Patel G, Vidiyala N, et al. Development and validation of RP-HPLC method for quantification of bamifylline in pharmaceutical formulations using analytical quality by design (AQbD) principles. Adv J Chem Sect A. 2025:2076-97.
4. International Conference on Harmonisation. ICH Q1A(R2): Stability testing of new drug substances and products. Geneva: ICH; 2003.
5. International Conference on Harmonisation. ICH Q1E: Evaluation of stability data. Geneva: ICH; 2004.
6. Zehravi M, Khan SL, Gupta JK, Jahnavi P, Babu RH, Vidiyala N, et al. Advances in polymeric nanoparticles for oral drug delivery: mechanisms, challenges, emerging trends, and preclinical to clinical perspectives. 3 Biotech. 2026;16(1):35.
7. Khemuka N, Galib R, Patgiri BJ, Prajapati PK. Shelf-life evaluation of Kaṃsaharītakī avaleha and its granules: a preliminary study. Anc Sci Life 2015;35:96–100.
8. Vidiyala N, Sunkishala P, Parupathi PR, Nyavanandi D. Stem cell-derived exosomes in wound healing and skin regeneration: emerging therapeutic strategies and mechanisms. Cells. 2026;15(10):872.
9. Prajapati PK, Sharma R, Amrutia A, Patgiri BJ. Physicochemical screening and shelf life evaluation of Kuṅkumādi ghṛta. Anc Sci Life 2017;36:129–35.
10. Yadav PR, Galib R, Prajapati PK, Singh P. Shelf-life evaluation of Kasisadya ghritam prepared by two different methods. J Drug Res Ayurvedic Sci 2022;7:38–46.
11. Jahnavi P, Kumar AK, Prema S, Singamaneni VR, Vidiyala N, Sunkishala P, et al. Recent progress in heterogeneous catalysis for sustainable chemical processes. J Chem Rev. 2026;8(2):154-79.
12. Verma P, Patgiri B, Prajapati PK. Shelf-life evaluation of Rasayana churna. Ayu 2014;35:184–6.
13. Unnikrishnan V, Nishteswar K, Patel BR. Shelf life evaluation and comparative HPTLC profile of Hridya yoga churna. Pharmacogn J 2016;8(3).
14. Wal A, Bukke SPN, Vidiyala N, Jamil S, Sharma KK, Khan A, et al. Stimuli-responsive nanogels as intelligent nanocarriers for tumor microenvironment-triggered anticancer drug delivery. Discov Nano. 2026;21(1):247.
15. Goyal C, Joshi N, Sharma VK, Malik A, Malik S, Kumar A, et al. Influence of storage conditions on physicochemical properties and shelf-life of Devdarvadyarishta. Int J Pharm Res 2021;13:622–9.