

Pharmaceutical Standardization

Shelf-life evaluation of *Rasayana Churna*: A preliminary study

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Abstract

Background: Concept of *Saviryta Avadhi* (shelf-life) of Ayurvedic dosage forms is well-defined in classics of Ayurveda. Information on this is scattered in initial classics of Ayurveda like *Charaka Samhita*, but focused well after 13th Century AD in texts such as *Vangasena Samhita*, *Sharangadhara Samhita* and *Yogaratanakara*. Though the concepts have a strong background; considering the pharmaceutical development, a need is felt to re-evaluate the age old concepts by following current norms. **Aim:** To evaluate shelf-life of two samples of *Rasayana Churna*. **Materials and Methods:** Raw material was procured from The Pharmacy, Gujarat Ayurved University and authenticated at Pharmacognosy Laboratory. Individual drugs were powdered and blended in specified ratio to obtain *Rasayana Churna* (RC). RC was levigated with decoction of *Amalaki*, *Guduchi* and *Gokshura* to prepare *Bhavita Rasayana Churna* (BRC). Both the samples were subjected to accelerated stability studies by following standard guidelines. **Results:** Both the samples are bitter and astringent with characteristic odor. RC is creamish brown in colour, while BRC is dark blackish brown. These Organoleptic characters were unchanged till the 6th month of study. On comparison, BRC is found to be more stable than RC. **Conclusion:** This signifies that, *Bhavana* not only incorporates additional therapeutic attributes, but also helpful in increasing shelf-life.

Key words: Accelerated stability, *Bhavana*, *Churna*, *Rasayana*, *Saviryta Avadhi*, shelf-life

Introduction

Shelf-life is the length of time, after which all substances starts to degrade in their qualities and become unsuitable for consumption or sale. To precise, shelf-life of a product guarantees potency of a drug. Most of the medications continue to be effective and safe for a time after the expiry date. It is often mathematically modeled around a parameter such as concentration of a chemical compound, a microbiological index, or moisture content, etc.^[1]

Significance of shelf-life is highly appreciated and recognized in classics like *Charaka Samhita*. But the information is hidden in verses and scattered. To refer, it has been said that the drug can be utilized for therapeutic purposes until it retains its fragrance, color, and taste etc.^[2] Seers of later period attempted compiling information pertaining to this concept and succeeded

in proposing *Saviryta Avadhi*, which reflected in *Vangasena Samhita*,^[3] *Sharangadhara Samhita*,^[4] and *Yogaratanakara*,^[5] etc.

Considering the changing scenario in pharmaceutical development and storage techniques; classical concepts of *Saviryta Avadhi* cannot be implemented today. Hence, a need is felt to re-establish these concepts following the current guidelines. Published reports on this aspect are very few. With this background, it has been planned to evaluate shelf-life of two samples of *Rasayana Churna* (RC).^[6] It is a poly herbal formulation composed of fine powders of *Amalaki* (*Emblia officinalis* Linn.), *Guduchi* (*Tinospora cordifolia* Linn.), and *Gokshura* (*Tribulus terrestris* Linn.) in equal quantities.

Materials and Methods

Preparation of drug

Components of the RC were procured from the Pharmacy, Gujarat Ayurved University, Jamnagar. Physical impurities were removed manually; botanical identity has been authenticated in the Pharmacognosy Laboratory. Fine powders (# 72) of individual components were prepared and blended together to prepare RC.

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Table 1: Physico-chemical profile of BRC and RC at different intervals

Parameters	Initial		'1' month		'3' months		'6' months	
	BRC	RC	BRC	RC	BRC	RC	BRC	RC
pH (1% w/v)	3.67	3.56	3.57	3.54	3.51	3.54	3.38	3.37
Moisture	9.08	8.91	9.86	9.00	10.24	9.47	10.35	10.08
Total ash	10.55	10.08	10.43	10.02	10.38	9.91	10.27	9.64
Alcohol soluble extractive	20.96	20.16	19.04	20.04	18.88	18.32	18.28	17.24
Water soluble extractive	33.84	27.04	34.34	28.24	34.48	27.84	34.94	23.03

BRC: *Bhavita Rasayana Churna*; RC: *Rasayana Churna***Table 2: Functional groups and bitterness in BRC and RC at different intervals**

Parameters	Initial		'6' months	
	BRC	RC	BRC	RC
Tannin	25.40	12.22	7.04	9.31
Alkaloid	0.197	0.147	0.08	0.112
Saponin	6.22	10.31	4.29	4.19
Bitter	6.09	6.01	5.98	5.95

BRC: *Bhavita Rasayana Churna*; RC: *Rasayana Churna*

In the other batch, RC was subjected to three *Bhavanas* (levigation) with freshly prepared *Kwatha* (decoction) of RC ingredients. At the end of three levigations, the product was allowed to dry completely that is labeled as *Bhavita Rasayana Churna* (BRC).

Packing

The final products (RC and BRC) in required quantities were packed in low-density polyethylene containers.

Sample quantity

Five containers of the final products (RC and BRC) of 50 g each were packed and stored in accelerated stability study chamber.

Storage conditions in the stability chamber

Samples were stored at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$, and $75 \pm 5\%$ relative humidity.

Frequency of withdrawal

Samples were withdrawn at the intervals of 01, 03, and 06 months.

Parameters of evaluation

Basic analytical parameters including loss on drying at 110°C ,^[7] ash value,^[8] pH value^[9] water soluble extractives,^[10] methanol soluble extractives,^[11] percentage of tannins, bitterness, alkaloids and saponins were evaluated at regular intervals.

Results

Organoleptic characters and physico-chemical profiles were evaluated initially and at the end of 1, 3, and 6 months. Both the powders have characteristic odor, bitter and astringent taste. RC is creamish brown in colour, while BRC is dark

blackish brown. These Organoleptic characters were unchanged till the 6th month of study. Results obtained in both the drugs are shown in Table 1. Bitterness, tannins, alkaloids, and saponins were estimated in both groups initially and at the end of 6th month [Table 2]. Based on the values obtained at different stages; intercept, slope, expected time (in months) for 10% of degradation [Table 3] were calculated for individual parameters of both drugs. As India falls in Zone III; the mean obtained of these months was multiplied with 3.3 to extrapolate shelf-life [Table 4].

Discussion

On comparison, no changes in organoleptic characters were found in both the drugs at all the levels of investigations. RC was found to be creamish brown in color with characteristic odor and bitter and astringent in taste. BRC was dark blackish brown in color with characteristic odor with bitter and astringent taste. Insignificant differences were observed in basic physico-chemical profiles in both the drugs at different stages of analysis. Water soluble extractive was found to be slightly higher (34.4%) in BRC than RC (26.3%). On overall observation of all the parameters, except alcohol soluble extractive, other areas were found to be more stable in BRC than RC. Stability of bitterness was maximum in BRC (60) in comparison to all other parameters. Analysis revealed that the drug BRC has more shelf-life than RC. Though studies have been reported on conceptual aspects,^[12] and shelf-life of different Ayurvedic formulations,^[13] impact of *Bhavana* has not been so far attempted. The current study provided some leads in this direction.

Conclusion

Shelf-life defined for *Churna* at Rule 161-B, Drugs and Cosmetics Act is 2 years. In the current study, RC found to have shelf-life of 2 years 11 months, while the BRC is found to have more stability with a shelf-life of 5 years 3 months. This implies that, *Bhavana* not only attributes therapeutic qualities in a product, but also helps in keeping the product more stable for longer duration. Though, the current attempt is a primitive one; extensive studies focusing on the exact mechanism and changes that take place during the process of *Bhavana* are needed.

Table 3: Intercept, slope, 10% degradation and months of both the formulations for different parameters

Parameters	Intercept		Slope		10% degradation		Months	
	BRC	RC	BRC	RC	BRC	RC	BRC	RC
Formulae pH	3.645	3.58	0.045	0.03	3.30	3.204	12.5	12.53
Moisture	9.42	8.86	0.18	0.2	8.18	8.02	5.7	4.2
Total ash	10.5	10.1	0.04	0.07	9.50	9.072	25.1	14.68
Alc. Sol. Extr.	20.19	20.24	0.36	0.5	18.87	18.144	3.68	4.2
Wat. Sol. Extr.	33.37	28.37	0.21	0.7	30.46	24.33	13.88	5.76
Tannin	12.22	25.4	0.48	3.06	11.00	22.86	2.54	0.83
Alkaloid	0.147	0.197	0.005	0.02	0.132	0.177	29.5	9.67
Saponin	10.31	6.22	1.02	0.32	9.23	5.6	19.38	13.84
Bitter	6.01	6.09	0.01	0.02	5.41	5.481	60.0	30.45
Mean months							19.14	10.68

BRC: Bhavita Rasayana Churna; RC: Rasayana Churna

Table 4: Extrapolation of shelf life in both BRC and RC

Drug	Months	Multiplication factor	Shelf life	
			Months	Years
BRC	19.14	3.33	63.74	5.3
RC	10.68	3.33	35.56	2.11

BRC: Bhavita Rasayana Churna; RC: Rasayana Churna

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हिन्दी सारांश

रसायनचूर्ण की सवीर्यतावधि परीक्षा-एक प्रारम्भिक अध्ययन

प्रियंका वर्मा, गालिब, बिस्वाज्योति पटगिरी, प्रदीपकुमार प्रजापति

आयुर्वेद कल्पनाओं की सवीर्यता अवधि की अवधारणा को आयुर्वेदिक ग्रन्थों में परिभाषित किया गया है। यह जानकारी चरक संहिता जैसे आयुर्वेदिक ग्रन्थों में अलग-अलग स्थानों पर मिलती हैं, परन्तु १३ वीं सदी के बाद वंगसेन, शारङ्गधर एवं योगरत्नाकर जैसे ग्रन्थों में आयुर्वेदिक कल्पनाओं की सवीर्यता अवधि पर ध्यान केन्द्रित करते हुए, उसे पूर्ण रूप से परिभाषित किया गया है। यद्यपि इस अवधारणा की एक मजबूत पृष्ठभूमि है फिर भी, औषधि निर्माणात्मक विकास पर विचार करते हुए, सदियों पुरानी इस अवधारणा को मौजूदा मापदण्डों का पालन करते हुए फिर से मूल्यांकन करना जरूरी है। इन सब बातों का ध्यान रखते हुए रसायन चूर्ण के दो नमूनों की सवीर्यता अवधि का मूल्यांकन करने का प्रयास किया गया है। दोनों नमूनों की ऐक्सलेरेटेड स्टैबिलिटी अध्ययन के अन्तर्गत पाया गया कि भावित चूर्ण की सवीर्यता अवधि सादे चूर्ण की अपेक्षाकृत अधिक है। इससे पता चलता है कि भावना न केवल औषधि के चिकित्सीय गुणों का वर्धन करती है, अपितु उसकी सवीर्यता अवधि को भी बढ़ाती है।