



Review Article

www.ijrap.net

(ISSN Online:2229-3566, ISSN Print:2277-4343)



STABILITY STUDY FOR VARIOUS AVALEHA FORMULATIONS: A REVIEW

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Received on: 23/1/24 Accepted on: 16/3/24

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DOI: 10.7897/2277-4343.15385

ABSTRACT

Avaleha kalpana is the most commonly used secondary dosage form that is prepared with the addition of madhura dravya in prescribed swarasa or kwatha. It is used as Rasayana by Acharya Charaka, Sushruta and Vagbhata. It is gaining popularity day by day because of its easy administration, palatability and long shelf life. A stability study is done to provide evidence on how the quality of a drug substance or product varies with time under the influence of various environmental factors such as temperature, humidity and light. A stability study is also conducted to establish the shelf life of the drug product and recommend storage conditions. This article reviewed the stability study of various Avaleha formulations obtained through Google Scholar over the past ten years.

Keywords: Avaleha, Stability study, Shelf life

INTRODUCTION

Avaleha Kalpana is a semisolid secondary dosage form ¹, predominantly used for internal administration. Avaleha is prepared by the addition of madhura dravya such as jaggery, sugar candy, etc., along with ghrita, madhu, and prakshepa dravya, i.e. the fine powders of medicinal drugs are added in the prescribed swarasa or kwatha as mentioned.² Avaleha kalpana was a modified form prepared from panchavidha kashaya kalpana to make the availability of the formulation throughout the year, long shelf life, palatability, and produce quick action with low doses.³

Stability can also be defined as “The capacity of a drug to remain within specifications established to assure its identity, strength, quality and purity”, as per ICH.

Stability studies are done to define the shelf life of a formulation and provide evidence on how the quality of a drug substance or product varies with time under the influence of various environmental factors such as temperature, humidity, and light.⁴ The primary reason for stability testing concerns the patient's well-being suffering from the disease for which the products are designed.⁵ It also permits the establishment of recommended pack, storage condition, retest periods and shelf life. It also helps in improving the current shelf life.

It is pertinent to emphasise the stability and quality improvement of these formulations. Therefore, it would be unforeseen and customary to remind the discerning views of Acharya Sharangdhara, who has judiciously enlightened the concept of the shelf life of various Ayurvedic formulations.

This study aims to overview Avaleha kalpana and to conduct a review on the stability study of various Avaleha formulations; for

this study, ten articles were obtained regarding the stability study of Avaleha formulation with the help of Ayurveda Journals in Google Scholar, and two were obtained through Research Gate.

In the ten articles studied, the stability study method was found to be the same for nine articles, i.e., the Accelerated Stability Study was carried out by keeping the Avaleha in three different glass containers at varying temperatures for six months.

Only a single article was found where the Accelerated Stability Study was done for three months, and it did not state the shelf life but stated that the formulation was stable for more than three months.

Out of the ten, nine articles gave us information regarding the shelf life and the storage conditions required for the stability of that particular Avaleha.

It has been more clearly illustrated with the help of a chart demonstrating all information regarding the articles that were sourced.

DISCUSSION

The study aimed to review the stability of various Avaleha formulations; for this study, ten articles were obtained regarding the stability study of Avaleha formulations from various Ayurveda journals with the help of Google Scholar. The shelf life in the above article was known through the Accelerated Stability Study, which predicts the shelf life by accelerating the decomposition rate, preferably by increasing temperature and humidity through the advancement in the branch of kinetics.¹⁶ Also, the Arrhenius equation explains the effect of temperature on the reaction rate.¹⁶

Table 1: Details that were sourced regarding the Stability study of Avaleha Kalpana

Avaleha Name	Method for Stability Study	Duration	Parameters through which Investigations were done	Result
Chitrak Haritaki Avaleha ⁶	Accelerated Stability Study	6 months	1. Reducing sugar, phyto-constituents (total tannins, piperine, vitamin C, and total polyphenols contents), microbial load, and organoleptic characteristics. 2. The sample was evaluated for total polyphenol content, total tannin content, vitamin C content, piperine content and reducing content to see the variation over six months. The microbial load was estimated for the total bacterial count, fungal count, <i>E. coli</i> , etc, and organoleptic properties were evaluated by sensory organs by the authors.	Product stability for two years in the light of the Arrhenius equation, as no significant variation was found.
Kamsaharitaki Avaleha ⁷	Accelerated Stability Study	6 months	Total solid content, moisture %, ash value, acid insoluble ash, pH value, water-soluble extractives, methanol soluble extractives, total fats, total sugars, microbial contamination, and heavy metals were evaluated.	Avaleha - 18 months; Granules - 27 months
Vasaharitaki Avaleha ⁸	Accelerated Stability Study	6 months	Moisture content, total ash value, acid-insoluble ash value, pH value, extractive (water soluble and alcohol soluble), and total fat and total sugar contents as per Ayurvedic Pharmacopeia of India were assessed.	Avaleha - 3.3 years and Granules - 2.8 years
Trivrit Avaleha ⁹	Accelerated Stability Study	6 months	Basic analytical parameters, including moisture %, ash value and water-soluble extractive, were evaluated at intervals specified earlier. Tests for microbial contamination were done initially and at the end of six months of storage, following standard guidelines.	Avaleha - 1 year and 11 months
Shirisha Avaleha ¹⁰	Accelerated Stability Study	6 months	Samples were studied for changes in organoleptic parameters and physicochemical parameters like pH value, moisture content, total ash, water-soluble extractive value, methanol-soluble extractive value, total fat, total solids, and total sugar in the abovementioned intervals. Total saponin, total alkaloids, total tannins, and tests for microbial contamination were done initially and at the end of six months by following standard guidelines.	Avaleha - 5 years 9 months
Vyaghri Haritaki Avaleha ¹¹	Accelerated Stability Study	3 months	Samples were studied for changes in organoleptic parameters and physicochemical parameters of Vyaghri Haritaki samples, such as loss on drying - 110 °C, ash value, acid-insoluble ash, alcohol soluble extractive values, water-soluble extractive values, and determination of pH were evaluated and total saponin, total alkaloids, total tannins, and tests for microbial contamination were done initially and at the end of three months.	It can be said that this formulation is stable for more than three months
Bhallataka Rasayana ¹²	Accelerated Stability Study	6 months	Samples were studied for changes in organoleptic parameters and physicochemical parameters like pH value, moisture content, total ash, water-soluble extractive value, methanol-soluble extractive value, total fat, total solids, and total sugar in the abovementioned intervals. Total saponin, total alkaloids, total tannins, and tests for microbial contamination were done initially and at the end of six months by following standard guidelines. Heavy metal estimation was carried out initially only.	Avaleha - 4 years 4 months
Kantakari Avaleha ¹³	Accelerated Stability Study	6 months	Samples were studied for changes in organoleptic parameters and physicochemical parameters like pH value, moisture content, total ash, water-soluble extractive value, methanol-soluble extractive value, total fat, total solids, and total sugar in the abovementioned intervals. Total saponin, total alkaloids, total tannins, and tests for microbial contamination were done initially and at the end of six months by following standard guidelines.	Avaleha - 13.05 months
Shirishashwagandhadi Avaleha ¹⁴	Accelerated Stability Study	6 months	Basic analytical parameters including total solid content, moisture %, ash value, acid insoluble ash, water-soluble extractives, and methanol soluble extractives, were evaluated at intervals specified earlier. Microbial contamination was done initially and at the end of six months of storage. Chromatography and Toxicity tests were also tested.	Avaleha - 8 years 7 months
Agastya Haritaki Avaleha ¹⁵	Accelerated Stability Study	6 months	The parameters considered for the evaluation of the stability study are organoleptic characters (colour, odour, and taste) and physicochemical parameters such as pH value, moisture, total ash, acid insoluble ash, water soluble extractive value, methanol soluble extractive value, total fat, total solid, total sugar, total saponin, total alkaloids, and total tannins. Microbial load and determination of heavy metals were also estimated in test drug samples.	Avaleha - 1.57 years

According to Yogratnakar, Avaleha's shelf-life is six months, and according to Sharangdhara Acharya, Avaleha's shelf-life is one year.¹⁷ And later according to G.S.R. 789(E) dated 12th August, 2016, it is three years.¹⁷ Through the review, it is known that the shelf life that was found of several Avaleha formulations that were tested through Accelerated Stability Testing was more than one year, but out of the ten articles that were reviewed only 4 Avaleha formulations that is Vasaharitaki Avaleha, Shirisha Ashwagandhadi Avaleha, Shirisha Avaleha, and Bhallataka Rasayana were known to have shelf period over three years.

CONCLUSION

Through these kinds of studies, we learn about the scarcity of scientific research on the stability of specific Avaleha formulations. Establishing a shelf life helps prevent degradation, spoilage or microbial contamination. Defined shelf life also instils consumers' confidence regarding the formulations' quality and reliability. Through stability study, we get information regarding sensitivity to storage conditions such as temperature and humidity, which may affect stability, posing challenges for real-world applications. This may help in standardised quality control, leading to no variation in quality and efficacy.

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Cite this article as:

Shweta Sunil Pandey and Archana P. Gharote. Stability study for various Avaleha formulations: A Review. *Int. J. Res. Ayurveda Pharm.* 2024;15(3):136-138

DOI: <http://dx.doi.org/10.7897/2277-4343.15385>

Source of support: Nil, Conflict of interest: None Declared

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