

Stability Profiling of Gokshuradi Kashaya under Accelerated Conditions: An Analytical Study

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ABSTRACT

Background: *Gokshuradi Kashaya* is a classical formulation mentioned in Sahasrayoga, which is widely used for its therapeutic benefits. Traditionally, the *saviryata avadhi* of *Kashaya* is considered to be less i.e. 24 hr, but modern pharmaceutical practices makes it necessary for a scientific evaluation of its stability. **Objectives:** To identify the stability of *Gokshuradi kashaya* by using accelerated stability study method. **Materials and Methods:** *Gokshuradi Kashaya* was prepared as per the standard classical procedure. Samples were stored under accelerated conditions (40±2°C and 75±5% RH) for 6 months as per ICH Q1A (R2) guidelines. Stability study had 3 timepoints for assessments i.e. 0th month, 3rd month and 6 months. Parameters like organoleptic characters and microbial load and TLC profile was been assessed. **Results:** There was no significant changes observed in organoleptic characters. Slight reductions in pH and minor variations in total solids and viscosity were present but within acceptable limits. Microbial load showed reduced bacterial load and no fungal contamination during 6 months. There was no change observed in TLC profiles. **Conclusion:** *Gokshuradi Kashaya* was found to be stable in physicochemical, microbial load. These findings can provide a provisional shelf life of six months, it needs to be confirmed by long-term real-time stability studies.

Keywords: Accelerated Stability Study, *Gokshuradi Kashaya*, Microbial Load, TLC Profile.

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INTRODUCTION

Ayurveda is one the oldest system of medicine used for maintaining health and healing. Various ayurvedic formulations are mentioned in ayurveda classics viz. *Kashaya* (liquid decoction), *Avaleha* (semi solid form), *Asava* (alcoholic preparation), *Taila* (medicated oil), *vati* (tablet), etc. *Kashaya/kwatha* is one the most commonly used formulation for treating various diseases. *Gokshuradi Kashaya* is one the potent *Kashaya* mentioned in Sahasrayoga.^[1] It mainly contains drugs like *Gokshura*, *varshabhu*, *Ardraka*, *pathya*, *devadaru*, *rasona*, etc. Shelf-life is the duration during which a product retains its intended quality, efficacy and safety. Essentially, it says about a drug's potency within a specified time frame.^[2] The concept of shelf - life can be related to *Saviryta Avadhi*, which is mentioned in texts like *Vangasena Samhita*,^[3] *Sharangadhara Samhita*,^[4] and *Yogaratanakara*,^[5] etc. According to *Yogaratanakara*, shelf life of *Kashaya* is 24 hr.^[6] Considering the changing scenario in pharmaceutical development and storage techniques, this classical concepts of *Saviryta Avadhi* cannot be implemented for

today. Stability study provides evidence on how quality of a drug substance or product varies with time under influence of variety of environmental factors such as, temperature, humidity and light and also to establish a retest period for the drug substance or product and recommended storage conditions.^[7] To evaluate the stability, shelf life of the formulation i.e. *Gokshuradi Kashaya*, this study was adopted.

MATERIALS AND METHODS

Gokshuradi Kashaya

The Raw drugs were obtained from the GMP Certified KLE Ayurveda Pharmacy, Kashbarg, Belagavi, Karnataka. Ingredients of *Gokshuradi Kashaya* are tabulated in Table 1.

Method of preparation of *Gokshuradi Kashaya*

All the drugs of *Gokshuradi Kashaya* were collected and subjected to pulverization and the coarse powder was then sieved through mesh size #40. All the 8 drugs coarse powder were taken in equal quantity and mixed together thoroughly. The coarse powdered drugs were taken in a stainless steel vessel and mixed with 8 parts of water. The mixture was then heated and then reduced to one-fourth of its original volume. After boiling, the decoction was filtered through a clean cloth, and the remaining residue was discarded.



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Storage conditions and Evaluation parameters

Samples were filled in 100 mL bottles with a tight cap. They were divided into 3 batches. An accelerated stability study was conducted as per the ICH guideline Q1A (R2).^[8]

Storage conditions are mentioned as below:

- Accelerated stability: Temperature: 40±2°C and Relative Humidity (RH): 75±5%.
- The change was observed during 6 months for accelerated stability at an interval of 0, 3, and 6 months for all 3 batches.

The following parameters were considered for evaluation of stability study.

Organoleptic characters such as appearance, colour, consistency, odour, pH, weight per mL (g/mL), total solids, viscosity, migration of content and intact pack.

TLC profile

Microbiology testing such as total plate count for bacteria, yeast and mould,

Based on the analytical values obtained before and after 6 months of storage, the product was found to be stable during whole study period.

OBSERVATION AND RESULTS

In the accelerated stability study, temperature 40±2°C and RH: 75±5% was maintained up to 6 months.

Over 6 months study period, the organoleptic characters which includes colour, odour, appearance and consistency remained unchanged in all three batches of the *Gokshuradi Kashaya*. The formulation remained a dark brown liquid with characteristic odour and no observable changes or migration within the packaging.

Minor changes were noticed in physicochemical parameters like pH, weight/mL, total solids and viscosity. These changes were within the acceptable limits. Marginal increase was noted in

weight/mL and total solids whereas slight decrease was observed in pH over time. Details are mentioned in Tables 2-4.

Test for microbial growth were also conducted at 0th, 3rd and 6th month for all 3 batches and the observations are tabulated in Table 5. In this Total plate count for bacteria decreased significantly from 63,000-67,000 CFU/mL in 0th month to 16,000- 19,000 CFU/mL by 6th month across all the 3 batches. This indicates there is improvement in microbial stability over time. Total Yeast and mold count remained consistent i.e. <10 CFU/mL, this helps in confirming absence of fungal contamination.

Thin-layer chromatography profile represented in Figure 1, The R_f values were recorded for the sample at the initiation of the study, on 3rd month and at the end of the 6th month at 254 nm and 366 nm. It was observed at all three time points i.e. 0th, 3rd, 6th month there were consistent band patterns across all batches. No additional bands appeared or disappeared during 6 months of study. The R_f value remained stable at 254 nm and 366 nm.

DISCUSSION

Stability studies are conducted to determine how long a product remains safe and effective under specified storage conditions. The primary goal of this study is to ensure that the product continues to meet the established specifications for identity, strength, quality, and purity over time. The collected stability data for any dosage form involves specific parameters that together define its stability profile. This profile serves as the foundation for determining the appropriate storage conditions for pharmaceutical products. The accelerated stability study of the *Gokshuradi Kashaya* showed stability of the organoleptic characters and the absence of content migration across all batches which indicates that the formulation's good physical and packaging integrity. The minor decrease in pH i.e. below 5% observed over time is consistent as its the typical trends observed in aqueous herbal formulations, likely because of natural oxidative or fermentative processes, but remains within the acceptable limits as per ICH.^[9] The consistency in total solids and viscosity values supports the preservation of the formulation concentration and flow characteristics. The microbiological analysis of the *Gokshuradi kashaya* showed a progressive decline in bacterial load over time, which indicates

Table 1: Ingredients of Gokshuradi Kashaya.

Sl. No.	Ingredients	Botanical name	Part used	Ratio
1	Gokshura	<i>Tribulus terrestris</i>	Fruit	All drugs in equal quantity
2	Varshabhu	<i>Boerhaavia diffusa</i>	Root	
3	Ardraka	<i>Zingiber officinale</i> (wet)	Rhizome	
4	Pathya	<i>Terminalia chebula</i>	Fruit Pulp	
5	Devdaru	<i>Cedrus deodara</i>	Heart wood	
6	Mahaushadha	<i>Zingiber officinale</i> (dry)	Rhizome	
7	Rasona	<i>Allium sativum</i>	Bulb	
8	Ikshuraka	<i>Asteracantha longifolia</i>	Root	

Table 2: Organoleptic parameters at 0th month of 3 batches.

Organoleptic parameters	Batch 1	Batch 2	Batch 3
Appearance	Dark Brown coloured liquid	Dark Brown coloured liquid	Dark Brown coloured liquid
Odour	Characteristic	Characteristic	Characteristic
Colour	Dark Brown	Dark Brown	Dark Brown
Consistency	Liquid	Liquid	Liquid
pH	4.58	4.56	4.57
Weight per mL (g/mL)	1.0190	1.0193	1.0194
Total Solids	7.35	7.38	7.39
Viscosity, rpm-0.3 Spindle no:62(cp)	1200	1300	1920
Migration of content and intact pack	Not observed	Not observed	Not observed
TLC Profile	No band disappeared / No secondary band appeared	No band disappeared / No secondary band appeared	No band disappeared / No secondary band appeared

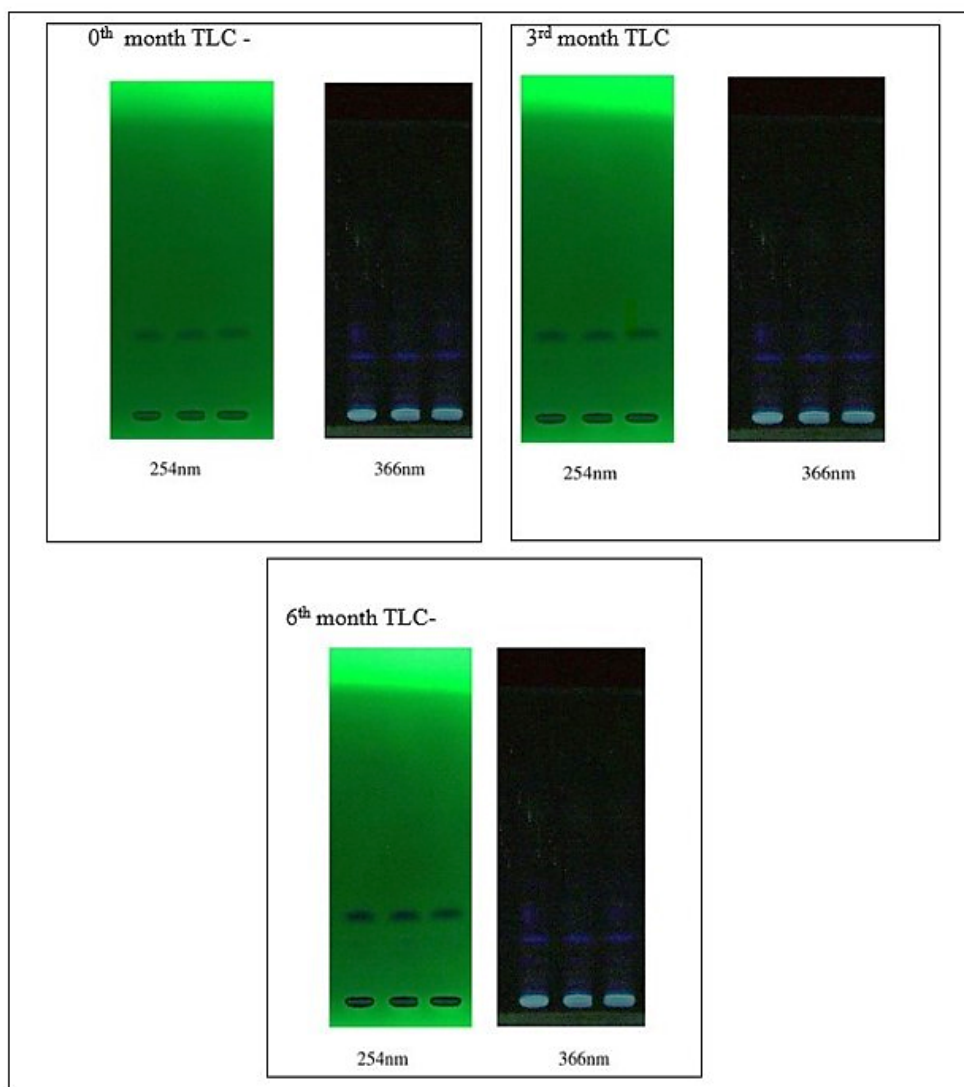
**Figure 1: TLC at 0th, 3rd and 6th month.**

Table 3: Organoleptic parameters at 3rd month of 3 batches.

Organoleptic parameters	Batch 1	Batch 2	Batch 3
Appearance	Dark Brown coloured liquid	Dark Brown coloured liquid	Dark Brown coloured liquid
Odour	Characteristic	Characteristic	Characteristic
Colour	Dark Brown	Dark Brown	Dark Brown
Consistency	Liquid	Liquid	Liquid
pH	4.52	4.53	4.53
Weight per mL (g/mL)	1.0261	1.0230	1.0227
Total Solids	7.31	7.33	7.27
Viscosity, rpm-0.3 Spindle no:62(cp)	1270	1290	1870
Migration of content and intact pack	Not observed	Not observed	Not observed
TLC Profile	No band disappeared / No secondary band appeared	No band disappeared / No secondary band appeared	No band disappeared / No secondary band appeared

Table 4: Organoleptic parameters at 6th month of 3 batches.

Organoleptic parameters	Batch 1	Batch 2	Batch 3
Appearance	Dark Brown coloured liquid	Dark Brown coloured liquid	Dark Brown coloured liquid
Odour	Characteristic	Characteristic	Characteristic
Colour	Dark Brown	Dark Brown	Dark Brown
Consistency	Liquid	Liquid	Liquid
pH	4.47	4.48	4.49
Weight per mL (g/mL)	1.0332	1.0323	1.0312
Total Solids	7.22	7.28	7.32
Viscosity, rpm-0.3 Spindle no:62(cp)	1100	1280	1830
Migration of content and intact pack	Not observed	Not observed	Not observed
TLC Profile	No band disappeared / No secondary band appeared	No band disappeared / No secondary band appeared	No band disappeared / No secondary band appeared

Table 5: Microbiology test results of 0th, 3rd and 6th month of 3 batches.

	0 th month			3 rd month			6 th month		
	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Total Plate count for bacteria	67,000 CFU/mL	67,000 CFU/mL	63,000 CFU/mL	18,000 CFU/mL	17,000 CFU/mL	19,000 CFU/mL	17,000 CFU/mL	16,000 CFU/mL	18,000 CFU/mL
Total Yeast and Mold Count	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL	<10 CFU/mL

enhanced microbiological stability during the storage period. The persistent absence of fungal growth throughout all the time points suggests that the formulation possesses inherent antifungal properties and helps in confirming compliance with acceptable microbial limits for pharmaceutical preparations.

No change in TLC profile over 6 month analysis helps in confirming the chemical stability of *Gokshuradi Kashaya*. The consistency of bands noticed at both 254 nm and 366 nm helps to suggest that there was no adulteration or degradation during storage.

CONCLUSION

This study helps to confirm that *Gokshuradi Kashaya* remains stable over 6 months in parameters like organoleptic characters, and microbiological load. The absence of microbial load and unchanged TLC test helps to support its quality, safety for its use. This study helps in providing the provisional shelf life of six months can be assigned to the *Gokshuradi kashaya*, it needs to be confirmed through long-term real-time stability study.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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