

Comprehensive Phytochemical Evaluation and Stability Analysis of Traditional Ayurvedic Preparations

Dhrubajyoti Sarma^{*1}, Manas Jyoti Kapil^{*2}, Dhiren Deka³, Ramakanta Sharma⁴, Neelakshi Sharma⁵

^{*1}Sr.Scientific Officer(Pharmacognosy), State Drugs Testing Laboratory, Ayush, Jalukbari, Guwahati-Assam.

Email ID: dhrubajyoti.dtassam@gmail.com

^{*2}Institute of Pharmacy, Assam Don Bosco University, Tapesia, Sonapur, Assam. 782402. India.

Email ID: manas.kapil@gmail.com

³M.D. (Ayu) Ph.D., Professor & Head Dept. of Swasthavritta & Yoga, Govt. Ayurvedic College & Hospital

Email.ID: dhiren.deka6@gmail.com

⁴Principal, IAMC, USTM, Meghalaya.

Email.ID: ramakanta.sharma@rediffmail.com

⁵Assistant Professor, Institute of Pharmacy, The Assam Royal Global University, Guwahati, Assam.

Email.ID: nshar0150@gmail.com

***Corresponding Author:**

Dhrubajyoti Sarma, Manas Jyoti Kapil

ABSTRACT

Traditional Ayurvedic formulations have been used for centuries as safe and effective remedies, yet their global acceptance is limited due to insufficient standardization and lack of rigorous quality evaluation. The present study emphasizes comprehensive phytochemical investigation and stability analysis of selected Ayurvedic preparations, namely Vaishwanar Churna, Ashwagandha Churna, Brahmi Ghrita, Lavangadi Vati, and Gandhakadi Malaham. An array of qualitative phytochemical tests were conducted to identify secondary metabolites including alkaloids, glycosides, flavonoids, tannins, saponins, phenols, proteins, and steroids. These compounds are known to contribute to the therapeutic potential of formulations while serving as chemical markers for quality control.

The stability of these formulations was examined under accelerated storage conditions ($40^{\circ}\text{C} \pm 2$ and $75\% \pm 5$ RH) for a period of twenty-four months, simulating long-term storage. Comparative analysis demonstrated that most formulations retained their phytochemical integrity during the study period, though slight variations in intensity of responses were noted for certain constituents. Microbial safety was assessed at different intervals, and the total bacterial and fungal counts consistently remained below 10 CFU/g throughout the study, indicating excellent microbiological stability. Additionally, supporting tools such as microscopic characterization and thin-layer chromatography (TLC/HPTLC) were utilized to provide diagnostic features and chemical fingerprints of the selected drugs.

Overall, the study highlights the need for establishing standardized methodologies in evaluating Ayurvedic preparations. Reliable phytochemical markers, microbial limits, and chromatographic profiling together form the basis for developing robust quality control systems. Standardization would not only improve patient safety and therapeutic reliability but also enhance international acceptance of Ayurvedic medicines. This work reinforces the importance of aligning traditional wisdom with modern analytical approaches to ensure consistency, efficacy, and safety of herbal formulations.

Keywords: Ayurvedic formulations, phytochemical screening, stability testing, microbial safety, standardization, quality control.

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1. INTRODUCTION

In Asia, traditional medical knowledge is generally categorized into codified systems and non-codified practices. In India, systems like Ayurveda, Siddha, and Amchi fall under codified traditions. These are documented in ancient texts and have been practiced for generations, continuing to play an important role in health and culture today. On the other hand, non-codified medicine includes folk and indigenous practices that are mainly shared orally within certain communities and are not formally written down.

Although modern allopathic medicine has greatly advanced healthcare over the decades, it is important to remember that much of this development is rooted in traditional therapies. Surveys have shown that about 75% of herbal remedies used around the world come from indigenous medical knowledge. In India alone, nearly 70% of modern drugs are derived from natural substances, along with synthetic versions modeled on compounds originally obtained from plants.

Medicinal plants have long been essential sources of treatment. One clear benefit of plant-based medicines is their generally low toxicity and fewer side effects. Nevertheless, synthetic medicines have become the most common treatment method today. The shift towards urban lifestyles has also led to new health issues, with mental stress making matters worse.

While chemically manufactured drugs can provide quick relief, they are often associated with side effects that are becoming more prevalent. Another significant issue is drug resistance, where the repeated and sometimes improper use of synthetic medicines reduces their effectiveness over time. Because of these concerns, dependence on such drugs has been declining in many areas.

The World Health Organization has reported that herbal medicine remains the main form of healthcare for around 80% of people living in developing nations, due to its affordability and safety. This has motivated many to turn back to herbal treatments instead of modern pharmaceuticals. The cost benefits have also increased interest in natural remedies worldwide. As a result, the herbal medicine market has grown rapidly and is expected to reach a value of around 7 trillion US dollars by 2050. In fact, many leading pharmaceutical companies are now revisiting and expanding their efforts in herbal drug development.

Lacunae in the present knowledge / understanding

- Herbal medicines usually have fewer side effects than modern drugs. But because there are no clear ways to check their identity and quality, Ayurvedic products are not widely accepted internationally. One main problem is that there isn't enough standardized information about single-herb and multi-herb formulations, which makes quality control difficult.
- Traditionally, labels on herbal products include details like shelf life based on old texts. However, changing climate and environmental conditions have created a need for scientific studies to confirm how stable these products are so they can work effectively.
- Under the Drugs and Cosmetics Act of 1940, Ayurvedic companies must give proof of the shelf life of their products to the authorities. This means reliable scientific data on shelf life is needed, considering different regions.
- To improve and extend the shelf life, many companies are now using new technologies. There is still a need to better understand shelf life, stability, and standardization so more research can be done and the quality of herbal medicines can be improved.

Justification of the proposed research work

- India has a rich heritage and extensive documentation of Ayurvedic medicine, which has been practiced for centuries. However, one of the major challenges with Ayurvedic formulations is the incomplete evaluation of their components, primarily because of their complex composition. Assessing these constituents is essential to guarantee the quality, purity, and consistency of the final product.
- Stability studies play a crucial role in demonstrating how the quality of a drug or formulation changes over time when exposed to various environmental conditions like temperature, humidity, and light. These studies also help determine the appropriate retest period and recommended storage guidelines. In this way, stability testing serves as an important tool for evaluating and maintaining product quality.

The Evolution of Ayurveda

Ayurveda is India's ancient medical tradition, with its origins in the Rigveda and Atharvaveda over 3,000 years ago. Classic texts like the Charaka Samhita, Sushruta Samhita, and Ashtanga Hridaya laid the foundations for medicine, surgery, and internal health.

Despite periods of decline during invasions and British colonial rule, scholars such as Vaghbhata preserved this knowledge. After independence, the Indian government established institutions like the CCRAS in 1978 to promote Ayurvedic research.

Core concepts include the Tri-Dosha theory, which describes three energies—Vata, Pitta, and Kapha—that maintain balance in the body, and the Sapta Dhatu, the seven vital tissues. Ayurveda uses over 1,200 plants, such as turmeric for inflammation, holy basil for immunity, and Triphala for digestion. Scientific studies increasingly support many of these remedies, blending tradition with evidence-based practices.

Shelf Life and Stability of Ayurvedic Medicines

Ayurvedic products often combine many natural ingredients, making it important to test how long they stay effective. Shelf life is the period a product remains safe and potent under recommended storage. Stability studies check how heat, moisture, and light affect quality over time.

Without proper testing, ingredients can lose their benefits or become contaminated. For example, Triphala churna stored at room temperature lost much of its active compounds within a year. Moisture can lead to microbial growth, as seen in ashwagandha powder stored in humid conditions.

Regulatory agencies like the Ministry of AYUSH, US FDA, and WHO require stability data before approving products. In India, the CCRAS enforces testing under different climates. Good packaging, like using foil instead of glass jars, can significantly extend shelf life.

Some traditional formulations may contain metals or complex mixtures that react over time. Stability studies help detect harmful changes and protect patients.

Although ancient texts rarely detailed shelf life, modern regulations now require manufacturers to provide scientific data under the Drugs and Cosmetics Act. Continued research, standardization, and improved testing are essential to maintain the quality, safety, and credibility of Ayurvedic medicines today.

Shelf life of Ayurvedic medicine as per Drugs & Cosmetics Act 1940	
Name of the group of Ayurvedic medicine	Shelf life
Arka, eye drops	1 year
Churna, Kwath Churna, Dant Manjan powder, Dant Manjan paste, Varti, Shweta Parpati, Ear/Nasal drops, Dhoopans (inhalers), Ghrita	2 years
Gutika tablet containing Kasthaushadhi, Avleha, Taila, Lepa Churna, Lepa Gutti, Lepa Malahar, Ghana Vati, soft gelatin capsules containing Kashta-Aushadhi, syrup, Granule/Khand, PravahiKwath	3 years
Rasa Gutika, Guggulu, Dravaka, Lavana, Ksara, Naga Bhasma, Vanga Bhasma, Tamra Bhasma*, hard gelatin capsules	5 years
Mandura-Lauha	10 years
Rasaushadhes, Asava Arista, Kupipakva, Parpati, Pisti and Bhasma, Swarna, Rajata, Lauha, Mandura, Abhraka, Godanti, Shankha Bhasma	10 years

Stability testing of herbal formulations is complex because the entire plant or preparation is considered active, not just specific compounds. The goal of such testing is to assess how environmental factors—like temperature, humidity, light, oxygen, particle size, microbial or metal contamination, and packaging materials—affect the product's quality over time. This helps determine proper storage conditions and the product's shelf life.

Ayurveda includes various dosage forms based on shelf life: solids (e.g., vati - tablets, churna - powders, capsules), liquids (e.g., kwath - decoctions, asava/arista - fermented liquids), and semisolids (e.g., kalka - pastes, avaleha - jams). These formulations often contain multiple active ingredients, making standardization and quality control challenging. The absence of consistent testing standards often raises concerns about product quality. Stability, as per ICH guidelines, refers to how long a product maintains its intended characteristics under specified storage conditions.

2. MATERIALS & METHODS

Collection and authentication of formulations:

All the selected ayurvedic formulations named as Vaishwanar churna, Ashwagandha churna, Brahmi ghrita, Lavangadi vati and Gandhakadi malaham that were been recently prepared was collected from local market as well as ten numbers of samples from each batch no. was been collected for detailed studies.

Storage of formulations was done as per ICH guidelines at different temperature and pressure and evaluation of different parameters in respective time intervals.

Microbial load:

Microbial load was carried out as per standard procedure mentioned in Indian Pharmacopoeia. It included Total bacterial count, Total Fungal Count, Presence of Escherichia coli, Salmonella spp., Pseudomonas aeruginosa and Staphylococcus aureus. Pure culture of Escherichia coli (NCIM: 2065; ATCC: 8739), Salmonella spp. (NCIM: 2257 NCTC: 6017), Pseudomonas aeruginosa (ATCC 9027), Staphylococcus aureus (ATCC 6358) were obtained from NCIM Pune. The media used for the microbial limit test were of Hi Media Pvt. Ltd.

Hot Continuous Extraction (Using Soxhlet apparatus)

SOXHLET APPARATUS: A Soxhlet extractor is a lab equipment designed for processing certain kinds of solids. These devices allow for continuous treatment of a sample with a solvent over a period of hours or days to extract compounds of interest.

COMPONENTS: 1: Stirrer bar 2: Still pot (the still pot should not be overfilled and the volume of solvent in the still pot should be 3 to 4 times the volume of the soxhlet chamber) 3: Distillation path 4: Thimble 5: Solid 6: Siphon top 7: Siphon exit 8: Expansion adapter 9: Condenser 10: Cooling water in 11: Cooling water out.

Powdered drugs (200 g) were extracted starting with petroleum ether, benzene, toluene, chloroform, ethanol and methanol as per the increasing order of solvent polarity using Soxhlet apparatus for getting the different fractions of extracts. The extract was concentrated to semisolid under reduced pressure to yield a dried crude ethanol extract. The extracts were then stored at 4°C till the time of use for phytochemical screening.

Thin Layer Chromatographic study: For understanding the medicinal values of different herbs, including its formulations, different types of chromatography like TLC, Gas chromatography, HPLC, HPTLC are used widely. In this study, TLC and HPTLC have been adopted as a separation technique.

3. PHYTOCHEMICAL ANALYSIS

Detection of Alkaloids

About 50 mg of solvent - free extract was stirred with little quantity of dilute hydrochloric acid and filtered. The filtrate was tested carefully with various alkaloid tests viz.-

- **Mayer's test:** To a few ml of filtrate, a drop or two of Mayer's reagent are added by the side of the test tube. A white or creamy precipitate indicates test as positive.
- **Wagner's test:** To a few ml of filtrate, few drops of Wagner's reagent are added by the side of the test tube. A reddish-brown precipitate indicates test as positive.
- **Hager's test:** To a few ml of filtrate, 1 or 2 ml of Hager's reagent are added by the side of the test tube. A prominent yellow precipitate indicates test as positive.
- **Dragendorff's test:** To a few ml of filtrate, 1 or 2 ml of Dragendorff's reagent are added by the side of the test tube. A prominent yellow precipitate indicates test as positive.

Detection of Carbohydrates

About 100mg of the extract was dissolved in 5 ml of distilled water and filtered. The presence of carbohydrates was tested by following tests:

- **Molish's test:** To 2 ml of filtrate, 2 drops of alcoholic solution of alpha-naphthol are added, the mixture is shaken well & 1 ml of conc. H₂SO₄ is added slowly along the side of the test tube & allowed to stand. A violet ring indicates the presence of carbohydrate.
- **Fehling's test:** 1 ml of filtrate is boiled on water bath with 1 ml each of Fehling solution A & Fehling solution B; a red precipitate indicates the presence of sugar.
- **Benedict's test:** To 0.5 ml of filtrate, 1 ml of Benedict's reagent is added. The mixture is heated on a boiling water bath for 2 min. a characteristic coloured precipitate indicates the presence of sugar.
- **Barfoed's test:** To 1 ml of filtrate, 1 ml of Barfoed's reagent is added & heated on a water bath for 2 min. Red precipitate indicates presence of sugar.

Detection of Glycosides

For detection of glycosides, about 50 mg of extract was hydrolyzed with concentrated hydrochloric acid for 2 hrs on a water bath, filtered and the hydrolysate was subjected to the Glycoside test, Borntrager's Test, Legal's Test.

Detection of Proteins and Amino Acids

About 100 mg of extract was dissolved in 10 ml of distilled water and filtered through Whatmann No.1 filter paper and the filtrate was subjected to the following tests:

- **Borntrager's test:** To 2ml of filtered hydrolysate, 3ml of CHCl_3 is added & shaken, CHCl_3 layer is separated & 10% NH_3 solution is added to it; pink colour indicates the presence of glycosides.
- **Modified Borntrager's test:** 2 ml of filtrate was treated with 2 ml of 5 % aq. FeCl_3 solution for 5 min, shake with equal volume of chloroform and continue the test as above. A rose pink to red colour indicates the presence of glycosides.
- **Keller Killiani Test:** Test solution was treated with few drops of glacial acetic acid and Ferric chloride solution and mixed. Concentrated sulphuric acid was added, and observed for the formation of two layers. Lower reddish brown layer and upper acetic acid layer which turns bluish green would indicate a positive test for glycosides.
- **Bromine water test:** Test solution was dissolved in bromine water and observed for the formation of yellow precipitate to show a positive result for the presence of glycosides.

Detection of Phenolic Compounds and Tannins

- **Ferric chloride test:** About 0.5 g of the extract was boiled in 10 ml of water in a test tube and then filtered. A few drops of 0.1 % FeCl_3 were added. brownish colour indicates the presence of Tannins.

Detection of Flavonoids

About 100mg of extract was taken in a test tube and added few drops of dilute NaOH . An intense yellow colour appeared in the test tube. It became colourless on addition of few drops of dilute acid.

4. RESULTS



Fig: Five different Ayurvedic formulations

Phytochemical study results

Phytochemical screening is very essential for Ayurvedic formulations to determine the efficacy of the formulations. The presence and absence of different phytochemicals like flavonoids, alkaloids, glycosides, tannins, fats, lipids, steroids etc.



Fig: Phytochemical screening

Table: Results of phytochemical screening of Ayurvedic formulations at accelerated stability testing methods of 40 °C ± 2 and 75% ± 5 RH in 0 (zero) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins					
	Millions test	+	-			
	Ninhydrin test	-	-			
2.	Test for carbohydrates					
	Fehling's test	+	+		+	
	Benedict's test	+	+			
3.	Test for phenols and tannins	+	+		+	
		+	+			
4.	Test for flavonoids					
	Alkaline reagent test	+	+		+	
5.	Test for saponins	+	+		+	
6.	Test for glycosides					
	Keller kilani test	+	+		+	
	Libermann's test	-	+			
	Salkowskis test	+	+			
7.	Test for steroids	+	+		+	
8.	Test for alkaloids	+	+		+	

Table: Results of physicochemical screening of Ayurvedic formulations at accelerated stability testing methods of 40 °C ± 2 and 75% ± 5 RH in 3 (three) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins					
	Millions test	+	-			
	Ninhydrin test	-	-			
2.	Test for carbohydrates					
	Fehling's test					
	Benedict's test	+	+		+	

		+	+			
3.	Test for phenols and tannins	+	+		+	
4.	Test for flavonoids Alkaline reagent test	+	+		+	
5.	Test for saponins	+	+		+	
6.	Test for glycosides Keller kilani test Libermann's test Salkowskis test				+	
		+	+			
		-	+			
		+	+			
7.	Test for steroids	+	+		+	
8.	Test for alkaloids	+	+		+	

Table: Results of physicochemical screening of Ayurvedic formulations at accelerated stability testing methods of $40^{\circ}\text{C} \pm 2$ and $75\% \pm 5$ RH in 6 (six) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins Millions test Ninhydrin test					
		+	-			
		-	-			
2.	Test for carbohydrates Fehling's test Benedict's test				+	
		+	+			
		+	+			
3.	Test for phenols and tannins	+	+		+	
		+	+			
4.	Test for flavonoids Alkaline reagent test	+	+		+	

5.	Test for saponins	+	+		+	
6.	Test for glycosides Keller kilani test Libermann's test Salkowskis test				+	
		+	+			
		-	+			
		+	+			
7.	Test for steroids	+	+		+	
8.	Test for alkaloids	+	+		+	

Table: Results of physicochemical screening of Ayurvedic formulations at accelerated stability testing methods of $40^{\circ}\text{C} \pm 2$ and $75\% \pm 5$ RH in 9 (nine) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins Millions test Ninhydrin test					
		+	-			
		-	-			
2.	Test for carbohydrates Fehling's test Benedict's test				+	
		+	+			
		+	+			
3.	Test for phenols and tannins	+	+		+	
		+	+			
4.	Test for flavonoids Alkaline reagent test	+	+		+	
5.	Test for saponins	+	+		+	
6.	Test for glycosides Keller kilani test Libermann's test Salkowskis test				+	
		+	+			

		-	+			
		+	+			
7.	Test for steroids	+	+		+	
8.	Test for alkaloids	+	+		+	

Table: Results of physicochemical screening of Ayurvedic formulations at accelerated stability testing methods of $40^{\circ}\text{C} \pm 2$ and $75\% \pm 5$ RH in 12 (twelve) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins Millions test Ninhydrin test	+ -	- -			
2.	Test for carbohydrates Fehling's test Benedict's test				+	
		+ +	+ +			
3.	Test for phenols and tannins	+ +	+ +		+	
4.	Test for flavonoids Alkaline reagent test	+	+		+	
5.	Test for saponins	+	+		+	
6.	Test for glycosides Keller kilani test Libermann's test Salkowskis test				+	
		+ - +	+ + +			
7.	Test for steroids	+	+		+	

8.	Test for alkaloids	+	+		+	
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Table: Results of physicochemical screening of Ayurvedic formulations at accelerated stability testing methods of $40^{\circ}\text{C} \pm 2$ and $75\% \pm 5$ RH in 18 (eighteen) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins Millions test Ninhydrin test	+	-			
2.	Test for carbohydrates Fehling's test Benedict's test	-	-		+	
3.	Test for phenols and tannins	+	-		-	
4.	Test for flavonoids Alkaline reagent test	-	-		-	
5.	Test for saponins	+	+		+	
6.	Test for glycosides Keller kilani test Libermann's test Salkowskis test	-	-		-	
7.	Test for steroids	+	+		+	
8.	Test for alkaloids	-	-		-	

Table: Results of phytochemical screening of Ayurvedic formulations at accelerated stability testing methods of 40 °C ± 2 and 75% ± 5 RH in 24 (twenty four) month.

Sl. No	Parameters	Vaishwanar churna	Ashwagandha churna	Brahmi ghrita	Lavangadi vati	Gandhakadi malaham
1.	Test for proteins Millions test Ninhydrin test	+ -	- -			
2.	Test for carbohydrates Fehling's test Benedict's test				+	
		+ +	+ +			
3.	Test for phenols and tannins	+	+		+	
4.	Test for flavonoids Alkaline reagent test	+	+		+	
5.	Test for saponins	+	+		+	
6.	Test for glycosides Keller kilani test Libermann's test Salkowskis test				+	
		+ - +	+ + +			
7.	Test for steroids	+	+		+	
8.	Test for alkaloids	+	+		+	

Result of microbial load

Microbial load was carried out as per standard procedure mentioned in Indian Pharmacopoeia. It included Total bacterial count, Total Fungal Count, Presence of *Escherichia coli*, *Salmonella* spcies, *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

The result of the formulations for 0,3,6,9,12,18, and 24 months were tabulated in a single table as the results showed the limit was less than <10 CFU for total bacterial and yeast, and mould count.

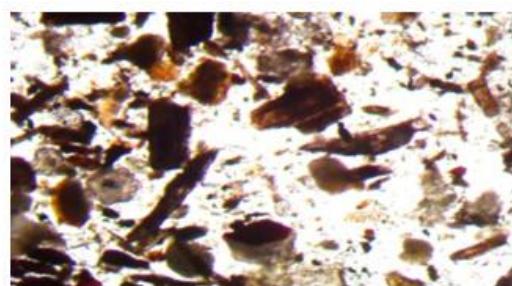
Table: Result of microbial load

Sl. No	Parameters	Vaishwana r churna	Ashwagand ha churna	Brahmi ghrita	Lavang adi vati	Gandhak adi malaham
1.	Total bacterial count (CFU/g)	<10 CFU	<10 CFU		<10 CFU	<10 CFU
2.	Total yeast and mould (CFU/g)	<10 CFU	<10 CFU		<10 CFU	<10 CFU

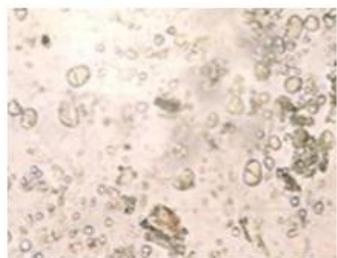
Microscopic study results: Microscopic studies of Aswagandha Churna at 0 (zero) month under Trinocular Research Microscope was as mentioned below.



Pitted vessel



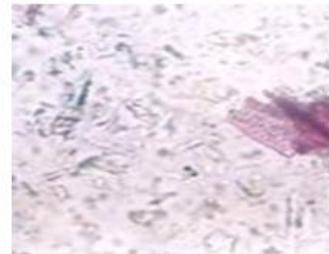
Scleroids



Starch grain



Tracheids



Fibres

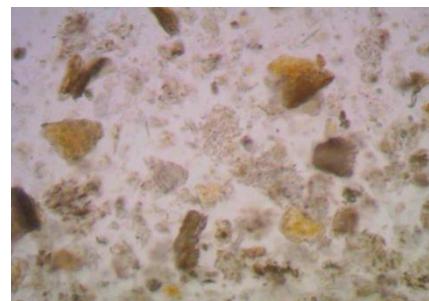


Trichome

Microscopic studies of Vaishvanara Churna at 0 (zero) month under Trinocular Research Microscope was as mentioned below.



Starch grains of shunthi



Vitae cells of Ajwain



Pitted vessel of haritaki



Oleo resins of shunthi

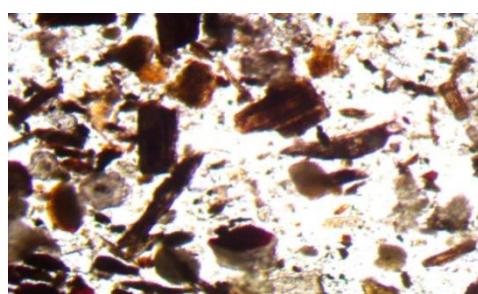
Microscopic studies of Aswagandha Churna at 24 (twenty-four) months under Trinocular Research Microscope were as mentioned below.



Yellowish brown vittae



Pitted vessel

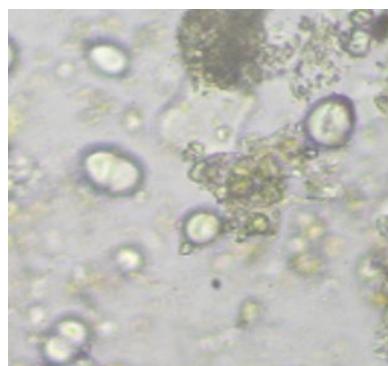


Scleroids

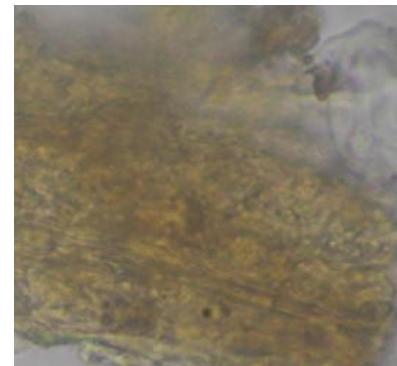


Starch grain

Microscopic studies of Vaishvanara Churna at 24 (twenty four) month under Trinocular Research Microscope was as mentioned below.



Starch granules



Vitae



Scleroids

Thin Layer Chromatographic study:

TLC Study of Lavangadi Vati at 0 (zero) month



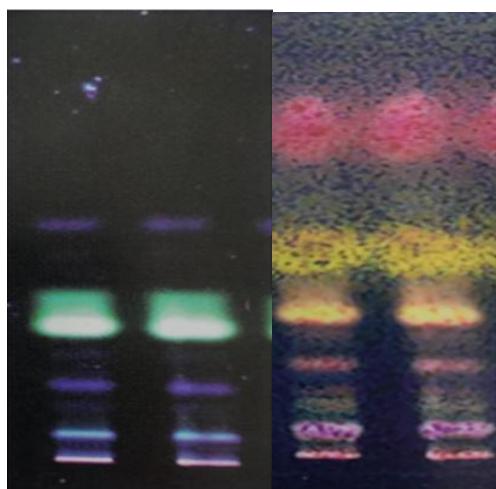
a. At 254 nm



b. At 366 nm

The mobile phase was toluene: ethyl acetate: glacial acetic acid (8:2:1)

HPTLC (CAMAG LINOMAT-V) profile of Lavangadi vati



IPBRS TEST

(at 366 nm)

IPBRS TEST

(at 366 nm after spraying with vanillin sulphuric acid reagent)

TLC of Vaishvanara churna



a. At iodine chamber

TLC finger print profile under iodine chamber and the mobile phase was toluene :Ethyl acetate:Formic acid:Meathanol.

TLC of Ashwagandha churna



(at 254 nm)

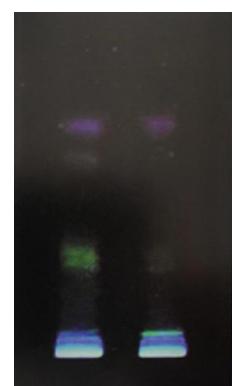


(at 366 nm)

HPTLC profile of Ashwagandha churna

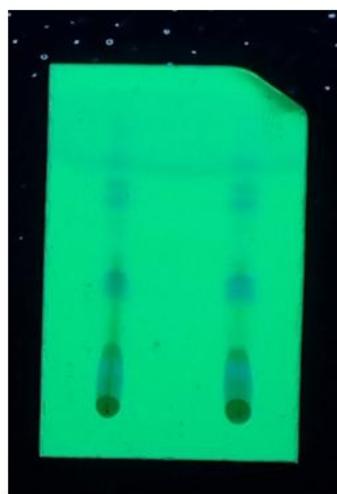


IPBRS TEST
(at 254 nm)

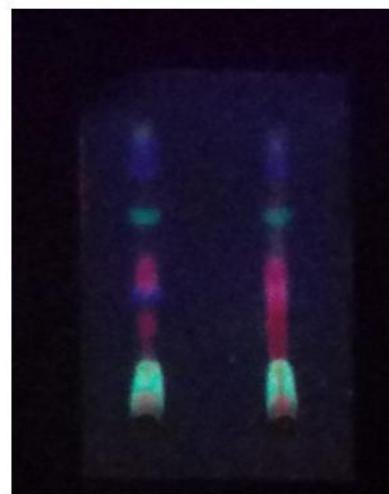


IPBRS TEST
(at 366 nm)

TLC Study of Lavangadi Vati performed after 24 months:



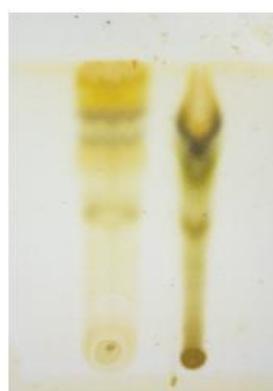
a. At 254 nm



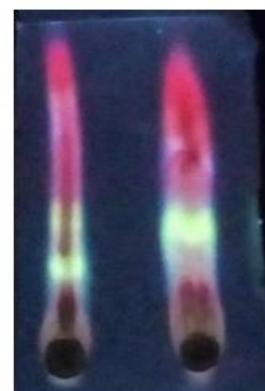
b. At 366 nm

The mobile phase was toluene: ethyl acetate: glacial acetic acid (8:2:1)

HPTLC profile of Lavangadi vati performed after at 24 months:



IPBRS TEST
(At 254 nm)



IPBRS TEST
(At 366 nm)

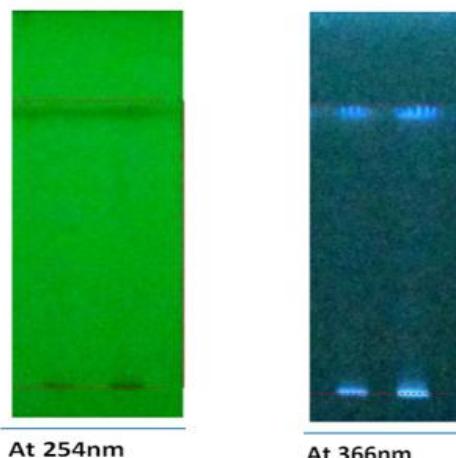
TLC of Vaishvanara churna performed after 24 months:



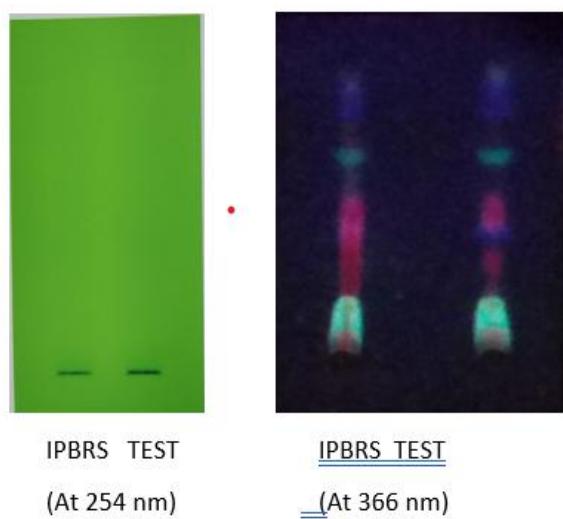
a. At iodine chamber

TLC finger print profile under iodine chamber and the mobile phase was toluene :Ethyl acetate:Formic acid:Methanol.

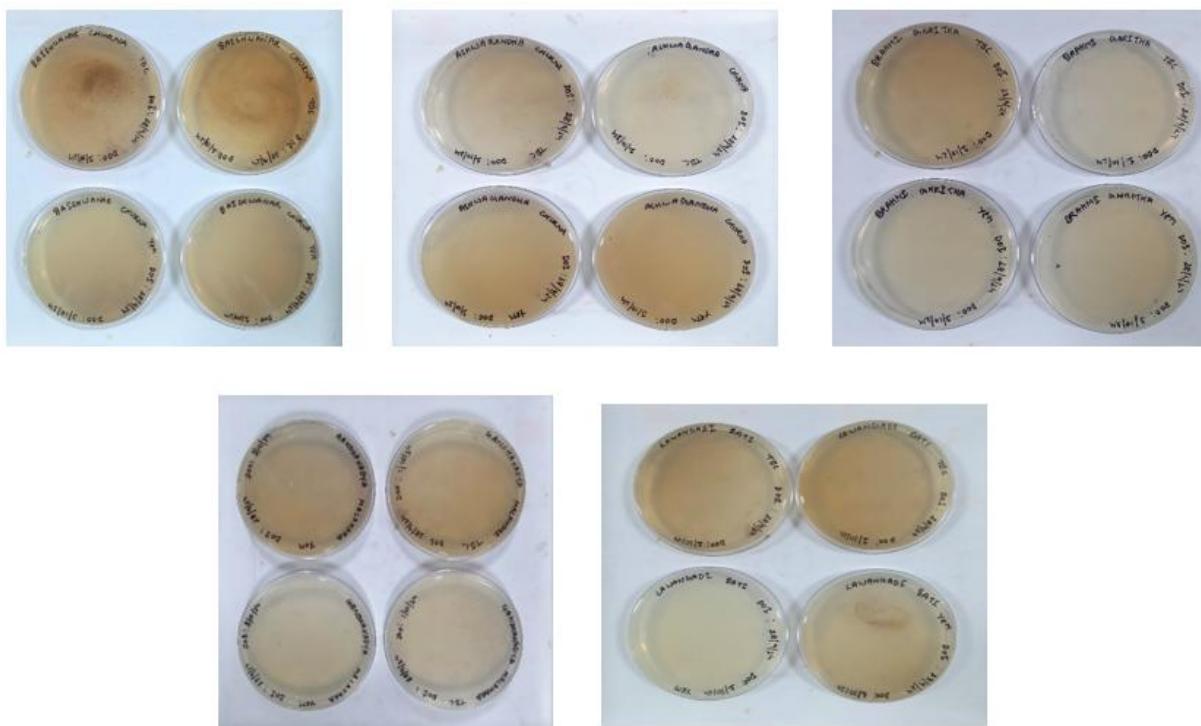
TLC of Ashwagandha churna performed after 24 months:



HPTLC profile of Ashwagandha churna performed after 24 months:



Results of microbial tests:



No microbial load has been seen. Results are less than 10 CFU (Colony forming unit)

5. DISCUSSION

The Ayurvedic lexicon and government notifications in India mention shelf life but do not explain how it should be measured. In contrast, the International Conference on Harmonization (ICH) provides clear methods for testing quality and shelf life, which can also be applied to Ayurvedic medicines.

Today, shelf life assessment of these products uses tests described in the PLIM Protocol, Ghaziabad. However, doing long-term studies on items with very long shelf lives, like rasa preparations or fermented products (asava, arishta), is often not practical. In these cases, accelerated stability testing with the 10% degradation method helps estimate shelf life scientifically and supports traditional claims.

There is a strong need to standardize testing methods for Ayurvedic formulations. This will help laboratories check their quality, strength, and purity consistently. At present, many companies produce similar Ayurvedic medicines. Drug inspectors collect samples from factories and send them to government labs. Analysts struggle to test products when no official methods exist. A unified testing protocol would solve this problem and make quality checks easier.

Ayurvedic products contain herbs and minerals that can break down over time. Stability studies are important to show how long a product stays safe and effective in different conditions like heat, moisture, and light. These tests help detect harmful changes or contamination and guide storage and packaging practices. Stability data also builds consumer trust and meets international quality standards.

Microbiological studies showed no contamination during the study. Phytochemical tests revealed that active compounds gradually degrade over time.

According to the Drugs and Cosmetics Act, medicines should be stored at 25 °C and 60% humidity. In this study, samples were kept at higher temperatures (40 °C) and humidity (75%) to estimate shelf life faster. Using the Arrhenius equation, the shelf lives of products like Vaiswanar churna and Brahmi ghrita were calculated and found to match the rules requiring expiry dates on labels.

6. CONCLUSION

The study of five Ayurvedic formulations showed that they maintained stability and quality over 24 months of accelerated testing. No significant changes were found in active ingredients, basic components, or microbial levels after six months at high temperature and humidity. The use of modern packaging played a key role in protecting the products and extending their shelf life beyond traditional expectations. Regular monitoring of bioactive compounds proved essential for ensuring consistent quality. This work offers valuable data that can guide manufacturers and testing labs in selecting good-quality raw materials and maintaining reliable standards for Ayurvedic medicines.

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