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Research Article

Dadrughna Malahara

Evaluation the Accelerated Stability of Dadrughni Vati (Lepa) and Dadrughna Malahara: A Comparative Approach

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Introduction: The shelf life and stability of traditional herbal formulations are essential for their efficacy and safety. Stability studies of Dadrughni Vati (Lepa) (DL) and its modified form, Dadrughna Malahara (DM), have not been conducted. This study evaluates their shelf life under accelerated storage conditions per ICH guideline Q1A, analyzing organoleptic, physicochemical, microbial, and chemical stability parameters.

Methods: DL and DM were stored under accelerated conditions for six months, with stability assessments at 0, 3, and 6 months. Evaluations included organoleptic properties (color, texture, odor), physicochemical parameters (pH, extractive values, moisture content for DL; specific gravity, iodine value, acid value, viscosity, spreadability for DM), microbial contamination (total plate count, yeast and mold, pathogens), and chemical stability through HPTLC fingerprinting at 254 nm, 366 nm, and 540 nm. Shelf life was estimated using degradation curve analysis.

Results: Both formulations remained stable in organoleptic properties. DL exhibited changes in pH, extractive values, and moisture content, while DM showed increases in specific gravity, iodine value, and acid value. The microbial limit test confirmed pathogen-free status. HPTLC analysis indicated consistent chemical composition without significant degradation.

Conclusion: DL and DM demonstrated stability under accelerated conditions, with slight physicochemical variations. Shelf-life estimates suggest DL is stable for 6.89 years and DM for 3.59 years in climate zones III and IV, ensuring their quality and therapeutic efficacy.

Keywords: Shelf life, Stability Study, Dadrughni Vati (Lepa) (DL), Dadrughna Malahara (DM), ICH guidelines

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Introduction

Stability refers to the ability of a pharmaceutical formulation to maintain its original quality and effectiveness over time, under specified conditions. It is a critical parameter in ensuring the safety, efficacy and therapeutic value of medicinal products. Stability encompasses a broad spectrum of characteristics including physical, chemical, biochemical, microbial, toxicological and medicinal properties. Stability studies are essential for understanding how a formulation behaves when exposed to various environmental factors, such as temperature, humidity, light and oxygen over time.

These studies provide valuable insights into the degradation pathways of active ingredients, helping to establish the product's shelf life and optimal storage conditions. As such, stability testing is fundamental in ensuring that the therapeutic benefits of a product are preserved throughout its shelf life and during use. In the context of pharmaceutical product development, stability testing is generally categorized into two types: real-time stability testing and accelerated stability testing. Real-time stability testing involves storing the product under standard, controlled conditions (e.g., at ambient temperature and humidity) and observing its performance over an extended period. This process allows for the observation of gradual degradation and the long-term behaviour of the product. In contrast, accelerated stability testing is designed to simulate the effects of long-term storage by exposing the product to elevated stress conditions, such as higher temperatures and humidity levels. These controlled stress conditions expedite the degradation processes, enabling the prediction of a product's shelf life within a shorter duration.

While stability testing is well-established for conventional pharmaceutical products, traditional Ayurvedic formulations such as *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* require similar attention to ensure their continued efficacy and safety. Ayurvedic preparations such as *Lepa, Lepaguti*, and *Malahara* have been known to retain their therapeutic potency for up to 3 years.

The aim of the present study is to conduct an accelerated stability assessment of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara*.

The primary objective is to determine their shelf life and identify any potential degradation over time under various stress conditions, including elevated temperature and humidity. This study adheres to the International Council for Harmonisation (ICH) guidelines, specifically ICH Q1A(R2)3,**[1]** to ensure a robust and systematic evaluation of the formulations' organoleptic, physico-chemical, and microbiological properties.

By subjecting these formulations to controlled environmental conditions, we aim to detect any signs of instability, degradation or changes in quality. The findings from this stability study will provide critical data regarding the shelf life and stability of these Ayurvedic formulations.

This research will not only establish scientifically supported stability profiles but also inform optimal storage guidelines to preserve the formulations' therapeutic efficacy over time. Ultimately, the results will contribute to enhancing the reliability and safety of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara*, ensuring their continued role in modern Ayurvedic practice while maintaining their therapeutic value for patients.

Materials and Methods

Procurement of the raw materials

Tankana, Sphatika and *Tila Taila* were procured from the Government Ayurved Pharmacy, Rajpipla, Gujarat. *Gandhaka, Sarjarasa, Chakramarda Beeja, Siktha, Go-Ghrita* and *Go-Dugdha* were procured from the local traders of Vadodara, Gujarat. *Jambiri Nimbu* was procured from the farmer of Amreli, Gujarat.

Identification of raw material

The samples of *Chakramarda* (*Cassia tora* Linn), *Sarjarasa* (*Shorea robusta* Gaertn), and *Jambiri Nimbu (Citrus jambhiri* Lush.) were identified in the Pharmacognosy Laboratory, Upgraded Department of Dravyaguna, Government Ayurveda College, Vadodara, Gujarat. The samples of *Gandhaka*, *Sphatika*, and *Tankana* were identified at the Quality Testing Laboratory of the Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurveda College, Vadodara, Gujarat. *fssai* (Food Safety and Standards Authority of India) standard *Tila Taila, Go-ghrita* and *Go-dugdha* were procured.

Preparation of *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara*

All the batches of *Dadrughni Vati* (*Lepa*) were prepared as per the reference of Bheshaj Samhita**[2]** and *Dadrughna Malahara* was a modified dosage form of *Dadrughni Vati* (*Lepa*) prepared in the Pharmaceutical Laboratory of Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat.

Place of study

Vasu Research Centre, Division of Vasu Healthcare PVT. LTD. Vadodara, Gujarat.

Packing & Sample quantity

Both *Dadrughni Vati* (*Lepa*) (DL) and *Dadrughna Malahara* (DM), 100 g of each sample, were packed in three transparent, airtight, food-grade plastic containers and stored in an accelerated stability chamber.

Study period

The study was conducted from April 2023 to September 2024.

Storage condition

An accelerated stability study was conducted as per the ICH Guidelines. The samples were stored at 40℃ ± 2℃, while the relative humidity was 75% + 5%. The products were analyzed for the accelerated stability study at 0, 3rd and 6th months.

Frequency of withdrawal of the samples

Samples were withdrawn from the chamber at an interval of 0, 3 and 6thmonths.

Evaluation of Accelerated Stability Testing

Both samples were filled in containers and labelled properly including the drug name and date of preparation. At the six-month-long expedited stability investigation was conducted. Relative humidity (RH) was set at 75 % ± 5 % with a controlled temperature of 40°C ± 2°C.

The acceptable point was determined at 10 % degradation for extrapolating the accelerated stability data. Real-time ageing factor 3.3 are used for extrapolating shelf life for countries in climate zone IV.

Result obtained at different stages (0, 3 and 6 months) were analyzed to calculate intercept, slope and 10 % degradation was set as the acceptable point to extrapolate the accelerated stability data. Months when 10% degradation occurs = (0-month assay value [0-month assay value × 10/100])-intercept/slope. Both samples were assessed at different intervals for changes in organoleptic parameters and physico-chemical parameters in the intervals of 0, 3 and 6 months. HPTLC fingerprinting and microbial limit test in the intervals of 0 and 6 month.

Observations and Results

Data of organoleptic characters and physico-chemical parameters of DL at the interval 0, 3rd and 6th months and HPTLC fingerprinting and Microbial limit test of DL at the interval of 0 and 6th months are tabulated in table no. 1 to 4.

Table 1: Details of organoleptic characters of DL at the interval of 0, 3 and 6 months

SN	Organoleptic Characters	0 month	3 months	6 months
1.	Description	Brown-colored cylindrical Vati	Brown-colored cylindrical Vati	Brown-colored cylindrical Vati
2.	Odor	Characteristic	Characteristic	Characteristic

Table 2: Details of Physico-chemical parameters of DL at the interval of 0, 3 and 6 months

SN	Physicochemical analysis	0 month	3 months	6 months
1.	Average Weight	3652	3657	3650
2.	Ph	3.93	3.92	3.90
3.	Hardness	10.1	10.2	10.2
4.	Loss on Drying (%)	14.20	15.46	16.78
5.	Total Ash (%)	20.04	19.78	18.68
6.	Acid Insoluble Ash (%)	5.76	5.48	5.34
7.	Water Soluble Extractive (%)	43.96	42.58	40.03
8.	Alcohol Soluble Extractive (%)	13.79	14.80	15.54

Table No. 3: Details of Microbial limit test of DL at the interval of 0 and 6 months

SN	Microbial Limit Test (cfu/g)	0 month	6 months
1.	Total Microbial Plate Count	91	06
2.	Total Yeast & Mould Count	Absent	Absent
3.	Staphylococcus aureus	Absent	Absent
4.	Salmonella sp.	Absent	Absent
5.	Pseudomonas aeruginosa	Absent	Absent
6.	Escherichia coli	Absent	Absent

Table 4: Details of HPTLC fingerprinting observed under UV light 254 nm, 366 nm and 540 nm of DL at the interval of 0 and 6 months

Solvent system (v/v)	Observed under UV light	Rf value		No. of spots	
		0 month	6 months	0 month	6 months
Toluene: Ethyl acetate: Acetic acid (7: 2: 1 v/v)	254 nm	0.20	0.20	8	8
		0.30	0.30		
		0.41	0.41		
		0.49	0.49		
		0.59	0.59		
		0.64	0.64		
		0.71	0.71		
		0.95	0.95		
	366 nm	0.41	0.41	5	5
		0.49	0.49		
		0.64	0.64		
		0.71	0.71		
		0.95	0.95		
	540 nm	0.17	0.17	11	11
		0.20	0.20		
		0.30	0.30		
		0.41	0.41		
		0.49	0.49		
		0.56	0.56		
		0.64	0.64		
		0.71	0.71		
		0.76	0.76		
		0.84	0.84		
		0.91	0.91		

Data of organoleptic characters and physico-chemical parameters of DM at the interval of 0, 3rd and 6th months and microbial limit test, HPTLC fingerprinting of DM at the interval of 0 and 6th months are tabulated in table no. 5 to 8.

Table 5: Details of organoleptic characters of PPA at the interval of 0, 3 and 6 months

SN	Organoleptic Characters	0 month	3 months	6 months
1.	Description	Dark brown-colored smooth & uniform cream	Dark brown-colored smooth & uniform cream	Dark brown-colored smooth & uniform cream
2.	Odor	Characteristic	Characteristic	Characteristic

Table 6: Details of Physico-chemical parameters of DM at the intervals of 0, 3 and 6 months

SN	Physicochemical analysis	0 month	3 months	6 months
1.	Specific Gravity	0.930	0.941	0.945
2.	Ph	Not detected	Not detected	Not detected
3.	Refractive Index	Not detected	Not detected	Not detected
4.	Acid Value	2.25	2.93	3.76
5.	Saponification Value	118.97	117.7	114.95
6.	Iodine Value	76.95	82.97	88.83
7.	Viscosity	15,62,000 cP	14,32,000 cP	13,46,000 Cp
8.	Spreadability	662.15 g	645.06 g	634.17 g

Table 7: Details of Microbial limit test of DM at the interval of 0 and 6 months

No.	Microbial Limit Test (cfu/g)	0 month	6 months
1.	Total Microbial Plate Count	306	61
2.	Total Yeast & Mould Count	Absent	Absent
3.	Staphylococcus aureus	Absent	Absent
4.	Salmonella sp.	Absent	Absent
5.	Pseudomonas aeruginosa	Absent	Absent
6.	Escherichia coli	Absent	Absent

Table No. 8: Details of HPTLC fingerprinting observed under UV light 254 nm, 366 nm and 540 nm of DM at the interval of 0 and 6 months

Solvent system (v/v)	Observed under UV light	Rf value		No. of spots	
		0 month	6 months	0 month	6 months
Toluene: Ethyl acetate: Acetic acid (7: 2: 1 v/v)	254 nm	0.35	0.35	3	3
		0.71	0.71		
		0.95	0.95		
	366 nm	0.17	0.17	6	6
		0.44	0.44		
		0.46	0.46		
		0.71	0.71		
		0.76	0.76		
		0.84	0.84		
	540 nm	0.12	0.12	12	12
		0.20	0.20		
		0.30	0.30		
		0.38	0.38		
		0.46	0.46		
		0.56	0.56		
		0.61	0.61		
		0.71	0.71		
		0.74	0.74		
		0.76	0.76		
		0.82	0.82		
		0.84	0.84		

Intercept and slope value of DL and DM are mentioned in table no. 9 and 10 respectively.

Table 9: The results of intercept and slope for shelf-life evaluation of DL

Physicochemical analysis	Intercept	Slope
	DL	DL
pH	3.931	-0.005
Hardness	10.116	0.016
Loss on Drying (%)	14.19	0.43
Total Ash (%)	20.18	-0.226
Acid Insoluble Ash (%)	5.736	-0.07
Water Soluble Extractive (%)	44.155	-0.655
Alcohol Soluble Extractive (%)	13.835	0.291

Table 10: The results of intercept and slope for shelf-life evaluation of DM

Physicochemical analysis	Intercept	Slope
	DM	DM
Specific Gravity	0.931	0.0025
Acid Value	2.225	0.251
Saponification Value	119.21	-0.67
Iodine Value	76.976	1.98
Viscosity	15,54,667	-36000
Spreadability	661.11	-4.663

Table 11: The results of approximate period for 10 % degradation for shelf-life evaluation of DL

Physicochemical analysis	DL		
	Initial	10% Degradation	Month required for 10% Degradation
pH	3.93	3.537	78.80 months
Hardness	10.1	9.09	64.12 months
Loss on Drying (%)	14.20	12.78	3.27 months
Total Ash (%)	20.04	18.036	9.48 months
Acid Insoluble Ash (%)	5.76	5.184	7.88 months
Water Soluble Extractive (%)	43.96	39.564	7.00 months
Alcohol Soluble Extractive (%)	13.79	12.411	4.89 months

Table 12: The results of approximate period for 10 % degradation for shelf-life evaluation of DM

Physicochemical analysis	DM		
	Initial	10% Degradation	Month required for 10% Degradation
Specific Gravity	0.930	0.837	37.6 months
Acid Value	2.25	2.025	0.79 months
Saponification Value	118.97	107.073	18.11 months
Iodine Value	76.95	69.255	3.89 months
Viscosity	15,62,000 cP	14,05,800 cp	4.13 months
Spreadability	662.15 g	595.93 g	13.97 months

Table 13: The results of extrapolation of shelf life of DL and DM

Formulation	Mean months for 10% degradation	Multiplication factor	Shelf life	
			Months	Years
DL	25.062	3.3	82.70	06.89
DM	13.081	3.3	43.16	03.59

Discussion

The shelf life or stability of a drug refers to the period from its manufacturing and packaging until its chemical or biological activity remains at or above the predetermined level of labeled potency, Without significant changes in its physical characteristics. This period indicates when the formulation begins to deteriorate.

In the study of *Dadrughni Vati* (*Lepa*) (DL) and *Dadrughna Malahara* (DM) over 0, 3, and 6 months, various parameters were assessed, including organoleptic characters (Color, appearance, texture and Odor), physicochemical properties for DL (pH, Loss on drying (% w/w), Ash value (% w/w), Acid insoluble Ash (% w/w), Water soluble extractive (% w/w), Alcohol soluble extractive (% w/w), Hardness kg/cm2) and for DM (Specific gravity, viscosity, iodine value, acid value, saponification value, spreadability) and microbial limits and HPTLC fingerprinting were assessed at 0 and 6 month by following ICH guidelines.

The results indicated that the organoleptic characters of DL and DM remained consistent throughout the study.

The pH of the DL sample was found to be acidic and decreased over six months. This reduction may indicate the release of fatty acids or the formation of acidic substances in the sample.**[3]** The loss on drying (LOD) increased as the sample absorbed moisture, leading to a higher weight and increased LOD.**[4]** Temperature and humidity changes could significantly affect the composition and stability of the sample. High humidity may contribute to the increased LOD, while fluctuations in temperature can alter the stability of certain minerals, leading to a decrease in total ash content.**[5]** Additionally, if microbial growth occurs, it could break down some inorganic materials, further reducing the acid-insoluble ash content.**[6]** Conditions, including temperature and humidity, may also influence the solubility of compounds. During the stability period, some compounds may migrate from being water-soluble to alcohol-soluble, which could explain the observed decrease in water-soluble extractives and the increase in alcohol-soluble extractives.**[7]**

Over six months, the specific gravity of the DM sample increased, likely due to phase transitions influenced by temperature fluctuations.**[8]** The iodine value also rose, indicating a higher degree of unsaturation, which could lead to rancidity, particularly in humid conditions that promote oxidative reactions.**[9]** Acid value increased as well, suggesting presence of free fatty acids resulting from moisture-induced glyceride breakdown.

High humidity can accelerate this process, fostering rancidity.**[10]** Microbial growth, influenced by temperature and humidity, may further break down fats and oils, leading to a decrease in saponification value.**[11]** Temperature variations can also affect viscosity and spreadability, with higher temperatures reducing product's stability. Overall, both temperature and humidity significantly impact the physical and chemical properties of the DM sample.**[12]**

Microbial contamination can impact the chemical composition of raw materials, diminishing the medicinal properties of herbal drugs. To assess this, a microbial limit test was performed**[13]** on DL and DM, which included evaluations of total plate count, total yeast and mould count, as well as tests for four pathogens: E. coli, Salmonella, S. aureus, and P. aeruginosa. The absence of pathogens and total plate counts within acceptable limits at the initial stage and six months indicate that DL and DM were free from microbial contamination. This outcome demonstrates the diligence applied during the pharmaceutical process, including the careful selection of containers and storage duration, which ultimately contributes to reducing formulation degradation and extending shelf life.

HPTLC study of DL and DM was carried out in comparison. HPTLC tracks of both samples were scanned under UV light of 254 nm, 366 nm (after derivatization) and 540 nm (after derivatization) with their Rf value mentioned in Table No.5.21 and Table No.5.25. Track 1: *Dadrughni Vati* (*Lepa*) / *Dadrughna Malahara* (0 months) Track 2: *Dadrughni Vati* (*Lepa*) / *Dadrughna Malahara* (6 months). At 254 nm: 8 prominent spots bearing Rf value 0.20, 0.30, 0.41, 0.49, 0.59, 0.64, 0.71, 0.95 were spotted in track of DL. While in the track of DM, 3 prominent spots were observed at Rf values 0.35, 0.71, 0.95. At 366 nm (after derivatization): 5 prominent spots bearing Rf values 0.41, 0.49, 0.64, 0.71 and 0.95 were spotted in the track of DL. 6 prominent spots were observed at Rf values 0.17, 0.44, 0.46, 0.71, 0.76 and 0.84 in the track of DM. At 540 nm (after derivatization): 11 prominent spots were observed at Rf value 0.17, 0.20, 0.30, 0.41, 0.49, 0.56, 0.64, 0.71, 0.76, 0.84, 0.91 spotted in track of DL. While 12 prominent spots bearing Rf values 0.12, 0.20, 0.30, 0.38, 0.46, 0.56, 0.61, 0.71, 0.74, 0.76, 0.82 and 0.84 were spotted in track of DM.

The same spots observed in HPTLC at both the 0 and 6-month periods during the stability study indicate consistent chemical composition and stability of the product over time. Based on the physicochemical values, intercept and slope were calculated followed by the expected time for 10% degradation for individual parameters. On the extrapolation of these values, the shelf life of DL and DM in accelerated conditions was found to be 6.89 years and 3.59 years.

Conclusion

The present investigation supports that the *Dadrughni Vati* (*Lepa*) and *Dadrughna Malahara* were suitable at accelerated conditions for up to 6-month storage. It can be extrapolated that the shelf life of DL is 6.89 years and the shelf life of DM is 3.59 years for countries that come under climate zones III and IV.

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