

Standard Manufacturing Procedure of Dadrughni Vati (Lepa) and Its Modified Dosage Form Dadrughna Malahara: Tradition to Innovation

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Date of Submission: 05-02-2025

Date of Acceptance: 15-02-2025

ABSTRACT: **Introduction:** Herbo-mineral formulations, require systematic pharmaceutical procedures to ensure efficacy, safety, and consistency. The increasing global demand for high-quality Ayurvedic products necessitates the development of Standard Manufacturing Procedures (SMPs). This study aims to design and establish an SMP for two Ayurvedic formulations, Dadrughni Vati (Lepa) and Dadrughna Malahara, ensuring reproducibility and quality across multiple batches. **Materials and Methods:** The study involved the procurement, identification, and preparation. The preparation of Dadrughni Vati (Lepa) involved mixing powdered ingredients and levigating them with Jambiri Nimbu Svarasa, followed by drying and cutting them into uniform Vati. Dadrughna Malahara was prepared by levigating powdered ingredients with Jambiri Nimbu Svarasa, followed by incorporation to Siktha Taila to achieve a semisolid consistency. All stages of preparation were standardized for time, temperature, and ingredient weights. **Results:** In the preparation of Dadrughni Vati (Lepa), the average final weight was 1046.8 g, showing an average weight gain of 4.68% due to levigation with Jambiri Nimbu Svarasa. The levigation took 8 hours, and the drying period was consistent across all batches, requiring 6 days. For Dadrughna Malahara, the final yield averaged 98.96%, with an average weight increase of 4.2% to 6% during levigation. Temperature control during preparation was maintained, with the melting of Siktha Taila occurring at 65°C, and the final Malahara achieved a semisolid consistency at 30°C. The entire Malahara preparation took 60 minutes per batch. **Discussion:** The study successfully developed an

SMP for both formulations, ensuring consistency in potency and quality across batches. The formulation of Dadrughni Vati (Lepa) showed minimal weight variation, while the preparation of Dadrughna Malahara demonstrated effective temperature control and consistency in achieving the desired semisolid consistency. The use of Jambiri Nimbu Svarasa as a levigating medium contributed to uniformity in both formulations.

Keywords: Ayurvedic pharmaceuticals, Standard Manufacturing Procedure (SMP), Herbo-mineral formulations

I. INTRODUCTION

Herbo-mineral formulations must undergo essential pharmaceutical procedures to enhance their efficacy in human and animal biological systems. These procedures are customized based on the formulation's characteristics, the drug's nature and the targeted pathology, ensuring optimal pharmacological effectiveness and safety.

The field of Ayurvedic pharmaceuticals is expanding globally, driven by the need for high-quality, effective and safe medicines in a competitive market. Integrating traditional Ayurvedic knowledge with modern pharmaceutical techniques addresses contemporary health needs while preserving Ayurveda's heritage.

In ancient times, Ayurvedic formulations were prepared by physicians for individual patients without commercial intent. Currently, pharmaceutical companies are responsible for manufacturing these medicines to meet large-scale healthcare demands.

Standard Manufacturing Procedures (SMPs) have been developed to ensure consistency

and quality in the production of medicines. Here, an attempt has been made to design the SMP (Standard Manufacturing Procedure) of Dadrughni Vati (Lepa) and Dadrughna Malahara in different batches. This protocol ensures consistency in potency and safety, allowing each batch to maintain uniform effectiveness and quality.

II. MATERIALS AND METHODS

The pharmaceutical study aimed at developing a Standard Manufacturing Procedure (SMP) for Dadrughni Vati (Lepa) and Dadrughna Malahara was carried out through systematic procurement, identification and preparation of raw materials. The raw materials for the formulations were sourced from multiple suppliers: Tankana, Sphatika and Tila Taila were obtained from the Government Ayurved Pharmacy in Rajpipla, Gujarat, while Gandhaka, Sarjarasa, Chakramarda Beeja, Siktha, Go-ghrita and Go-dugdha were procured from local traders in Vadodara, Gujarat. Jambiri Nimbu was sourced directly from a farmer in Amreli, Gujarat. All materials were carefully identified and authenticated at respective laboratories; for instance, Chakramarda (*Cassia tora* Linn.), Sarjarasa (*Shorea robusta* Gaertn.) and Jambiri Nimbu (*Citrus jambhiri* Lush.) were confirmed in the Pharmacognosy Laboratory, Government Ayurved College, Vadodara. while Gandhaka, Sphatika and Tankana were tested at the Quality Testing Laboratory, Government Ayurved College, Vadodara.

Both formulations were prepared in the Pharmaceutical Laboratory of the Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara. The drugs were prepared in five separate batches for each formulation to establish a Standard Manufacturing Procedure. This approach ensured the consistency and reproducibility of the preparation process, helping to standardize the formulations and confirm their quality across multiple batches. Whole pharmaceutical procedure was done as given below.

Preparation of Dadrughni Vati (Lepa):

The powdered ingredients (Table no. 01) were carefully measured and thoroughly mixed using a mortar and pestle. The resulting mixture was then levigated with Jambiri Nimbu Svarasa until a smooth, uniform dough was formed. After that Vati was prepared using a 5 ml syringe, and each Vati was carefully cut to a consistent size of 3 cm with a cutter. The Vati was subsequently left to

dry completely. After drying, the Vati were weighed and stored in an airtight, properly labeled container for further use.

Preparation of Dadrughna Malahara:

The powdered ingredients (Table no.03) were weighed according to the specified quantities and thoroughly mixed using a mortar and pestle. The mixture was then levigated with Jambiri Nimbu Svarasa, and the levigation process was continued until the mixture transformed into a dry form. Subsequently, the dried mixture was ground into a fine powder using a mixer grinder and passed through a 120 # sieve.

The required quantity of Siktha Taila was then measured and placed in a stainless-steel vessel, where it was gently heated. After heating, the Siktha Taila was transferred to a porcelain mortar and pestle, and the powdered material was gradually added in small amounts. Continuous trituration was performed in the mortar and pestle until a semisolid consistency was achieved. The final preparation was weighed and stored in an airtight, labeled container for future use.

III. OBSERVATIONS AND RESULTS

Dadrughni Vati (Lepa):

The mixture of powdered ingredients initially appeared light brown. Upon the addition of Jambiri Nimbu Svarasa, the color changed to dark brown, and the mixture transformed into a semi-liquid form. The characteristic aroma of Jambiri Nimbu Svarasa was noticeable during the levigation process. After drying, the product returned to a light brown color.

In all five batches of Dadrughni Vati (Lepa), the initial weight of the total ingredients was 1000 g. for each batch, and the quantity of Jambiri Nimbu Svarasa used was consistently 1000 ml. The final weight of the Dadrughni Vati (Lepa) varied slightly across the batches. The average final weight across all batches was 1046.8 g. (Table no.03)

The total weight gain in each batch, attributed to the addition of Jambiri Nimbu Svarasa, with an average gain of 46.8 g (4.68%). The levigation process took 8 hours for each batch, and the drying time was consistent across all batches, requiring 6 days for complete drying. (Table no.03)

The preparation of Dadrughni Vati (Lepa) showed a consistent increase in weight due to the incorporation of Jambiri Nimbu Svarasa, with the entire process, including levigation and drying,

taking a standardized amount of time for each batch.

Dadrughna Malahara:

The preparation of Dadrughna Malahara was systematically monitored across five batches to evaluate key parameters, including temperature control, ingredient weights, and process outcomes.

The melting of Siktha Taila required an average of 8 minutes, maintaining a consistent temperature of 65°C across batches, ensuring effective control over the melting phase. Upon adding the powdered ingredients, the temperature ranged from 38°C to 40°C. As the preparation continued and the desired Malahara consistency was achieved, the final temperature stabilized around 30°C. These results indicate that temperature control was well-maintained throughout the process. (Table no. 04)

The powdered ingredients initially had a light brown color. Following levigation with Jambiri Nimbu Svarasa, the mixture turned dark brown, accompanied by the distinct aroma of the Svarasa. After levigation, the powder took on a creamish brown shade. When combined with Siktha Taila, the mixture changed from yellow to brown. Through continuous trituration, the consistency gradually became thicker and smoother, resulting in a final brown-colored semisolid Malahara.

The initial weight of the ingredients was consistent at 500 g. per batch. During levigation, 500 ml of Jambiri Nimbu Svarasa was added, resulting in a final weight average increase of 525.8 g., corresponding to a weight gain of 21 to 30 g. (4.2% to 6%). The increase was attributed to the levigation of Jambiri Nimbu Svarasa, and the total time for levigation was consistent across all batches, taking 5 hours. (Table no. 05)

After sieving with a 120-mesh sieve, the final weight of the mixture passed through the sieve was approximately 69.33% of the initial weight, with an average loss of 30.66%. This loss was attributed to the powdering and sieving process. (Table no. 05)

For the final Malahara preparation, the initial ingredient weight was 1200 g. per batch. The final product's average yield of 98.96%. The loss during this stage (0.75% to 1.34%) was primarily due to material sticking to the vessel. The total time for preparation, including cooling, was consistent at 60 minutes across all batches. (Table no. 05)

IV. DISCUSSION

A pharmaceutical study has been aimed to develop SMP of Dadrughni Vati and Dadrughna Malahara. Dadrughni Vati prepared as per the reference mentioned in Bhesaja Samhita and modified this dosage form into Malahara. The pharmaceutical process was carried out in several stages for the preparation of Dadrughni Vati (Lepa) and Dadrughna Malahara. First, Shodhana of Sphatika, Tankana and Gandhaka was performed. Next, the powdering of all ingredients was done and Svarasa preparation of Jambiri Nimbu was done. Siktha Taila was then prepared for Dadrughna Malahara Preparation.

Sphatika Shodhana was carried out as per the reference of Ayurveda Prakash., resulting in an average yield of 39.2%. The Shodhana of Tankana was carried out based on the references from Rasatarangini, the average yield during the Shodhana process was 68.33%. The Shodhana of Gandhaka was performed following the guidelines provided in reference of Rasatarangini. An average yield was 90.5 % during the Shodhana procedure. Powders were prepared as per the reference of Sharangdhara Samhita. During the powder preparation of all ingredients, Shuddha Sphatika, Shuddha Tankana, Shuddha Gandhaka, Sarjarasa, and Chakramarda were sieved through a 120# sieve, resulting in yields of 85.96%, 88.3%, 82.85%, 40.2%, and 35%, respectively. Jambiri Nimbu Svarasa was used as liquid media for the levigation in Dadrughni Vati (Lepa). Svarasa was prepared as per the reference of Sharangdhara Samhita. 45 % average yield was obtained during the preparation of Jambiri Nimbu Svarasa.

An average weight gain was 4.68 % during Vati preparation. The reason for the gain was due to the addition of Jambiri Nimbu Svarasa. An average 1000 ml Jambiri Nimbu Svarasa was used for the levigation and the average time taken was 8 hrs. for levigation and 6 days for drying of the Vati.

Siktha Taila was prepared as per the reference of Rasatarangini. Siktha Taila was prepared with a 1:5 ratio. The yield was 99 %.

The temperature observed during different stages of Malahara preparation in all five batches was an average of 65 °C during the melting of Siktha Taila. 40 °C when powder material was added in Siktha Taila. 30 °C when Malahara consistency started to form. An average yield was 98.96% during Malahara preparation. The reason for the loss was due to sticking to the vessel. An average 500 ml Jambiri Nimbu Svarasa was used

for the levigation and the average time taken for Malahara preparation was 60 min.

Cost analysis:

The cost analysis for the preparation of Dadrughni Vati (Lepa) and Dadrughna Malahara reveals distinct pricing structures based on batch sizes and material requirements. Producing 1046.8 g of Dadrughni Vati in a 1000 g batch costs approximately Rs. 2130 per kg. In contrast, the preparation of 1187.5 g of Dadrughna Malahara in a 1200 g batch amounts to about Rs. 1800 per kg. The higher cost for Dadrughni Vati is primarily due to the higher quantity of raw materials needed for

its production. Overall expenses encompass raw materials, labor, gas charges, and packaging costs.

V. CONCLUSION

The pharmaceutical study successfully developed the SMP for both Dadrughni Vati (Lepa) and Dadrughna Malahara. Five batches of both Dadrughni Vati (Lepa) and Dadrughna Malahara were prepared, with an average weight gain of 4.68 % for Dadrughni Vati and a yield of 98.96 % for Dadrughna Malahara, indicating the efficiency of the production process.

Table No. 01: Details of ingredients used for all five batches of DL

Sr. No.	Name of Ingredient	Latin / English Name	Part used	Ratio	Quantity				
					B-1	B-2	B-3	B-4	B-5
3.	Shuddha Tankana (g)	Sodium borate/ Borax	Mineral	1 Part	200	200	200	200	200
	Shuddha Sphatika (g)	Potash Alum	Mineral	1 Part	200	200	200	200	200
	Shuddha Gandhaka (g)	Sulphur	Mineral	1 Part	200	200	200	200	200
4.	Sarjarasa (g)	Shorea robusta Gaertn.	Gum resin	1 Part	200	200	200	200	200
5.	Chakramarda (g)	Cassia tora Linn.	Seed	1 Part	200	200	200	200	200
6.	Jambiri Nimbu (ml)	Citrus jambhiri Lush.	Fruit	Q.S.	1000	1000	1000	1000	1000

Table No. 02: Details of results of all five batches of Dadrughni Vati (Lepa)

Sr. no.	Parameters		B-1	B-2	B-3	B-4	B-5	Average
1.	Initial weight of total ingredients (g)		1000	1000	1000	1000	1000	1000
2.	Quantity of Jambiri Nimbu Svarasa (ml)		1000	1000	1000	1000	1000	1000
3.	Final weight of Dadrughni Vati (Lepa)	(g)	1044	1058	1039	1048	1045	1046.8
4.	Total gain	(g)	44	58	39	48	45	46.8
		(%)	4.4	5.8	3.9	4.8	4.5	4.68
5.	Reason of gain		Due to addition of Jambiri Nimbu Svarasa					
6.	Total time taken for preparation of Vati (Lepa)	For levigation (hr.)	8	8	8	8	8	8
		For drying (days)	06	06	06	06	06	06

Table No. 03: Details of ingredients used for all five batches of Dadrugghna Malahara

Sr. No.	Name of Ingredient	Latin / English Name	Part used	Ratio	Quantity				
					B-1	B-2	B-3	B-4	B-5
Use for levigation									
1.	<i>Shuddha Tankana</i> (g)	Sodium borate/ Borax	Mineral	1 Part	100	100	100	100	100
2.	<i>Shuddha Sphatika</i> (g)	Potash Alum	Mineral	1 Part	100	100	100	100	100
3.	<i>Shuddha Gandhaka</i> (g)	Sulphur	Mineral	1 Part	100	100	100	100	100
4.	<i>Sarjarasa</i> (g)	<i>Shorea robusta</i> Gaertn.	Gum resin	1 Part	100	100	100	100	100
5.	<i>Chakramarda</i> (g)	<i>Cassia tora</i> Linn.	Seed	1 Part	100	100	100	100	100
6.	<i>Jambiri Nimbu</i> (ml)	<i>Citrus jambhiri</i> Lush.	Fruit	Q.S.	500	500	500	500	500
Use for <i>Malahara</i> Preparation									
1.	Fine powder of all ingredients (g)	-	-	1 part	200	200	200	200	200
2.	<i>Siktha Taila</i> (g)	-	Oil	5 Parts	1000	1000	1000	1000	1000

Table No. 04: Details of Temperature at different stages of preparation of Dadrugghna Malahara

Batch No.	Duration of Melting Siktha (min.)	of Taila	Temperature (⁰ C)		When powder of all drugs added in Siktha Taila	when Malahara consistency form
			Siktha	Taila during melting		
B-1	08		65		40	30
B-2	07		63		38	28
B-3	08		65		38	30
B-4	09		65		40	28
B-5	09		62		40	30
Average	08		65		40	30

Table No. 05: Details of results of all five batches of Dadrughna Malahara

Sr. no.	Parameters		B-1	B-2	B-3	B-4	B-5	Average
Levigation								
1.	Initial weight of total ingredients (g)		500	500	500	500	500	500
2.	Quantity of <i>Jambiri Nimbu Svarasa</i> for levigation (ml)		500	500	500	500	500	500
3.	Final weight of total ingredients after levigation (g)	(g)	524	521	530	524	530	525.8
4.	Total gain after levigation	(g)	24	21	30	24	30	25.8
		(%)	5	4.2	6	5	6	5.24
5.	Reason of gain after levigation		Due to addition of <i>Jambiri Nimbu Svarasa</i>					
6.	Total time taken for levigation (hr.)		5	5	5	5	5	5
Sieving								
7.	The final weight of total ingredients (g) after passing through 120# used for <i>Malahara</i> preparation	(g)	364	365	365	364	365	364.6
		(%)	69.46	70.05	68.86	69.46	68.86	69.33
8.	Total loss after passing through 120# sieve	(g)	160	156	165	160	165	161.2
		(%)	30.54	29.95	31.14	30.54	31.14	30.66
9.	Reason of loss after passing through 120# sieve		Due to powdering and sieving					
Malahara Preparation								
10.	Initial weight of ingredients (g)		1200	1200	1200	1200	1200	1200
11.	Final weight of <i>Dadrughna Malahara</i>	(g)	1190	1191	1184	1188	1185	1187.5
		(%)	99.16	99.25	98.66	99.00	98.75	98.96
12.	Total loss	(g)	10	09	16	12	15	12.4
		(%)	0.84	0.75	1.34	1.00	1.25	1.04
13.	Reason of loss		Due to stick to the vessel.					
14.	Total time taken for preparation of <i>Malahara</i> (min.) (For <i>Malahara</i> preparation and cooling)		60	60	60	60	60	60

Unit operative procedure of Dadrughni Vati (Lepa)



Fig.01



Fig.02



Fig.03



Fig.04



Fig.05



Fig.06



Fig.07



Fig.08

Unit operative procedure of Dadrughna Malahara



Fig.09



Fig.10



Fig.11



Fig.12



Fig.13



Fig.14



Fig.15



Fig.16



Fig.17



Fig.18



Fig.19

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