ISSN No: 0976-5921

Research Article

Pharmaceutical Standardisation of *Lakshadi Guggulu Vati* and Tablet w.s.r to the Method of Preparation

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Received: 07-12-2024 Accepted: 17-07–2025 Published: 30-09-2025

Abstract

Introduction: Standard operating procedure for pharmaceutical preparation of *Lakshadi Guggulu Vati* and Tablet has been developed in the present research work to compare the traditional method of Tablet preparation with the modern pharmaceutical procedure. Material and Methods: Three samples each of classical *Lakshadi Guggulu vati* were prepared as per *Vrindmadhav* and A.F.I to develop Standard Operating Procedure (SOP) for the drug. Also three samples each of *Lakshadi Guggulu* tablet by wet granulation method according to the same references were prepared for comparison of the pharmaceutical procedures. For the purification process of *Guggulu* 1:4 ratio of crude *Guggulu* and purification media (*Triphala Kwatha*) was taken. Observation and Result: Mean % yield of *Lakshadi Guggulu Vati* and Tablet as per the references of *Vrindmadhav* and A.F.I. were found to be 87.28%, 92.92% and 90.26%, 95.88% respectively. 700g of *Guggulu Shodhana* by *Parisravana* requires 3-4 hrs duration with an average yield of 62-66 %. In the preparation of drug by classical pharmaceutical procedure 10-12% loss was observed while preparing drug by modern pharmaceutical procedure 4-8% loss was observed irrespective of references taken for the process. Conclusion- Pharmaceutically it is better to prepare tablet instead of *Vati*, as the percentage loss in *Vati* preparation was high which in turn elevates the cost of medicine.

Keywords: *Lakshadi Guggulu, Vati, Tablet, Standardisation*

Access this article online

Website: https://ijam.co.in

DOI: https://doi.org/10.47552/ijam.v16i3.5540

Introduction

Pharmaceutical research is the fortitude of any stream of medical science. The superlative entity of pharmaceutical study is to generate good quality product. Synthetic drugs don't offer any issues with quality control as they were having very well-defined parameters of analysis. On the contrary, ayurvedic medicines are prepared from material of plant origin, which are prone to contamination, deterioration and variation in composition. Therefore, quality control of Ayurvedic medicine offers a host of problems.

Validation literally means to render the process valid after substantiating known process with a scientific ground in order to deliver a particular product which hereby can be divided in two important components -

1- The equipment validation; 2- The process validation

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An elaborate comprehension of the preparation of compound drug with respect to the changes during the processes creates a unique opportunity for formulating the new/existing compounds with improved stability and for superior nutritional, dieting and therapeutic qualities. This arise the necessity to study the preparation of a drug to comprehend the underlying principles, document the findings for further comparison, corroborate the document with therapeutic efficacy and then formulate the resolutions. Considering the above facts, here an attempt is made to compare the traditional method of *Vati* preparation with the modern pharmaceutical procedure taking *Lakshadi Guggulu* as the test drug. Also to explore a standard "Pharmaceutical Protocol" for preparation of *Lakshadi Guggulu Vati* and tablet as per the references of *Vrindmadhav* and A.F.I. *Lakshadi Guggulu Vati* and tablet had been prepared repeatedly for three times to ensure the process validation.

Materials and Methods

Three samples each of classical *Lakshadi Guggulu vati* were prepared as per *Vrindmadhav* (V1,V2,V_3) and A.F.I (S_1,S_2, S_3) to develop Standard Operating Procedure (SOP) for the drug.(1,2). Also three samples each of *Lakshadi Guggulu* tablet by wet granulation method according to the same references (Sv1, Sv2,

S_V3 and S_T1, S_T2, S_T3) were prepared for comparison of the pharmaceutical procedures.

Table 1: Details of Ingredients and weight taken for *Lakshadi Guggulu Vati* preparation

S.No	Ingredients	Weight taken (gm)					
		V1	V2	V3	S1	S2	S3
1	*Laksha*	25	25	25	25	26.5	25.5
2	*Asthi-shrinkhala*	25	25	25	25	26.5	25.5
3	*Arjun*	25	25	25	25	26.5	25.5
4	*Ashwagandha*	25	25	25	25	26.5	25.5
5	*Nagbala*	25	25	25	25	26.5	25.5
6	*Guggulu* + *Triphala Ghana*	31.5 (25+ 5.6)	31.5 (25+ 5.6)	31.5 (25+ 5.6)	170 (125.5 +45)	177 (132 +45)	172 (127 +45)
7	*Triphala Kwatha* (ml)	100	100	100	100	100	100

Table 2: Details of Ingredients and weight taken for *Lakshadi Guggulu* Tablet preparation

S.No	Ingredients	Weight taken (gm)					
		SV1	SV2	SV3	ST1	ST2	ST3
1	*Laksha*	80	82	80	100	100	100
2	*Asthishrinkhala*	80	82	80	100	100	100
3	*Arjun*	80	82	80	100	100	100
4	*Ashwagandha*	80	82	80	100	100	100
5	*Nagbala*	80	82	80	100	100	100
6	*Shuddha Guggulu* + *Triphala Ghana*	98 (80+ 18)	100.5 (82+ 18.5)	98 (80+ 18)	612 (500 +112)	612 (500 +112)	612 (500 +112)
7	*Triphala Kwatha* (ml)	100	100	100	500	500	500
8	Gum Acacia	72 (15% w/w)	72 (15% w/w)	72 (15% w/w)	100 (10% w/w)	100 (10% w/w)	100 (10% w/w)

Procurement and Preparation of Raw Drugs

All the raw drugs were collected from local market and were subjected to authentication as per API protocols. For *Kwatha* preparation RO/UV water was used. The whole pharmaceutical study includes four unit operations viz. Preparation of fine powder of ingredients for *Lakshadi Guggulu* , Preparation of *Triphala-Kwatha* for *Guggulu shodhan* as per *Sharangdhara Samhita, Shodhan* of crude *Guggulu* according to *Rasajalnidhi* (Modified) and preparation of *Lakshadi Guggulu Vati* and Tablet as per *Vrindamadhav and A.F.I.* Each of these unit operations were repeated three times so as to fix the S.O.P.

Preparation of fine powder of ingredients for *Lakshadi Guggulu*

After proper identification, authentication, cleaning and drying, all the ingredients were taken in known amount which were then crushed first into coarse powder and successively into fine powder, separately with the help of iron mortar and pestle. After that they were sieved and the fine powder was kept in separate airtight containers for further experiment.

Preparation of *Triphala-Kwatha* for *Guggulu shodhan* as per *Sharangdhara Samhita*

700 gm Triphla Yavakuta-churna (Coarse powder of 22/40 mesh size) was soaked in 11.2 Litre water (16 times of Triphala coarse powder) for 12 hours in a big stainless steel cauldron. The whole bulk was crushed by proper rubbing and kept over mild heat so as to reduce the volume of water to one fourth of its original volume. Utensil was withdrawn from fire and filtered through fine marking cloth. The bulk of liquid so obtained was required *Triphala-Kwatha* which can authentically be used in purification procedure of crude *Guggulu.*(3)

Calculation of total Solid Matter in *Triphla kwatha* (100gm of *Triphla* was taken)

Triphla Kwatha was prepared by adding 16 times water to *Triphla* and reducing the content up to one fourth of initial amount. *Triphla-Kwatha* so formed was put into a stainless steel cauldron, and the whole system was kept over mild fire to evaporate the whole liquid portion. Solid bulk so obtained was the required *Ghana Triphla Kwatha.*

***Shodhan* of crude *Guggulu* according to *Rasajalnidhi* (Modified)**

All the physical impurities like stone etc. *Guggulu* were removed manually. Crude *guggulu* was added into purification media, afterwards stirred it well and allow it to stand for 2-3 hours which was then rubbed vigorously with ladle. Before filtration of prepared solution of crude *guggulu* by muslin cloth, it was heated slightly, after filtration the residue in cloth was discarded. Now the filtered liquid was heated on gas stove on mild fire with continuous stirring. (Gas knob was set on sim) as water got evaporated its consistency increased gradually, and it started to thickened *(Avaleha Vata)*. The thickened matter so obtained was the required *Shuddha Guggulu*.(4)

Table 3: Ingredients used for Guggulu Shodhana (G1, G2, G3)

S.No	Ingredients	Amount
1	*Guggulu*	700, 700, 700 gm
2	*Triphala-Kwatha*	2800, 2800, 2800 ml

Preparation of *Lakshadi Guggulu Vati* and Tablet as per *Vrindamadhav and A.F.I.*

Preparation of Lakshadi Guggulu Vati

Triphala Kwatha was poured in iron cauldron and kept over mild fire. Now known amount of *Shodhit Guggulu* approx. 25 gm was mixed in *Kwatha* thoroughly with the help of spatula. It was heated with continuous stirring until it becomes some more viscous. Very fine powder of remaining *dravya* in aforesaid amount were added to it and mixed thoroughly to such an extent that physically every constituents were mixed up properly and a homogeneous mass was obtained. The above homogeneous mass was ultimately converted to a semisolid accumulate. Utensil was immediately withdrawn from heat and the stirring was continued till the disappearance of vapours. Semisolid accumulate so formed was transferred into iron mortar and pestle, for hammering. After pounding with little amount of *ghee*, semi-solid accumulate got softened. Rolls of soft mass of *Lakshadi Guggulu* were prepared and transferred in to the cylinder of stick making machine for stick manufacturing. To avoid the sticking of *Guggulu* sticks with each other, add little amount of *ghee* over them. Then sticks were taken one by one and with the help of knife, appropriate size pills

were made. Size of pills were checked and malformed were again subjected to the process. Pills were allowed to dry in shade.

Preparation of *Lakshadi Guggulu* Tablet

Triphala Kwatha was poured in a big stainless steel cauldron and kept over mild fire. Now known amount of pure *Guggulu* approx. 80 gm was mix in the *Kwatha* thoroughly with the help of spatula. Gum acacia of above mentioned amount was added and mix thoroughly. It was heated with continuous stirring until it becomes some more viscous. Very fine powder of remaining dravya in aforesaid amount were added to it and mixed thoroughly to such an extent that physically all contents were mixed up properly and a homogeneous mass was obtained. The above homogeneous mass was ultimately converted to a semisolid accumulate. Utensil was immediately withdrawn from heat and the stirring is continued till the disappearance of vapours. Semisolid accumulate so formed was transferred into iron mortar and pestle, for hammering. After pounding with little amount of ghee, semi-solid mass got softened. The softened mass was took out in a bio-friendly plastic sheet and dried properly in sunlight. After drying, granules were made with the help of sieve no. 14. Granules were punched into tablets of 500mg with the help of tablet punching machine.

Observations and Results

Table 4: Table showing the initial and final amount of ingredients along with the % loss and % yield obtained

S.No	Ingredient	Original Amount (gm)	Powder Obtained (gm)	Percentage Yield (%)	Percentage Loss (%)
1	*Laksha*	250, 250, 250	160.5, 201,205.5	64.2,80.4,82.2	35.8,19.6,17.8
2	*Asthishrinkhala*	250, 250, 250	18,62,02,180.5	74.4, 80.8,72.2	25.6,19.2,27.8
3	*Arjuna*	250, 250, 250	210.5,224,195	84.2,89.6,78	15.8,10.4,22
4	*Ashwagandha*	250, 250, 250	19,52,06,186	78,82.4,74.4	22,17.6,25.6
5	*Nagbala*	250, 250, 250	102.5,145,163	4,15,865.2	5,94,234.8

Table 5: Result of *Guggulu Shodhan*

Sample	Wt. of Raw *Guggulu* (gm)	Volume of *Triphala Kwatha* (ml)	Vessel Wt.	Wt. of *Triphala Ghana* (gm)	Wt. of *Shudha Guggulu* (gm)	Yield (%)
G1	700	2800	1078.5	157.5	440	62.85
G2	700	2800	1088.5	157.5	462	66
G3	700	2800	1074.5	156.9	444.5	63.5
Mean yield of *Guggulu* purification:	$\frac{\text{Yield}(1^{st}) + \text{Yield}(2^{nd}) + \text{Yield}(3^{rd})}{3}$		=	$\frac{62.85+66+63.5}{3}$	=	64%

Mean yield of *Guggulu* purification: $\frac{\text{Yield } (1^{st}) + \text{Yield } (2^{nd}) + \text{Yield } (3^{rd})}{3} = \frac{62.85 + 66 + 63.5}{3} =$ 64%

Approximately 5.6gm weight was added by per 100ml of *Triphala Kwatha* to the purified Guggulu.

Table 6: Observations during preparation of *Lakshadi GugguluVati (Vrindmadhav)*

S.No	Observation	Sample V1	Sample V2	Sample V3	
1	Total Wt. of Ingredients	160 gm	160 gm	160 gm	
2	Wt. of dough	242 gm	242 gm	242 gm	
3	Total wt. of *Vati*	140 gm	142 gm	137 gm	
4	% Yield	87.5%	88.75%	85.6%	

Mean yield by classical method (%) $\frac{\text{Yield (V1)} + \text{Yield (V2)} + \text{Yield (V3)}}{3} = \frac{87.5 + 88.75 + 85.6}{3} =$ 87.28%

Table 7: Observations during preparation of *Lakshadi Guggulu* tablet (*Vrindmadhav)*

S.No	Observation	SV1	SV2	SV3
1	Colour	Light Brown	Light brown	Light Brown
2	Total Wt. of Ingredients	575.6 gm	590.1 gm	575.6 gm
3	Total wt. of tablet	541 gm	542 gm	535 gm
4	Increase in wt. Of Tablet (%)	12.7	10.16	11.45
	% Yield	93.98%	91.84%	92.94%

Mean yield by modern method (%) $\frac{\text{Yield}(S_V1) + \text{Yield}(S_V2) + \text{Yield}(S_V3)}{3} = \frac{93.98 + 91.84 + 92.94}{3} =$ 92.92%

Table 8: Observations during preparation of *Lakshadi Guggulu Vati* (A.F.I)

S.No	Observation	S1	S2	S3
1	Total Wt. of Ingredients	300.6 gm	315.1gm	305.1gm
2	Wt. of Dough	392.5gm	416.5gm	392.0gm
3	Total wt. of Vati	274gm	280gm	277gm
4	Increase in wt. of Vati (%)	9.38%	5.86%	8.84%
	% Yield	91.15%	88.86%	90.78%

$$\text{Mean yield by classical method (\%)} = \frac{\text{Yield(S1)} + \text{Yield(S2)} + \text{Yield(S3)}}{3} = \frac{91.15 + 88.86 + 90.78}{3} = 90.26\%$$

Table 9: Observations during preparation of *Lakshadi Guggulu* tablet (A.F.I)

S.No	Observation	SV1	SV2	SV3
1	Colour	Dark Brown	Dark brown	Dark Brown
2	Total Wt. of Ingredients	1240 gm	1248 gm	1250 gm
3	Total wt. of tablet	1189 gm	1176 gm	1180 gm
4	Increase in wt. of Tablet (%)	18.9%	17.8%	18.6%
	% Yield	95.88%	93.86%	96.94%

Discussion

The ingredients used in preparation of powder are *Laksha (Laccifer lacca)*, *Asthishrinkhala (Cissus quadrangularis)*, *Arjuna (Terminalia arjuna)*, *Ashwagandha (Withania somnifera)*, *Nagbala (Grewia hirsuta)*. Three different batches of powder were prepared from initial amount of 250gm each of raw material. First batch exhibited lowest yield among all batches may be that part of sample contains major impurities. Foremost cause of loss during powdering is due to presence of fibrous part in crude drug, due to handling and some amount in fine particle scavenging in air.

Triphala Kwatha was prepared for the *shodhan* of *guggulu*. The quantity of *Triphala yavakuta* powder was taken equal to the quantity of *ashuddha guggulu* i.e. for 700g of crude *guggulu* 700g of *Triphala yavakuta* powder was taken. 16 times of water was added to *Triphala yavakuta* powder and was kept soaked for overnight. On next day it was heated on *Madhyamagni* to reduce it up to 1/4th quantity. 16 times water was taken for better preparation of *Kwatha* (5), in order to extract the maximum water-soluble parts from *Triphala yavakuta* powder. This water containing *Triphala Yavakuta* boils at 98^0 C and about 4 hrs are required to reduce it up to 1/4. Colour of prepared *Triphala Kwatha* was dark brown. Taste of *Kwatha* can provide the quality of preparation; more *Kashaya* taste represents the better preparation of *Kwatha*.

Three successive batches of *Triphala Shodhit Guggulu* were prepared. In each batch 700gm of crude *guggulu* and 2800ml of *Triphala Kwatha* were taken for the purification process. There were no references about the quantity of *Triphala Kwatha* to be taken for the purification. According to *Rasa Tarangini,* four times of cow's milk should be taken, than that of *ashuddha Guggulu* for the *shodhan.*(6) On the basis of it, for the present study four times of *Triphala Kwatha* was taken as per the opinion of experts. For the present study, common process of *Guggulu* purification, which is in practice at commercial level was adopted, instead of *dola yantra* method as per the opinion of the experts of subject. There are lots of problem with *dola yantra* method, first of all the quantity of purification media cannot be standardized for the purification process. Secondly squashing of *pottali* was required repeatedly because of blocking of cloth pores by *Guggulu* gum-resin. By this *dola yantra* method purification of *Guggulu* cannot be performed in large scale. Due to these practical difficulties, method of *parisravana* (dissolution and filtering) was adopted. *Parisravan* is method in which *Guggulu* is dissolved in liquid media and then filtered. Behind the purification process of *Guggulu* principal aim is to separate the liquid soluble and insoluble part from the crude *Guggulu*. This is supported by the process of extraction of *Guggulipid* from *Guggulu* in modern pharmaceutics. Gum resin *Guggulu* has two fractions. Our procedure of *shodhan* therefore appears to be a sensible way of purification, because in the process toxic insoluble part is removed from soluble part. The percentage of foreign matters should not exceed more than 8%. Than we dissolved the crude *Guggulu* in media for purification and little heat was given. After some time, the solution was filtered with the help of clean marking cloth. The residue in cloth was discarded and filtrate i.e. *Guggulu* solution in media, which is the soluble part of *Guggulu* was taken. Temperature was found around $62^0 – 70^0$ C inside the vessel during whole process. Temperature was recorded by mercuric thermometer. The total heating duration was found about 45min in each batch. *Guggulu* was found very sticky during handling so *Ghrita* smeared utensils and should be used to minimize the loss. Net yield found in each batch was 62.85%, 66% and 63.5% in first, second and third batch respectively. The colour of *Shuddha Guggulu* was found to be dark black. Reference for *Guggulu* purification was initially found in *Harit Samhita* (7) but detailed description was found in *Anandkanda* (8).

In the present study *Lakshadi Guggulu* was prepared as per *Vrindmadhav* and *Chakradatt*/A.F.I by two approaches i.e. one classical and another one modern pharmaceutical procedure. 3-3 samples of *Lakshadi Guggulu* were prepared by classical method as per *Vrindmadhav* and *Chakradatt*/A.F.I. 3 samples of drug were prepared by wet granulation method as per *Vrindmadhav* by adding 15% w/w of gum acacia as a binder.3 samples of drug was prepared by wet granulation method as per *Chakradatt/A*.F.I by adding 10% w/w of gum acacia as a binder. Albeit, *guggulu* is a good binder but since it being a herbal material, it's nature my vary as per the geographical origin, season and age etc. So, to have uniformity in the formulation, gum acacia was used as a binder.

For *Vati* preparation, purified *Guggulu* was mixed with other constituents of formulation after this it was pounded well with little amount of *ghrita*. This pounding gives the homogenous soft mass of *Lakshadi Guggulu*. After making sticks of *Lakshadi Guggulu* with the help of stick making machine, immediately they were subjected to pills cutting otherwise after drying of sticks, it was observed that cutting of pills was not found proper. During stick preparation rolling of handle of stick making machine should be slow, to bring out uniformity in the thickness of the sticks. After cutting of *Vatis*, they should be allowed for drying in dust free space. Little amount of *ghrit* applied over sticks and prepared *Vatis* to avoid sticking of them with each other. Drying of *Vatis* depends on climatic conditions, if temperature is high and moisture content is low in environment, they dry up soon in one or two days and otherwise it may take more time in reverse conditions. For proper drying, side of *Vati* should be turned time to time by gentle hand.

For tablet preparation, purified *Guggulu* was mixed with binder solution and other constituents of formulation after this it was pounded well with little amount of *ghrita*. This pounding gives the homogenous soft mass of *Lakshadi guggulu*. The softened mass was took out and dried properly in sunlight over bio friendly plastic sheet. After drying, granules were made; they were punched into tablets with the help of tablet punching machine.

The process employed for tabletting was wet granulation method.

Lakshadi Guggulu Tablet (*Vrindmadhav*) prepared was found light brown in colour and hard. Drug content present in formulation is approximately 425mg per unit dosage form, because of the presence of 15% binder (gum acacia) in formulation.

Lakshadi Guggulu Tablet prepared by modern method as per A.F.I - Percentage increase in weight of tablet sample is 18.9%. Whereas the net yield percentage is 95.88%. Drug content present in formulation is approximately 450mg per unit dosage form, because of the presence of 10% binder (gum acacia) in formulation. Increase in weight during pharmaceutical processing is because of solid matter present in purification media i.e. in *Triphala Kwatha* and to some extent due to moisture.

Conclusion

Guggulu has been used as *Dhoopana dravya* since *Vedic* period. Solid forms (*Vati*) of *Guggulu* were not preferred for internal administration in *Brihattrayee*. It was entered in the field of therapeutics after 9thAD (*Vrindmadhav*). Pharmaceutically *Parisravana* was considered better method for *Guggulu* purification over *Dola Yantra Vidhi*. The modified process for purification of *Guggulu* used in current study should be adopted for the general practice of purification of *Guggulu*. For better results 1:4 ratio of crude *Guggulu* and purification media (*Triphala Kwatha*) should be taken for the purification process of *Guggulu.* In the preparation of drug by classical pharmaceutical procedure 10-12% loss was observed while preparing drug by modern pharmaceutical procedure 4-8% loss was observed irrespective of references taken for the process. Pharmaceutically it is better to prepare tablet instead of preparing *Vati*, as the percentage of loss in *Vati* preparation was high which in turn elevates the cost of medicine.

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