

# Pharmaceutical and analytical evaluation of triphalaguggulka tablets

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## ABSTRACT

**Aim of the Study:** Development of standardized, synergistic, safe and effective traditional herbal formulations with robust scientific evidence can offer faster and more economical alternatives for the treatment of disease. The main objective was to develop a method of preparation of guggulka tablets so that the tablets meet the criteria of efficacy, stability, and safety. **Materials and Methods:** Triphalaguggulka tablet, described in sharangdharsanrita and containing guggul and triphala powder, was used as a model drug. Preliminary experiments on marketed triphalaguggulka tablets exhibited delayed *in vitro* disintegration that indicated probable delayed *in vivo* disintegration. The study involved preparation of triphalaguggulka tablets by Ayurvedic text methods and by wet granulation, dry granulation, and direct compression method. The tablets were evaluated for loss on drying, volatile oil content, % solubility, and steroidal content. The tablets were evaluated for performance tests like weight variation, disintegration, and hardness. **Results:** It was observed that triphalaguggulka tablets, prepared by direct compression method, complied with the hardness and disintegration tests, whereas tablets prepared by Ayurvedic text methods failed. **Conclusion:** Direct compression is the best method of preparing triphalaguggulka tablets.

**Key words:** Ayurveda, guggulka tablets, gutikas, quality control, triphala

## INTRODUCTION

Ayurvedic medicines are our rich cultural heritage. Traditional Ayurvedic textbooks list Ayurvedic medicines and dosage forms that are effective, stable, and safe. Ayurvedic medicines are gaining popularity among physicians and patients for better therapeutic value. Lack of quality standards and problems, in preparing or

testing them, are the main hurdles experienced by both practitioners and patients.

The Ayurvedic literature is full of praise for guggul describing its action as divine. Guggul means “gunjo vyadhe gurdati rakshati,” meaning to give relief from different diseases.<sup>[1]</sup> Ayurveda describes guggul as an antiseptic, antibacterial, astringent, antispasmodic, and as a carrier for other drugs.<sup>[2]</sup> Up to the present time, only the anti-inflammatory and hypolipemic actions of guggul have been confirmed.<sup>[3,4]</sup> Classical Ayurvedic texts never recommend administration of guggul as a single drug. It should be administered along with other herbs in combination such as triphala guggul, kaishore guggul, trayodashanga guggul, yograja guggul, or kanchanara guggul etc. The administration of guggul with other herbs has the effect of purging ama (toxic, morbid substance) from the body.<sup>[5]</sup>

Triphala powder is an Ayurvedic formulation consisting of powders of three fruits, amalaki (*Emblica officinalis*), haritaki (*Terminalia chebula*), and bibhitaki (*Terminalia bellerica*) in equal proportions. For improving shelf life, churnas (powders) are converted into gutikas (tablets).<sup>[6]</sup> Ayurveda suggests guggul as a binder in gutikas (tablets).

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Received: 09-July-2010

Revised: 14-Sept-2010

Accepted: 12-Oct-2010

### Access this article online

Quick Response Code:



Website:

[www.jaim.in](http://www.jaim.in)

Guggulkaipa means tablets that contain equal/more amount of guggul as compared to amount of other ingredients.<sup>[7,8]</sup> Ayurveda describes about 17 different guggulkaipa, namely triphalaguggulkaipa, punarnavaguggulkaipa, shatavariguggulkaipa,<sup>[9]</sup> all polyherbal formulations, prepared by sompakvidhi,<sup>[10]</sup> suryapakvidhi,<sup>[11]</sup> analpakvidhi.<sup>[12]</sup> Ayurvedic methods suggest that gutikas should be prepared manually.

Tablets can be manufactured by the methods of wet granulation, dry granulation, or direct compression.<sup>[13]</sup> Manufacturing of tablets should be followed by quality control tests such as the weight variation test or the disintegration test.<sup>[14]</sup> Factors affecting the disintegration of tablet dosage tablets<sup>[15]</sup> are physicochemical properties of drug (solubility, particle size, solid-phase characteristic, polymorphism), formulation factors (effect of excipients such as binder, disintegrant, diluents, and lubricant), the test apparatus (pH and surface tension of the medium, temperature of medium, and its viscosity), and the tablet-manufacturing process (method of granulation and compression). The advantages of direct compression include uniformity of blend, few manufacturing steps involved, (i.e., the overall process involves weighing of powders, blending and compression, hence less cost), elimination of heat and moisture, prime particle dissociation, and physical stability.<sup>[16]</sup>

There are very few attempts on systematic studies for the development and evaluation of Ayurvedic dosage forms. Pundarikakshudu developed tablet formulation of triphala using wet granulation and direct compression method.<sup>[17]</sup> Samanta prepared monoherbal and polyherbal neuroleptic tablets of various combinations using *Acorus calamus*, *Glycyrrhiza glabra*, and *Withania somnifera*.<sup>[18]</sup> Pundarikakshudu developed a tablet formulation of embelin employing the wet granulation and direct compression techniques and designed a suitable dissolution medium for embelin.<sup>[19]</sup> Soni validated different methods of preparation of vasaka juice by quantification of total alkaloids and vasicine.<sup>[20]</sup> Elamthuruthi has standardized marketed preparation of kumariasava by chromatographic and spectral studies.<sup>[21]</sup> John has standardized hingashtaka churna by using chemical methods.<sup>[22]</sup>

Triphalaguggulkaipa tablet, described in Sharandharsanhitā, was selected as a model drug.<sup>[23]</sup> Our preliminary experiments on marketed triphalaguggulkaipa tablets (manufactured as per the Ayurvedic text methods) exhibited delayed *in vitro* disintegration that might be associated with probable delayed *in vivo* disintegration. The main objective was to develop the method of preparation of triphalaguggulkaipa tablets so that the tablets meet the criteria of disintegration and hardness test. The present study involved preparation

of triphalaguggulkaipa tablets by different methods namely, sompakvidhi, suryapakvidhi, analpakvidhi, wet granulation, dry granulation, direct compression, and evaluation of the tablets. The study also aimed to evaluate the suitability of Ayurvedic methods (for preparation of tablets) and compare the performance characteristics of tablets prepared by Ayurvedic text methods with other methods.

## MATERIALS AND METHODS

Guggul. *Commiphora mukul* was obtained from the local market, Haritaki powder (*Terminalia chebula*), Amalki powder (*E. officinalis*), Bibhitaki powder (*Terminalia belerica*), Pippali powder (*Ficus benjamin*), were purchased, as “coarse powders” from a local market. They were dried in shade, packed in airtight containers, and stored at ambient temperature. All other reagents used were of analytical grade.

### Shodhana of guggul

Guggul was examined for foreign matter visually. Its size was reduced in a mortar and pestle to mesh size 44. Haritaki, amalaki, bibhitaki powders were also passed through sieve no 44 before being used in further study.

The amalaki, haritaki, and bibhitaki powders were weighed in equal amount and mixed. The powder mixture was treated as one part and 16 parts of distilled water were added to it. The mixture was boiled till the volume was reduced to one-eighth of its original volume. It was filtered through a muslin cloth. The filtrate, termed as triphala quath, was used for shodhana of guggul.<sup>[24,25]</sup>

Guggul was cut into small pieces and foreign organic matter was removed manually as far as possible. The guggul and warm triphala quath, in the ratio of 1:8, were mixed thoroughly and allowed to stand for 24 hours.<sup>[24,25]</sup> The mixture was filtered through a muslin cloth. The filtrate was collected and water was evaporated at a temperature not exceeding 60 °C, in an oven, to obtain shodhit guggul. The yield of shodhit guggul was 80%.

### Formulation of triphalaguggulkaipa gutikas

Triphalaguggulkaipa gutikas were prepared by different methods namely, sompakvidhi, suryapakvidhi, analpakvidhi, wet granulation, dry granulation, direct compression. Formulation of tablets is indicated in Table 1. Initially triphalaguggul powder admixture was prepared by mixing pippali powder, triphala powder, and guggul in 1:3:5 ratio.

In sompakvidhi, 25 ml of triphala quath was added to 90 g of triphalaguggul powder mixture. The mass was patted 1000 times before making gutikas. The mass was divided manually so that average weight of gutika was 500 mg and

**Table 1: Formulation of triphalaguggulka gutikas**

Ingredients (in g)	Sompakvidhi	Suryapakvidhi	Analpakvidhi	Wet granulation	Dry granulation	Direct compression
Guggul	50	50	50	50	50	50
Haritaki	10	10	10	10	10	10
Amalki	10	10	10	10	10	10
Bibhitaki	10	10	10	10	10	10
Pippali	10	10	10	10	10	10
Triphala-quath	25 ml	100 ml	—	—	—	—

**Table 2: Evaluation of triphalaguggulka tablets**

Weight variation test	Sompak vidhi	Suryapak vidhi	Analpak vidhi	Direct compression
No. of tablets showing deviation from average weight by more than $\pm 5\%$	15	17	13	1
No. of tablets showing average weight $\pm 5\%$	05	03	07	19

**Table 3: Evaluation of triphalaguggulka tablets**

Quality control test	Sompakvidhi	Suryapakvidhi	Analpakvidhi	Direct compression	Shodhit guggul
Disintegration test (min)	75	64	147	22	—
Hardness test (kg/cm <sup>2</sup> )	14.4	15.5	12.4	4.4	—
Loss on Drying (mg)	300.9	650.8	350.4	76	—
Volatile oil content (ml/100 g)	0.5	—	—	1	1
Solubility (%)	53.37	64.6	55.37	58.8	65.67
Total ash (%)	5.71	5.38	6.49	3.78	3.47
Absorbance at 525 nm	2.098	2.118	2.1	1.941	2.301

the gutikas were prepared by manual rolling. The gutikas weighed 86 g and 170 gutikas were prepared.

In suryapakvidhi, 90 g of triphalaguggul powder admixture was kneaded with 100 ml of triphala quath and the mass was dried in sun, in covered conditions, at a maximum temperature of 35 °C. Next day, 100 ml of triphala quath was mixed with the earlier mass. The procedure was repeated eight times before making gutikas. The mass was divided manually so that average weight of each gutika was 500 mg and the gutikas were prepared by manual rolling. The gutikas weighed 150 g and 285 *gutikas* were prepared.

In analpakvidhi, 200 ml of triphala quath was added to 50 g of guggul and the mixture was gently heated at a temperature of 80°C till a semisolid mass was formed. The heating was discontinued and the mass was mixed with triphala (30 g) and pippali powder (10 g). It was cooled. The mass was divided manually so that average weight of each gutika was 500 mg and the gutikas were prepared by manual rolling. The gutikas weighed 96 g and 180 gutikas were prepared.

In wet granulation method, 90 g of triphalaguggul powder admixture was prepared by mixing pippali, triphala, and guggul in 1:3:5 ratio. It was mixed with 20 ml of purified

water and the wet mass was sieved through sieve number 12 to obtain the granules.

In dry granulation method, 90 g of triphalaguggul powder admixture was prepared by mixing pippali, triphala and guggul in 1:3:5 ratio. The slugs were prepared, from the powder admixture, on a rotary tablet machine by using 12 kg/cm<sup>2</sup> pressure. The weight of the slug was adjusted to 2 g.

In direct compression method, 90 g of triphalaguggul powder admixture was prepared by mixing pippali, triphala, and guggul in 1:3:5 ratio. The powders were mixed and compressed into tablets, (average weight 500 mg) on a rotary tablet machine by using 5 kg/cm<sup>2</sup> pressure. The excipients like glidant, lubricant, anti-adherent were not used. The gutikas weighed 84 g and 168 gutikas were prepared.

### Evaluation of triphalaguggulka tablets

Triphalaguggulka tablets, prepared by various methods, were evaluated for weight variation test, disintegration test, hardness test, loss on drying, volatile oil content, % solubility, total ash<sup>[14]</sup> [Tables 2 and 3]. Hardness of tablets was tested by using Strong Cobb hardness tester. I.P. method for determination of steroidal content suggested addition of 2 ml of tetramethyl ammonium hydroxide

reagent to each, standard solution of beta-methasone and sample solution of triphalaguggulkaipa tablets and measurement of the absorbance of resultants at 525 nm.

## RESULT AND DISCUSSION

Ayurvedic texts suggest use of triphala quath, milk, and gomutra (cow's urine) for shodhana of guggul. In the present work, triphala quath was used for the shodhana of guggul since triphalaguggulkaipa tablets contain triphala powder.

Gutikas, prepared by sompakvidhi, were observed to be wet, in spite of drying, and lack hardness. Gutikas, prepared by suryapakvidhi, weighed more. This may be attributed to the presence of more triphala since triphala quath was used more times (eight) during their preparation. When gutikas were prepared by analpakvidhi, which involves heating; the guggul was partly burnt. It was observed that, in case of Ayurvedic methods, triphalaguggulkaipa tablets have to be rolled manually.

The wet granulation method resulted in the formation of a hard mass. So granules were not prepared and tablets could not be compressed. The dry granulation method was unable to form slugs or tablets. Triphalaguggul tablets were prepared by direct compression of triphalaguggul powder admixture. Hence the tablets prepared by using sompakvidhi, suryapakvidhi, analpakvidhi, and direct compression were used for further evaluation.

Manually prepared tablets exhibited more weight variation than tablets prepared by direct compression as indicated in Table 2. I.P. specifies disintegration time of guggul tablets as 60 minutes.<sup>[26]</sup> Triphalaguggulkaipa tablets, prepared by Ayurvedic methods, were found to exhibit more hardness and disintegration time, as compared to triphalaguggulkaipa tablets prepared by direct compression, as depicted in Table 3. It may be expected that tablets, prepared by Ayurvedic text methods, disintegrate in the body after prolonged time of administration and hence may show delayed onset of action. Disintegration time and hardness of directly compressed triphalaguggulkaipa tablets were found to be satisfactory. It may be attributed to adequate binding properties of guggul. Loss on drying values was found to be more for tablets prepared by Ayurvedic methods, whereas the corresponding values were less for directly compressed tablets since all the ingredients were dry and water was not used during direct compression.

Guggul contains volatile oil. Volatile oil content of tablets, prepared by sompakvidhi, analpakvidhi, suryapakvidhi, was found to be less, whereas it was more for tablets

prepared by direct compression, the reason being minimum exposure of tablets to atmospheric conditions and high temperature during direct compression. Total ash and % solubility values were less for tablets prepared by direct compression since triphala quath was added in optimum quantity compared to other methods.

For studying the effect of method of preparation on triphalaguggulkaipa tablets, the steroidal content of the tablets was determined by the I.P. method.<sup>[14]</sup> Steroidal content of directly compressed triphalaguggulkaipa tablets was found to be similar to that of guggul (raw material), indicating that the direct compression method has no adverse effects on the tablets/active constituents of guggul.

## CONCLUSION

The present study indicated that triphalaguggulkaipa tablets, prepared by Ayurvedic methods, exhibited more hardness and disintegration time. Triphalaguggulkaipa tablets, prepared by direct compression, exhibited optimum disintegration time, weight uniformity, and hardness. The tablets disintegrated quickly and complied with criteria for weight variation and hardness. It was concluded that direct compression was a suitable method for preparation of triphalaguggulkaipa tablets. Binding properties, flow, and compression properties of guggul should be studied so as to employ direct compression method for preparation of guggulkaipa tablets.

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Source of Support: Nil, Conflict of Interest: None declared.

**FORM IV**

Statement about ownership and other particulars about newspaper (*Journal of Ayurveda & Integrative Medicine*) to be published in the first issue every year after the last day of February

1. Place of publication : Mumbai
2. Periodicity of its publication : Quarterly (January, April, July and October)
3. Printer's Name : Medknow Publications and Media Pvt. Ltd.  
Nationality : Indian  
Address : B5-12, Kanara Business Center,  
Off Link Rd, Ghatkopar (E),  
Mumbai - 400075, India  
Phone: 91-22-6649 1818
4. Publisher's Name : Dr. D. K. Sahu  
Nationality : Indian  
Address : B5-12, Kanara Business Center,  
Off Link Rd, Ghatkopar (E),  
Mumbai - 400075, India  
Phone: 91-22-6649 1818
5. Editor's Name : Dr. Bhushan Patwardhan  
Nationality : Indian  
Address : Director, Institute of Ayurveda and Integrative Medicine,  
74/2, Jarakbande, Kaval, Post: Attur, Via Yelahanka,  
Bangalore - 560 106, India
6. Names and addresses of individuals who own the newspaper and partners or shareholders holding More than one per cent of the total capital. : Institute of Ayurveda and Integrative Medicine

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Date: 1<sup>st</sup> March 2010

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Dr. Bhushan Patwardhan