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Research Article

# ANALYTICAL PROFILE OF *KANCHANARA GUGGULU* TABLETS PREPARED AS PER REFERENCES IN *SHARANGADHARA SAMHITA* AND *BHAISHAJYA RATNAVALI*

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## ABSTRACT

Marketing of *Guggulu*, an exudate obtained from the plant *Commiphora mukul* and its preparations is a great concern of different ayurvedic pharmaceutical houses due to its adulteration, substitution and non-availability of genuine samples. Standardization of raw drugs and formulations with modern analytical tools increase their scope, acceptance and scientific validity. In the present study, an attempt was made for the physicochemical analysis of *Kanchanara guggulu* tablets (having *Guggulu* as the major ingredient) prepared as per references in *Sharangadhara Samhita* and *Bhaishajya Ratnavali* to develop an analytical profile of the formulation. The study was based on the standard analytical parameters proposed by API and PLIM. Six samples of tablets were prepared as per two references (three for each reference) which were available in market following the same manufacturing procedures. The study comprised of three stages- pharmacognosy of raw drugs, pharmaceutical work and analytical study. The analysis was done using the parameters like organoleptic evaluation, weight variation, hardness, friability, disintegration time, ash values, extractive values, loss on drying, pH, HPTLC and microbial contamination and an analytical profile was developed as per both references.

## INTRODUCTION

Ayurveda is one among the traditional Indian medicinal system that has been practiced since time immemorial. The four important pillars required for treatment in ayurveda are *Bhishak* (physician), *Dravya* (medicine), *Upashtatha* (attender) and *Rogi* (patient). So *Dravya* or medicine is a prime important part in the ayurvedic system of medicine.

Currently, there is an increasing demand for all forms & preparations of medicinal plants worldwide.[1] But the quality of the drugs available in market is depleting due to various reasons like deforestation leading to shortage of genuine herbal drugs, controversies of the drug, substitution and adulteration of drugs and also improper handling and preparatory procedures.

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Thus, for the global acceptance of ayurvedic medicines, proper validation is necessary in standardizing raw materials, preparatory procedures and final product and thereby increasing the quality, safety and efficacy of the drugs. Establishment of analytical profile with the help of modern analytical tools increases the scope and acceptance of ayurvedic formulations and increases scientific validity.

*Guggulu* is often found adulterated due to non-availability of genuine samples. *Kanchanara guggulu* is a formulation containing *Guggulu* as its major ingredient. It is explained in the 7th chapter of *Sharangadhara Samhita Madhyama khandam* i.e., *Gutika Kalpana*[2], *Yogaratnakara*[3], *Bhavaprakasha Gandamala Chikitsa*[4] and *Bhaishajya Ratnavali Galagandadi Roga Chikitsa Prakaranam* [5]. Monograph of *Kanchanara guggulu gulika* (pills) as per *Sharangadhara Samhita* reference is present in API [6] and AFI [7]. The ingredients of *Kanchanara guggulu* are *Kanchanara, Varuna, Triphala (Haritaki, Vibhitaki, Amalaki), Trikatu (Pippali, Marica, Sunti), Trijataka (Twak, Ela, Patra)* and *Guggulu* which is provided in table 1 and is widely used in the treatment of

*Galaganda* (goitre), *Granthi* (cyst), *Vrana* (ulcer), *Arbudha* (tumors) etc. The difference in the references of *Sharangadhara Samhita* and *Bhaishajya Ratnavali* is in the quantity of ingredients taken which is provided in table 2. The drugs *Marica, Nagara* etc also are often found adulterated other than *Guggulu*.

No previous studies based on the quality standards of the formulation have been published. So, there is a need for developing an analytical profile for the formulation in the form of tablets (as a greater number of pharmaceutical companies produce it as tablets) for ensuring the quality, efficacy and safety of the formulation.

## AIMS AND OBJECTIVES

1. To develop a standard analytical profile for *Kanchanara guggulu* tablets as per references in *Sharangadhara Samhita* and *Bhaishajya Ratnavali*
2. Physicochemical analysis of *Kanchanara guggulu* tablets

## MATERIALS AND METHODS

**The study involved three phases:** Pharmacognosy of raw drugs, pharmaceutical preparation of the formulation and analytical study of the prepared samples.

**Table 1: Ingredients of *Kanchanara guggulu* (Fig 1)**

| S.No | Drug | Botanical Name | Family | Part Used |
|---|---|---|---|---|
| 1 | *Kanchanara* | *Bauhinia variegata* | Leguminosae | Stem bark |
| 2 | *Haritaki* | *Terminalia chebula* | Combretaceae | Pericarp |
| 3 | *Vibhitaki* | *Terminalia bellerica* | Combretaceae | Pericarp |
| 4 | *Amalaki* | *Phyllanthus emblica* | Phyllanthaceae | Pericarp |
| 5 | *Pippali* | *Piper longum* | Piperaceae | Fruit |
| 6 | *Maricha* | *Piper nigrum* | Piperaceae | Fruit |
| 7 | *Nagara* | *Zingiber officinale* | Zingiberaceae | Rhizome |
| 8 | *Varuna* | *Crataeva nurvala* | Capparaceae | Stem bark |
| 9 | *Twak* | *Cinnamomum zeylanicum* | Lauraceae | Stem bark |
| 10 | *Sukshmaila* | *Elettaria cardamomum* | Zingiberaceae | Seed |
| 11 | *Tejapatra* | *Cinnamomum tamala* | Lauraceae | Leaf |
| 12 | *Shuddha Guggulu* | *Commiphora mukul* | Burseraceae | Oleo resin |


***a. Kanchanara twak, b. Haritaki, c. Vibhitaki, d. Amalaki, e. Maricha, f. Sunti, g. Pippali, h.Varuna twak, i. Sukshmaila, j. Tejapatra, k. Twak, l. Guggulu***

**Fig 1: Raw Drugs of *Kanchanara Guggulu* Tablets**

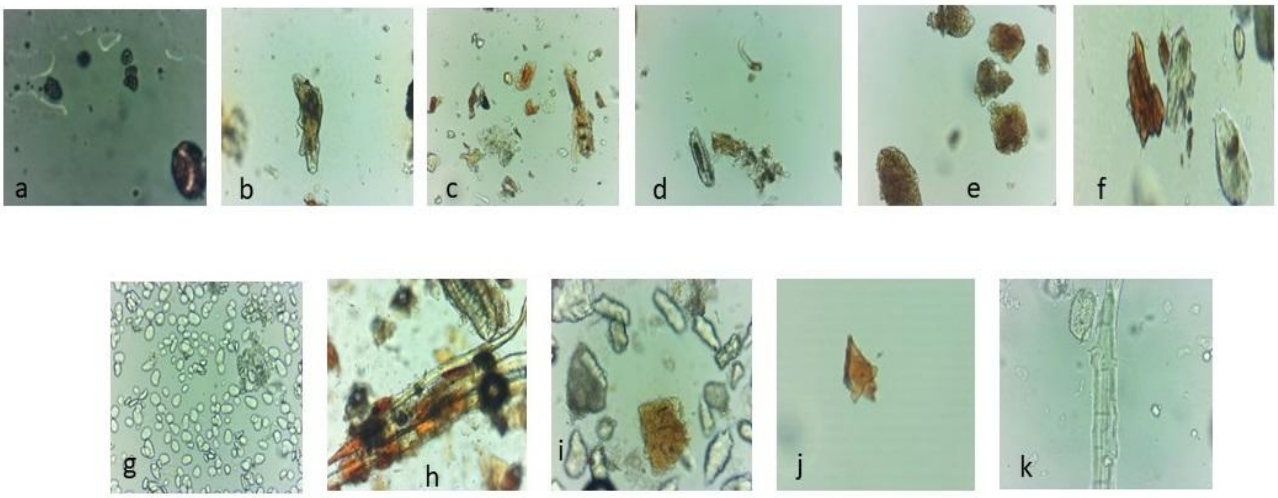
**Table 2: Quantities of ingredients of *Kanchanara guggulu* as per different references [2-7]**

| S.No | Ingredients | *Sh.Sam*, AFI, API, *Y.R* | *B.P, B.R* |
|---|---|---|---|
| 1 | *Kanchanara Twak* | 10 *pala* | 5 *pala* |
| 2 | *Triphala* | 6 *pala* | ½ *pala* each |
| 3 | *Trikatu* | 3 *pala* | 1 *pala* each |
| 4 | *Trijataka* | 3 *karsha* | 1 *saana* each |
| 5 | *Varuna* | 1 *pala* | 1 *karsha* |
| 6 | *Guggulu* | Equivalent to all | Equivalent to all |

*API: Ayurvedic Pharmacopoeia of India, AFI: Ayurvedic Formulary of India, B.P: Bhavaprakasha, B.R: Bhaishajya Ratnavali, Sh. Sam: Sharangadhara Samhita, Y.R: Yogaratnakara*

**Pharmacognosy of raw drugs (Fig 2)**

It was performed in Pharmacognosy Unit, Government Ayurveda College, Poojapura, Trivandrum. It includes organoleptic evaluation as well as powder microscopy of the raw drugs of the formulation.




**a. Cortex with coloured content of *Kanchanara,* b. Lignified tissue of *Haritaki,* c. Tracheids and short fibres of *Amalaki*, d. Sclereids of *Vibhitaki*, e. Oil globule cells of *Pippali*, f. Beaker shaped stone cells of *Maricha*, g. Starch grains of *Sunti,* h. Pitted sclereids of *Twak*, i. Rectangular cells with volatile oil of *Ela*, j. Volatile oil cell of *Patra,* k. Elongated fibres of *Varuna***

**Fig 2: Powder microscopy of raw drugs**

**Pharmaceutical Study**

It was carried out in the Department of *Rasasastra* and *Bhaishajya Kalpana*, Government Ayurveda College, Trivandrum, Kerala and Triveni Pharmaceutics, Kochuveli, Trivandrum, Kerala. It included:

Collection of raw drugs.

The ingredients were collected from local drug stores in Trivandrum, Kerala except *Kanchanara* and *Guggulu*. *Guggulu* was collected from drug dealers in Punjab and *Kanchanara* from Himachal Pradesh. All the ingredients were authenticated by subject experts.

**Processing of raw materials It included:**

- *Sodhana* (purification) of *Guggulu* which was done by *Dolayantra swedana* in *Triphala Kashaya* as per AFI.[8]
- Powdering of other raw materials to obtain fine powders of the drugs.

**Table 3: Quantities of ingredients taken for *Kanchanara guggulu* tablets**

| S.No | Drugs | *Sh.Sam* | *B.R* |
|---|---|---|---|
| 1 | *Kanchanara twak* | 80gm | 80gm |
| 2 | *Haritaki* | 16gm | 8gm |
| 3 | *Vibhitaki* | 16gm | 8gm |
| 4 | *Amalaki* | 16gm | 8gm |
| 5 | *Pippali* | 8gm | 16gm |
| 6 | *Maricha* | 8gm | 16gm |
| 7 | *Nagara* | 8gm | 16gm |
| 8 | *Varuna* | 8gm | 4gm |
| 9 | *Twak* | 2gm | 1gm |
| 10 | *Sukshmaila* | 2gm | 1gm |
| 11 | *Tejapatra* | 2gm | 1gm |
| 12 | *Shuddha Guggulu* | 166gm | 159gm |

**Preparation of *Kanchanara Guggulu* Tablets (Fig 3)**

The ingredients which were in fine powder stage was taken in the required quantity (table 3) as per the references and mixed together to form a homogeneous mixture. To this mixture, 1% w/w of Carboxy Methyl Cellulose sodium (disintegrating agent) was added. 5% w/w of gum acacia and 5% w/w of liquid glucose (binders) were mixed with water and made into a paste and it was then added to the above mixture. It was then dried in a dryer and later powdered to obtain uniform granules. This was done for granulating the mixture before compressing it into tablets. After powdering, 0.5% w/w aerosil (anti-caking agent) was added to it and mixed uniformly. It was then transferred to the tablet making machine and tablets of 1gm size were prepared by dry compression. Six batches of *Kanchanara guggulu* tablets were prepared (first 3 as per *Sharangadhara Samhita* and next 3 as per *Bhaishajya Ratnavali*) and named as PS1, PS2, PS3, PS4, PS5 and PS6. Number of tablets obtained is tabulated in table 4.


**a. Fine powders of individual drugs, b. Fine powders with excipients, c. Granulated mixture, d. Tablet making machine, e. Dry compression of tablets, f. Six sets of tablets prepared**

**Fig 3: *Kanchanara Guggulu* Tablet Preparation**

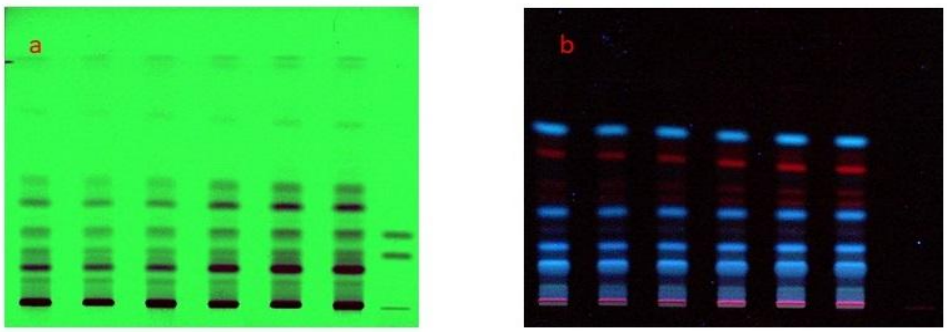
**Analytical Study**

Firstly, genuinity of the single herbal drugs were ensured at Drug Testing Lab, Department of *Rasasastra* and *Bhaishajya Kalpana*, Government Ayurveda College, Trivandrum by testing their identity, purity and strength as per API reference values which include foreign matter, ash values, extractive values and volatile oil content (Table 5).

Analysis of prepared samples was performed at Drug Standardisation Unit, Government Ayurveda College, Trivandrum and NGSM Institute of Pharmaceutical Sciences, Paneer, Mangalore. They were analysed for the standard parameters enlisted by PLIM for *Gulika* and *Guggulu kalpana* i.e., organoleptic evaluation of colour, odour and taste, hardness, friability, disintegration time, ash values, extractive values, pH, loss on drying and microbial contamination following API guidelines and guidelines of quality control of tablets [9,10]. The mean values obtained are tabulated in table 6.

**High Performance Thin Layer Chromatography (HPTLC) (Fig 4)**

HPTLC of the prepared samples was performed at CARe Kerala, Thrissur using Guggulsterone E&Z markers to quantify it in the prepared samples. Methanolic extract of the samples was used for HPTLC study. They were spotted on precoated silica gel 60F 254 aluminium plate (20×10cm) as 8mm bands by means of a Camag Linomat V sample applicator fitted with a 100µL Hamilton syringe. Mobile phase used was Petroleum ether: Ethyl acetate in the ratio 6:2[11]. The development time was 30 minutes. After development, detection was performed with Camag TLC scanner III at wavelengths of 254 and 366nm.




**a. At 254nm** **b. At 366nm**

**Fig 4: HPTLC Fingerprint of *Kanchanara Guggulu* Tablets with Guggulsterone markers**

**RESULTS**

**Pharmaceutical study results**

**Table 4: Number of tablets obtained**

| S.No | Name of prepared sample | No. of tablets obtained |
|---|---|---|
| 1 | PS1 | 285 |
| 2 | PS2 | 286 |
| 3 | PS3 | 289 |
| 4 | PS4 | 241 |
| 5 | PS5 | 243 |
| 6 | PS6 | 240 |

**Analytical study results**

**Table 5: IPS of individual drugs of the formulation**

| S.No | Drugs | Foreign matter % | Total ash % | AIA% | ASE% | WSE% | Volatile oil % |
|---|---|---|---|---|---|---|---|
| 1 | *Kanchanara* | 0.92 | 10.368 | 0.19 | 2.571 | 8.293 | - |
| 2 | *Hareetaki* | 0.531 | 3.26 | 1.35 | 50.149 | 64.607 | - |
| 3 | *Vibhitaki* | 0.594 | 5.131 | 0.92 | 12.32 | 36.45 | - |
| 4 | *Amalaki* | 1.392 | 5.431 | 1.102 | 42.186 | 53.667 | - |
| 5 | *Pippali* | 0.372 | 5.52 | 2.75 | 5.6 | 16.98 | - |
| 6 | *Maricha* | 0.973 | 4.857 | 0.476 | 8.037 | 6.09 | - |
| 7 | *Nagara* | Nil | 1.587 | 0.99 | 4.5 | 14.738 | - |
| 8 | *Varuna* | Nil | 9.547 | 0.885 | 4.621 | 8.33 | - |
| 9 | *Twak* | Nil | 2.79 | 1.694 | 6.415 | 3.417 | 1.67 |
| 10 | *Ela* | Nil | 5.346 | 3.762 | 4.643 | 12.152 | 4.57 |
| 11 | *Patra* | Nil | 2.725 | 0.561 | 8.614 | 11.324 | 1.35 |
| 12 | *Asodhita guggulu* | 2.536 | 2.328 | 0.325 | 27.372 | 55.442 | 1.12 |
| 13 | *Sodhitaguggulu* | Nil | 3.745 | 1.713 | 22.362 | 57.331 | - |

The IPS values of the individual drugs in the formulation were within the limits as per API.

**Table 6: Developed analytical profile of *Kanchanara guggulu* tablets**

| S.No | Analytical Parameters | ***Sh.Sam* Reference** | ***B.R* Reference** |
|---|---|---|---|
| 1 | Organoleptic evaluation | Colour: Light brown<br>Odour: Characteristic smell<br>Taste: Astringent, Sour | Colour: Light brown<br>Odour: Characteristic smell<br>Taste: Astringent, Sour |
| 2 | Weight variation | Within limits | Within limits |
| 3 | Hardness | 2.3300 ± 0.01700 kg/cm$^2$ | 2.2733 ± 0.3443 kg/cm$^2$ |
| 4 | Friability | 0.1763 ± 0.0142% | 0.1900 ± 0.0100% |
| 5 | Disintegration time | 16.3900 ± 0.3811 minutes | 16.5567 ± 0.5095 minutes |
| 6 | Total ash | 5.3403 ± 0.3620% | 5.3963 ± 0.3737% |
| 7 | Acid insoluble ash | 0.2690 ± 0.0425% | 0.2010 ± 0.0095% |
| 8 | Alcohol soluble extractive | 16.1840 ± 0.2150% | 15.3167 ± 0.3178% |
| 9 | Water soluble extractive | 25.9717 ± 1.4117% | 33.1813 ± 1.8326% |
| 10 | Loss on drying | 6.9980 ± 0.1674% | 6.0710 ± 0.0385% |
| 11 | pH | Acidic (3.88) | Acidic (4.05) |
| 12 | HPTLC $R_f$ values | 7 peaks with $R_f$ values 0.07, 0.13, 0.20, 0.29, 0.41, 0.50 and 0.80 | 8 peaks with $R_f$ values 0.06, 0.12, 0.19, 0.28, 0.33, 0.39, 0.47 and 0.76 |
| 13 | Quantification of Guggulsterone E&Z | GuggulsteroneE:92.83 ppm<br>GuggulsteroneZ: 164.5 ppm | GuggulsteroneE: 112.9ppm<br>GuggulsteroneZ: 215.8ppm |
| 14 | Microbial contamination | Not present | Not present |

**DISCUSSION**

The genuinity of the raw drugs, standardization of the procedure and standardization of the final product are essential for maintaining the proper potency of the formulation for its therapeutic efficacy. Although the monograph of *Kanchanara guggulu gulika* as per classical method is available in API, no standardisation studies were available about the tablets. So, it is necessary to generate quality standards profile among the manufacturers to produce the medicine within the limits.

Collection of the raw materials for the formulation was done with utmost care to avoid the

adulteration and controversial aspects. The genuinity of the raw drugs were confirmed using IPS standards in API and by its powder microscopy and genuinity of *Guggulu* was confirmed also using classical methods of *Prasasta guggulu lakshana*.

*Guggulu sodhana* was done as per AFI reference of *Dolayantra swedana* in *Triphala kashaya*. The major disadvantages of this method observed were the output loss and fuel consumption. More than 50% of *Guggulu* was lost after this purification method. For the preparation of the tablets, excipients like disintegrating agent, binders and anti-caking agents were also added along with the ingredients before compression of tablets. Excipients are inert substances which are added along with medicaments to prepare the granules from the solid medicaments. The percentage of active ingredients and excipients in the tablets was 90% and 10% respectively.

Physicochemical analysis was performed based on the parameters in PLIM for *Gulika* and *Guggulu kalpana*. Other than physicochemical analysis, HPTLC with guggulsterone markers and microbial contamination of samples were also done.

**Organoleptic Evaluation**

Organoleptic characters correspond to the physical nature and appearance of a formulation which depends on the raw drugs used and on the method of preparation. The colour, odour and taste of the samples were noted.

**Weight Variation**

Weight of each tablet in a batch should be uniform or within the limits as per the pharmacopoeia for the standardisation of the batch. Here the weight variation of the prepared samples was found to be nil.

**Hardness**

Hardness of the tablet determines the breaking point and structural integrity of the tablet and to find out how it changes under conditions of storage, transportation, packaging and handling before usage. Hardness of the tablet depends upon the binding nature of the raw drugs used or on quantity of binding agent added in it. Hardness can even affect the disintegration time of the tablet. Hardness was within the limits in the prepared samples.

**Friability**

Friability indicates the durability of tablets during transit. If the tablet is more friable than prescribed, it indicates that the binding in the tablet was not proper. Friability was found within the limits (less than 0.8%) in the prepared samples.

**Disintegration Time**

Disintegration time measures the ability of a tablet to breakdown into smaller particles or granules to allow the active drug to be absorbed into the body. It was around 17 minutes which is also within limits as per PLIM standards for *Guggulu* tablets i.e., not more than 60 minutes. Normally *Guggulu* take longer time to disintegrate but here the disintegration time was found less than mentioned may be due to the addition of disintegrating agents in the samples.

**Ash values**

Ash value indicates the quantity of inorganic substances presents in the sample and lesser the ash value, more is its purity. The ash values of the prepared samples were found within the limits as mentioned in API monograph of *Kanchanara guggulu* (not more than 9% for total ash and not more than 3.5% for acid insoluble ash).

**Extractive Values**

The extractive values determine the quantity of active constituents extracted with different solvents and more the extractive values, more is the purity and genuinity of the formulation. The alcohol soluble extractive values of the prepared samples were found less than the limits mentioned in API monograph of *Kanchanara guggulu* (not less than 22%). The water-soluble extractive values were within the limits in API (not less than 23%). The change in alcohol soluble extractive value might have occurred due to the difference in the preparatory procedure of the *Guggulu* tablet from the classical reference.

**Loss on Drying and pH**

Loss on drying indicates the moisture content of a formulation. More the moisture content, more the chance of easy spoilage and early microbial attack. LOD of the samples were found within the limits in API (not more than 12%). pH was found to be acidic in nature.

**Microbial contamination**

The samples were inspected for the presence of microbial contamination for a period of one month following its preparation and was found to be nil. The presence of microbes in a formulation may hamper the health of the individual consuming it, which can even turn fatal.

**HPTLC**

HPTLC was done in the solvent system Petroleum ether: Ethyl acetate (6:2) and both the samples had 7 peaks in common. An additional peak was observed in B.R reference. The difference in the number of peaks might have occurred due to the difference in the quantity of the raw drugs used in both the sets and anyone of the chemical constituent which may be present in trace amount did not get separate on the chromatogram. The markers used confirmed the presence of guggulsterone E&Z in the samples. The quantity of guggulsterone E&Z were found more in the second set of samples prepared as per *B.R* reference.

## CONCLUSION

*Kanchanara guggulu* is available as per references in *Sharangadhara Samhita* and *Bhaishajya Ratnavali* in the market. Greater number of pharmaceutical companies produces it in the form of tablets than in the pill form. It's clinically efficacy has been proved in many previous research studies but no analytical studies are available on the formulation affirming its quality. So, the results of the study can be used as a valuable tool for the quality assurance of this formulation for future references.

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