

INTERNATIONAL AYURVEDIC MEDICAL JOURNAL







PHARMACEUTICO-ANALYTICAL STUDY ON SANNIPATHANTAKAM GUTIKA

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https://doi.org/10.46607/iamj02p7022023

(Published Online: January 2023)

Open Access

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Article Received: 07/01/2023 - Peer Reviewed: 29/01/2023 - Accepted for Publication: 10/02/2023.



ABSTRACT

Sannipathantakam gutika (SG) is a herbo-mineral formulation that has its reference from sahasrayoga. The pharmaceutical study aimed to explore the practical methods according to classical ayurvedic references in the preparation of the drug SG from its herbo-mineral components. The analytical study of the pharmaceutically prepared drug was also conducted to obtain a preliminary report on physicochemical parameters, quantitative parameters, and heavy metal parameters as per the Ayurvedic pharmacopoeia of India. SG was prepared within 36 hours of the Bhavana with nimbu swarasa (Kharaliya Rasayana method). 1.9Kg SG was prepared from 2.420Kg of raw drugs. The values of analytical studies were as follows: Loss on drying- 4.53 %w/w, Total ash-5.91%w/w, Acid insoluble ash- 0.98%w/w, Water soluble ash- 4.31%w/w, Water soluble extractive-42.18%w/w, 0.5% HCl soluble extractive-46.31%w/w, pH-3, Average weight-121.25mg, weight variation- +/-15mg, Friability- 0.17%w/w, Hardness- 6.0Kg/cm2, Disintegration time- 85minute, Heavy metal test (ICP-MS) result showed that the quantity of mercury present is below the level of quantification. The preliminary data generated in the study can be utilized as a substratum for further laboratory studies using advanced instruments like HPTLC, XRD, GC-MS, etc., leading to more accurate standardization of the drug.

Key words: Herbomineral formulation, Mercury, Rasoushadhi, Sannipata, Rasashastra, Kharaliya Rasayana.

INTRODUCTION

Sannipathantakam Gutika (SG)⁽¹⁾ is a herbo-(Khalwi Rasayana) mineral formulation plained in the Gutika prakarana of Sahasrayoga. Gutika Kalpana is a convenient dosage form in the Ayurvedic repertoire of classical formulations. Its ease of storage, administration, comparatively longer shelf life, and palatability ensure patient compliance and thus make it a convenient dosage form for healthcare providers and patients alike. Now, it is time to establish Ayurveda as a pragmatic system of medicine in the current global health scenario among the scientific community. Hence, it is relevant to research the possibilities of Ayurvedic medicine in addressing communicable diseases. Here the intention is to understand the pharmaceutical and analytical parameters of this formulation. Sannipathantakam Gutika is a popularly practiced yoga in addressing the Sannipata condition. Sannipata is a condition where all three doshas are vitiated, and it is considered the final stage of the pathogenesis of the disease. In a clinical situation, Sannipata presents as an acute or emergency condition that needs aggressive or immediate intervention where a detailed Roga-rogi Pareeksha in terms of Dosha, Dushya, etc., becomes impractical there we can administer Ras aushadi as those are the practical solution in such a condition owing to their rapid action. Hence it is inevitable to explore and understand its various parameters. Further research in terms of modern scientific parameters is the necessity of the hour for the acceptance of these formulations among peers and

for the benefit of a wider population who need ayurvedic medical care. Furthermore, evidence-based medicine intends to integrate the current best available evidence from systematic research. Therefore, it is imperative to generate data and evidence in the Ayurvedic system of medicine to gamer acceptance in a wider scientific community across the globe. "Pharmaceutico-analytical study on Sannipathantakam Gutika" becomes an interesting subject of research on the above-mentioned backgrounds.

Aims and objectives: This study aimed to prepare Sannipathantakam Gutika as per the classical reference from Sahasrayoga, Gutika adhikara, and to conduct the analytical study of Prepared Sannipathantakam Gutika.

Materials and methods

A. Pharmaceutical Study

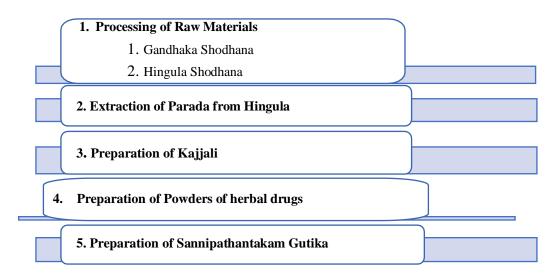
The pharmaceutical study involves various practical modalities of preparing efficacious medicines from raw drugs. The pharmaceutical procedures adopted in this study are *Shodhana*, *Bhavana*, *Churnikarana*, and *Gutika nirmana*. Raw materials were collected and authenticated at the Pharmacy of Rasa Shastra and Bhaishajya Kalpana Department, Pt. Khushilal Sharma Government (Autonomous) Ayurveda College and Institute, Bhopal. All the pharmaceutical processes were carried out in the Department of Rasa Shastra and Bhaishajya KalpanaLaboratory of the Institute. The ingredients used were listed below in table 1.

Table 1 Contents of Sannipathantakam Gutika

Sr.No.	Ingredients	Latin Name	Family/Group	Part used	Composition	
Metals/ minerals used						
1.	Shudha	Processed mercury	Maharasa/Group 12		1 part	
	Parada					
2.	Shudha	Processed Sulpher	Uparasa/ Group 16		1 part	
	Gandhaka					
Herbal drugs used						
3.	Haritaki	Terminalia	Combretaceae	Dried fruit	1 part	
		Chebula Retz.				
4.	Vibhitaki	Terminalia bellerica	Combretaceae	Dried fruit	1 part	
		(Gaertn.)Roxb.				

5.	Amalaki	Phyllanthus em-	Phyllanthaceae	Dried fruit	1 part	
		blica Linn.				
6.	Sunti	Zingiber officinaleRos-	Zingiberaceae	Dried	1 part	
		coe.		rhizome		
7.	Maricham	Piper niger Linn.	Piperaceae	Dried fruit	1 part	
8.	Pippali	Piper longum Linn.	Piperaceae	Dried fruit	1 part	
9.	Krishna	Nigella Sativa Linn.	Ranunculaceae	Dried fruit	1 part	
	Jeeraka					
Bhavana dravya of SG						
10.	Jambira Rasa	Citrus limon Linn.	Rutaceae	Juice	Q. S	

The preparation of Sannipathantakam Gutika involves the following steps:



Stage 1- Processing of Raw Materials

1. Gandhaka Shodhana (Processing of Sulphur)

The Gandhaka shodhana was carried out as per the reference of Rasa Ratna Samuchchaya⁽²⁾. The principle employed was "Dhalana". First, 500g Raw Gandhaka (Sulphur) was made into powder with mortar and pestle. Then 50g of ghee was taken in a stainless-steel steel vessel and melted on a gas stove. To the melted ghee, powdered Gandhaka was added and stirred until it melted. Next, 500-liter boiled milk was taken in another stainless-steel vessel, and its mouth was covered with a cotton cloth and ap-

propriately tied with the help of a thread. Molten *Gandhaka* was immediately poured into the milk through the cloth. The cloth covering was removed from the vessel, the milk part was discarded, and *Gandhaka* was obtained from the bottom of the vessel and thoroughly washed with hot water to remove *sneha*. The exact process was repeated thrice. Every time fresh milk was used. After completion of the procedure, *Gandhaka* was collected, washed thoroughly several times with hot water, and dried well. After complete drying, it was powdered finely, weighed, and stored properly.

Figure 1: Photographs of Gandhaka Shodhana







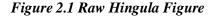
Figure 1.1 Raw Gandhaka Figure 1.2 Gandhaka in milk Figure

1.3 Shodhita gandhaka

2. Hingula Shodhana *Hingula shodhana* was done as a preparatory process for *Hingula satva Patana*. As per the reference of the *shodhana* procedure from *Rasa Paddhati* and *Ayurveda prakasha* (3), *Bhavana* of 500g of *Hingula* (Cinnabar) with 80 ml of *nimbu swarasa* was performed for one *Prahara* (4hrs).

Figure 2: Photographs of Hingula Shodhana







2.2 Powdered Hingula



Figure 2.3 Nimbu swarasa bhavita Hingula

Stage 2- Hingula satvapatana (Extraction of mercury from Hingula)

For the Extraction of *Parada* (mercury) from *Hingula* (cinnabar), *Kanduka Yantra* (*Nada yantra*) was used ⁽⁴⁾. The principle used was that of "*Urdhwa Patana*". 500gm of coarse powder of processed cinnabar was spread over a cotton cloth and folded to make a ball. The ball was wrapped with 500 gm of vertical-shaped cotton cloth strips of an equal weight of *Hingula* and placed over an earthen *Sharava*, that was placed over a

steel plate and ignited by coal. The *Nada yantra* was kept an inch above the steel plate to allow proper ventilation. A wet cloth was kept on the upper outer surface of the *nada yantra* for cooling, and throughout the process, cooling was kept intact. On termination of the heating process, the arrangement was left to cooldown on its own. The condensed mercury particles were collected by rubbing and washed with lukewarm water, filtered through four folded cloths, and kept properly in an airtight container.

Figure 3: Photographs of Hingula satvapatana



Figure 3.1 Shodhita Hingula granules spread on cotton clothes and rolled into a ball.





Figure 3.2 Nadayantra Figure 3.3 sublimated & Condensed mercury.



Figure 3.4 Cloth filtering of Mercury extracted via Hingula satvapatana.

Stage-3 Preparation of Kajjali (Black Sulphide of Mercury)

The principle for preparing *Kajjali* is "*Mardana samskara*" (Dry grinding). *Hingulottha parada* and *Suddha Gandhaka* were taken in equal quantity and triturated manually in *khalva yantra* ⁽⁵⁾. *Gradually*, the yellow colour of sulphur disappeared, and a grey powder was formed. Trituration continued till the powder became black and fulfilled all the criteria of *Kajjali*.

Figure 4: Photographs of Preparation of Kajjali



Figure 4.1 Ingredients of kajjali



Figure 4.2 Greyish mixture of Parada & Gandhaka



Figure 4.3 Final blackish kajjali

Stage 4- Preparation of powders of herbal drugs

All the raw herbal drugs were washed, dried, powdered, and sieved with sieve no. 60# (6).

Figure 5: Photographs of powders of herbal drugs



Figure 5.1 Pippali churna



Figure 5.2 Maricha churna



Figure 5.3 Shunti churna



Figure 5.4 Amalaki churna



Figure 5.5 Haritaki churna



Figure 5.6 Vibhitaki churna



Figure 5.7 Krishna jiraka churna

Preparation of Sannipathantakam Gutika

Sannipathantakam Gutika was prepared as per the reference of Sahasrayoga. Anagisadya method of Vati preparation was followed. Firstly, the Kajjali was triturated for an hour in a Khalwayantra. Then all the powders of herbal drugs were added and thoroughly mixed. That was followed by wet grinding with lemon juice for 4.5 hours a day for eight days.

Figure 6: Photographs of Preparation of Sannipathantakam Gutika



Figure 6.1 Ingredients of Sannipathantakam Gutika







Figure 6.2 Bhavana with nimbu swarsa

Figure 6.3 Sannipathantakam Gutika

Table 2: Ingredients of Sannipathantakam gutika in quantity

Ingredients	Qty
Kajjali	500g (250g each)
Triphala Powder	750g (250g each)
Trikatu Powder	750g (250g each)
Krishna jiraka Powder	250g
Total Qty	2250g

B. Analytical study

Analytical Parameters were taken according to "Protocol of Testing of Ayurvedic, Siddha, Unani Medicines" Published by the Government of India, Department of AYUSH Ministry of Health and Family Welfare and Table 2.1 Organoleptic test result of SG

Pharmacopeial Laboratory for Indian Medicines, Ghaziabad. The tests were conducted at S.R. Laboratory, Jaipur. The finished product has been subjected to analysis under the following parameters: Organoleptic Parameters, Physicochemical Parameters, Quantitative tests for tablets, and Tests for Heavy Metals.

Colour	Black
Odor	Acidic
Taste	Sour
Touch	Smooth
Appearance	Round pills

The values of analytical studies were as follows: Loss on drying- 4.53 % w/w, Total ash- 5.91% w/w, Acid insoluble ash- 0.98% w/w, Water soluble ash- 4.31% w/w, Water soluble extractive- 42.18% w/w, 0.5% HCl soluble extractive- 46.31% w/w, pH-3, Average weight- 121.25 mg, weight variation- +/- 15 mg, Friability- 0.17% w/w, Hardness- 6.0 Kg/cm2, Disintegration time- 85 minute, ICP-MS of Hg result showed that the quantity of mercury present is below the level of quantification.

DISCUSSION

Sannipathantakam Gutika (SG) is a herbo-mineral

preparation mentioned in Sahasrayoga. It consists of *Kajjali, Triphala, Trikatu, Krishnajiraka*. Dose mentioned in the *sahasrayoga* is 1 *gunja* (125mg). It is indicated in *Sannipata* condition and widely practiced by *Vaidyas* in febrile illnesses. SG was prepared by the *Kharaliya Rasayana* method. The main technique used for its preparation was *Bhavana*. *Nimbu swarasa* was used as *Bhavana dravya*. The pharmaceutical preparation of SG consisted of different stages. *Gandhaka shodhana* was carried out as per the reference of *Rasaratnasamucchaya*. The colour of the *Gandhaka* became light yellow after *Shodhana*. The crystal nature of *Gandhaka* was also lost, and it turned amorphous after the proce-

dure. A total of 11% loss from *Gandhaka* was observed after the procedure. The major cause of loss was a procedural loss; Some particles of *Gandhaka* remain adhered to cloth and vessel; While washing, tiny particles of *Gandhaka* float away with water. Weight loss might also be due to the removal of impurities. Lipid-soluble impurities were removed while melting on the ghee, water-soluble impurities were removed through milk, and some physical impurities were removed while filtering with the cloth. By *Shodhana*, the impurities in *Gandhaka* mentioned by *Rasajala Nidhi*, like *Shila churna* (Physical Impurities) and *Visha* (Toxic Chemical Impurities) were removed.

Three per cent weight gain was observed after Hingula shodhana, which may be due to the addition of organic constituents of the lemon juice to the Hingula. Raw Hingula was devoid of any odour, while after Bhavana, it had a sharp sour smell imparted by the lemon juice. *In addition, Hingula* became softer in texture after *Bhavana* because of continuous wet grinding. On completion of the Bhavana procedure, *Hingula* became fine.

When we try to explain Hingula satvapatana in

$$\begin{array}{ccc} \text{HgS+O2} & \text{HgO+SO2} \\ \text{2HgO+Heat} & \text{2Hg+O2} \end{array}$$

Several acharyas of rasa sastra state that the Hingulottha parada is devoid of Kanchuka dosha and can be used to prepare Kalpa (Formulations) without undergoing Shodhana or Samskaras. Hence for this study, Hingulottha parada was used. The elemental form of mercury cannot be used for internal administration. So, Murchana of Parada was done with Gandhaka. Kajjali is the 'sagandha niragni murchana' of parada, which can be safely administrated for the treatment internally. Samaguna kajjali is said to have samanya roganashaka property as per Rasa tarangini. 8.3 % loss was observed in Kajjali preparation, which may be due to spilling out during mardana, adherence of some amount to khalva yantra, and also while doing the confirmatory test. The obtained Kajjali was smooth, fine, black, and lustreless. We can infer that the whole terms of modern chemistry as Cinnabar disintegrated and decomposed on burning in the presence of atmospheric oxygen, the sulphur dioxide fumes were observed during the procedure simultaneously when mercury vapors were liberated. On the condensation of mercury vapors, elemental mercury was obtained. This procedure yielded 77.6 % mercury, which was quite a good amount confirming the efficiency of the ancient procedure of *Hingula satvapatana*.

The inner side of the nada yantra (pot) where mercury got collected was painted with lime paste aimed to cover the pores, and this act might have checked the loss of mercury by entering the minute pores.

Due to *Bhavana*, the particle size of the *Hingula* is reduced, thus exposing more surface area to the weak acid in the lemon juice. In addition, mild heat generated during the *Bhavana* and weak acid might have started some chemical changes in the *Hingula*. This chemical reaction also might have helped the easy decomposition of Cinnabar during burning, thereby liberating a significant amount of mercury. The chemical reaction that happened during the procedure:

mercury got bound with sulphur forming mercuric sulphide. It took 36 hours to get the Siddhilakshana of Kajjali. Peculiar colour and odour were observed in powders of different herbal drugs during the preparation of powders. A total of 36 hours (12 Yama) of Bhavana with lemon juice was taken to prepare SG, as mentioned by the sujanapriya commentary of sahasrayoga. Around 15 liters of lemon juice were used for the preparation of SG. On completion of Bhavana, the mass was very fine & smooth in consistency. After Bhavana, it was completely dried in the shade and stored. A 7.5% gain was observed on complete drying. Gutika's were prepared batch-wise by giving one *Bhavana* with lemon juice for an hour before rolling into pills of size around Gunja pramana (125 mg). The total duration of the pharmaceutical study was 22 days. Testing of various physicochemical parameters, quantitative parameters, and heavy metal tests is important to identify improper handling of the drugs and throws light on quality control measures taken during the procedure. The black colour of the final product might be imparted by Kajjali. The peculiar acidic odour and sour taste might be obtained from Bhavana dravya. Moreover, the smooth texture of the round pills might be acquired from continuous Bhavana. Low loss on drying value indicates minimal moisture content in the final product. Thus, we can infer that there is less chance of microbial growth and the product has more stability in the absence of moisture. In addition, low moisture content checks the degradation of the phytoconstituents present in the drug. This value also shows the efficient drying of the drug. The Ash values give an idea of the quality & purity of the drug and an idea of raw drugs and inprocess quality control maintained. A low total ash value indicates that the amounts of inorganic salts are less and may be of natural inorganic salts such as oxalate, citrate, etc., present in the raw drugs. Low Acid insoluble ash indicates less siliceous impurities. Furthermore, Water soluble ash indicates the presence of inorganic contents. The highest extractive value was found in 0.5% HCl, followed by alcohol and water. These values indicate the presence of lesser nonpolar compounds than polar ones. High water-soluble extractive value illustrates the presence of inorganic compounds, sugars, and acids. On the other hand, high alcohol soluble extractive value suggests the presence of polar constituents such as glycosides, steroids, and flavonoids (7). The value of the pH of SG indicates its highly acidic nature. It might be because of the presence of Kajjali and citric acid in the lemon juice (weak organic acid). The acidic pH of the stomachhelps in the faster absorption of weak acids (8). SG is composed of weak citric acid, and thus it will be absorbed at a faster rate. Moreover, it shows the *Thikshnata* and thereby, indirectly, the potency of the drug SG. The average weight was found to be 121.25mg, and a weight variation of +/- 15 mg was observed, which might be occurred due to manual preparation of the Gutika.

The Friability test value shows that the *gutika* possesses good physical strength. The hardness is presumably due to the low moisture content and efficient binding capacity of Kajjali. As a result, SG can withstand the mechanical shocks of handling. Moreover, 36 hours of Bhavana might be reduced the particle size, and the cohesion force between Kajjali and other herbal drugs might be increased by nimbu swarasa Bhavana. SG took 85 minutes to disintegrate in the water completely. Therefore, we can infer that this drug can act as a sustained-release tablet. Moreover, absorption of this drug can happen at different levels of the digestive tract due to its property. The test for heavy metals result shows that the quantity of mercury present in the SG is below the level of quantification.

CONCLUSION

SG gutika mentioned in the text Sahasrayoga is a widely prescribed drug by practitioners in infectious fevers though no published studies or research papers are available. This study provides preliminary data on the pharmaceutical and analytical characteristics of the drugs. The pharmaceutical study involved different stages: Gandhaka shodhana, Hingula shodhana, Hingula satvapatana, preparation of powders of herbal drugs, Kajjali preparation, and finally, SG preparation. Hingulottha parada was used in the preparation of SG. 77.6% parada was obtained by Hingula satvapatana. SG was prepared within 36 hours before the Bhavana with nimbu swarasa, and 7.5% weight gain was observed after Bhavana. The analytical study of the pharmaceutically prepared drug was also conducted to obtain a preliminary report on various physicochemical parameters. This study on the drug SG was the very first of its kind that employed various modern techniques to have a deeper understanding of the pharmaceutical and analytical characteristics of the drug. However, further animal experiments and clinical trials are inevitable to establishits safety and efficacy in terms of modern parameters and to generate more authentic data on the drug. The inference from this study may be used as a reference standard in further quality control and clinical research.

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Source of Support: Nil

Conflict of Interest: None Declared

How to cite this URL:Gayathri Devi U K et al: Pharmaceutico-Analytical Study on Sannipathantakam Gutika. International Ayurvedic Medical Journal {online} 2023 {cited January 2023} Available from: http://www.iamj.in/posts/images/upload/114_123.pdf