

## Pharmaceutical Standardization

Standard manufacturing procedure of *Shadguna Balijarita Makaradhwaja*Sanjay B. Khedekar, Pradeep Kumar Prajapati<sup>1</sup>

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## Abstract

**Background:** *Makaradhwaja* is one of the most potent herbomineral medicines of Ayurveda. Different references for the preparation of *Makaradhwaja* were reported in classics. According to the proportion of sulfur (*Gandhaka*), three references were mentioned in classics that is, *Dwiguna* (2:1 = S: Hg), *Triguna* (3:1 = S: Hg) and *Shadguna* (6:1 = S: Hg). *Makaradhwaja* is prepared by *Kupipakwa* system of heating. In the preparation of *Kupipakwa* medicine as the ratio of sulfur to mercury increases it becomes difficult to prepare medicine. **Aim:** To standardize manufacturing procedure of *Shadguna Balijarita Makaradhwaja* (SBM). **Materials and Methods:** Total four batches of SBM were prepared by using electrical muffle furnace (EMF). All the involved procedures were followed as per classical guidelines. **Results:** Average 13.68% yield of SBM was observed. **Conclusion:** SBM requires intermittent heating pattern, that is, mild heat (100-125°C) for 2.5 hrs, moderate heat (250-450°C) for 4.5 hrs and strong heat (450-600°C) for 5 hrs for 290.5 g *Kajjali*.

**Key words:** *Kupipakwa Rasayana*, mercury sulfide, *Shadguna Balijarita Makaradhwaja*

## Introduction

Global approach towards Ayurvedic herbomineral drugs is increasing day by day. Due to their therapeutic efficacy, safety and rational pharmacological results, their demand is increasing. Since centuries, *Makaradhwaja* is exercised as herbomineral medicine in Indian region. Its position among all the medicines is like king-size. Now a days heavy metal toxicity is considered at the highest level, but the sublimed compounds of mercury generally utilized in Ayurvedic therapeutics like *Makaradhwaja* are safer than others. It has been verified by many researchers through toxicity studies.<sup>[1-5]</sup> Though the formulation is clinically effective, its preparation is difficult.

Many references for preparation of *Makaradhwaja* are mentioned in texts of *Rasa-Shastra*. *Makaradhwaja* may be divided into three subtypes according to the proportion of sulfur. Sulfur (*Gandhaka*) and mercury (*Parada*) were found in the ratio 2:1 in *Dwiguna Balijarita Makaradhwaja* (DBM),<sup>[6]</sup> 3:1 in *Triguna Balijarita Makaradhwaja* (TBM)<sup>[7]</sup> and 6:1 in *Shadguna Balijarita Makaradhwaja* (SBM)<sup>[6]</sup> [Table 1]. Though SBM is more potent, its preparation is difficult. Many times failure

during preparation of *Kupipakwa* medicines was monitored at the equal proportion of sulfur and mercury (*Samaguna Balijarita*). The chances of failure often increases with the increase in proportion of sulfur. In the present study an attempt has made to standardize the method of preparation of *Shadguna Balijarita Makaradhwaja*.

## Materials and Methods

Hallmark certified 24 carat pure gold (*Swarna*) was collected from local jeweler. Cinnabar (*Hingula*), sulfur (*Gandhaka*), cow ghee (*Goghrita*), sesame oil (*Til Taila*) and *Dolichos biflorus* Linn. (*Kulattha*) were procured from the Pharmacy, Gujarat Ayurved University, Jamnagar. *Citrus medica* Linn. (*Nimbu*) and cow milk (*Godugdha*) was procured from local market. Cow urine (*Gomutra*) was collected from local cow shed. *Aloe barbadensis* Miller. (*Kumari*) and flowers of *Hibiscus rosa sinensis* Linn. (*Japa*) were collected from local herbal garden. All the herbal material were identified and authenticated in the Pharmacognosy Laboratory.

Preparation of *Shadguna Balijarita Makaradhwaja*

General purification (*Samanya Shodhana*) of gold was done by following classical guidelines.<sup>[8]</sup> Gold flakes were prepared and heated on gas blower followed by quenching in prescribed liquids for three times After purification (*Shodhana*) gold was converted into foils (*Swarna Varkha*) [Figure 1]. Sulfur

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was melted along with cow ghee and poured into cow milk [Figure 2], heated (*Swedana*) in the same medium for 24 min. At the end of the process, sulfur was collected, washed with hot water for 7 times, dried and stored in a glass bottle for further use.<sup>[9]</sup> Purification of cinnabar was done by levigating in the presence of *C. medica* juice for 3 times. It was dried and stored in a glass jar.<sup>[10]</sup> Mercury (*Parada*) was extracted from the cinnabar by *Nada Yantra* method [Figure 3].<sup>[11]</sup> Amalgamation of 20 g gold foils and 160 g mercury was done in a granite mortar [Figures 4 and 5]. This amalgam was added with 960g purified sulfur to prepare black sulfide of mercury (*Kajjali*) by triturating for 24 hrs. This *Kajjali* was levigated with fresh juice of *H. rosa sinensis* flowers and *A. barbadensis* for 3 hrs each.<sup>[6]</sup> The final contents were dried and stored in a glass jar.

**Table 1: Ingredients of Shadguna Balijarita Makardhwaja**

Ingredients	Part	Quantity (in g)
Shuddha Swarna Varkha	1	20
Hingulotha Parada	8	160
Shuddha Gandhaka	48	960
Japakusuma Swarasa	QS	--
Kumari Swarasa	QS	--

A glass bottle (of 750 ml capacity) was wrapped with mud smeared cotton cloth. Total seven consecutive layers were wrapped after complete drying of earlier layer. *Kajjali* was filled in this glass bottle, placed in electrical muffle furnace [Figure 6] and heat was given in gradual increasing manner. Heat was gradually increased as per schedule that is mild heat (*Mriduagni*) at 100–250°C for 2.5 h, moderate heat (*Madhyamagni*) at 250–450°C for 4.5 h and strong heat (*Tivragni*) at 450–600°C for 5 h [Graph 1]. During the course of heating, red hot iron rod (*Agni Tapta Shalaka*) was repeatedly inserted into the neck of glass bottle to remove settled sulfur. After achieving the confirmative tests, the mouth of glass bottle was sealed with cork (iron nut wrapped with cotton cloth and smeared with mud). Temperature was increased up to 600°C and maintained for next 2 h. After this, furnace was switched off and left for self-cooling. Next day morning, glass bottle was taken out from the furnace. The bottle was scraped to remove the burnt layers of cotton cloth followed by cleaning. Thread soaked in kerosene was tied on the bottle and thread was ignited. Thread was removed after complete burning and few drops of water was sprinkled over it, due to which, bottle was broken in two parts. *Makaradhwaja* was collected from the neck [Figure 7], and gold ash from the bottom of the bottle. *Makaradhwaja* was triturated in china clay mortar and pestle up to fine red



**Figure 1: Purified gold flakes**



**Figure 2: Steps involved in purification of sulfur**



**Figure 3: Steps involved in extraction of mercury from cinnabar**



**Figure 4: Preparation of amalgam**



colored powder [Figure 8]. Same procedure was adopted for the rest of three samples. Total four batches were prepared to determine the standard manufacturing procedure (SMP) for SBM [Table 2].

## Observations and Results

Without a need of trituration, gold foils were easily assimilated in mercury during amalgamation. *Rekhapurnatva* and *Nischandravta* were appeared in the *Kajjali* after 16 h of trituration. Average 2.46% *Kajjali* was lost during the process and total 1112 g of *Kajjali* was prepared. This *Kajjali* was levigated with *Japakusuma Swarasa* and *Kumari Swarasa* for 1 time each. An average  $1/4^{\text{th}}$  of *Bhavana Dravya* is found to be required for *Bhavana*. Average 3 hrs time is required for a single levigation process. 1162 g of dried *Kajjali* was collected after both levigation with a gain of 4.49% weight was gained by product after completion of *Bhavana* process. Levigated *Kajjali* was divided into four batches in an equal amount that is, 290.5 g in each batch [Table 2].

During 1<sup>st</sup> h heating, *Kajjali* started to melt. This was confirmed by cold iron rod (*Shita Shalaka*) test. Aroma of sulfur was noticed during this phase. When temperature was

increased to 404–409°C, *Kajjali* was melted completely. To avoid blocking of the neck with sulfur deposition, regular cleaning of the neck of the glass bottle was carried out by red-hot iron rod. After 7:15 hrs of heating; at temperature in between 450°C to 470°C flame appeared of 4–5 inches height. After 8:50 hrs of heating, the flame was gradually decreased. When temperature reached to around 545–550°C flame disappeared after heating for 9:00 hrs. On observation, the bottom of the glass bottle appeared to be red hot indicating the compound formation. Besides, copper coin test was also found to be positive. Corking of the bottle neck was done soon after the positive cold iron rod test. After corking, for proper sublimation of product temperature was raised to 600°C for 2:00 hrs and then allowed for self-cooling [Table 3].

## Discussion

The proportion of gold, mercury, sulfur in the preparation of the product is 1:8:48. It took around 24 hrs in the preparation of proper *Kajjali*. *Rekhapurnatva*<sup>[12]</sup> of *Kajjali* is important that signifies the particle size and homogeneousness of *Kajjali*. Ideally, free mercury shouldn't be available in prepared *Kajjali*.



Figure 5: Amalgam of the ingredients

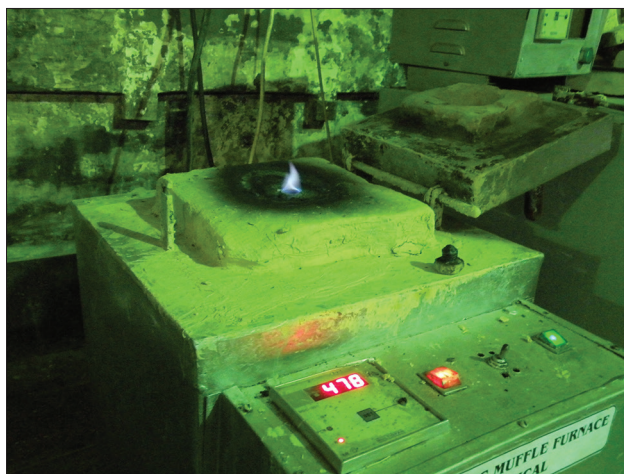


Figure 6: Placement of glass bottle in E.M.F. and heating in graded pattern



Figure 7: Sublimed product collected from the neck of glass bottle



Figure 8: Powdered finished product (*Shadguna Balijarita Makaradhwaja*)

**Table 2: Results of SBM**

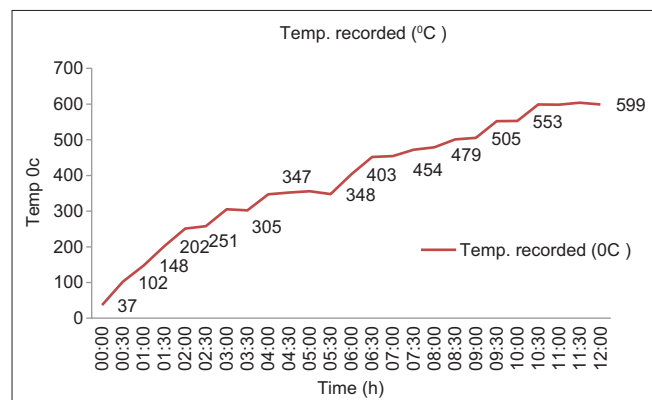
Batch	Heat duration (h)	Weight of <i>Kajjali</i> (g)	<i>Makaradhwaja</i> (g)	Flame duration (h)	Percentage of <i>Makaradhwaja</i> obtained	Residue as a gold powder (g)
SBM 1	12	290.50	42	2:05	14.46	7
SBM 2	12	290.50	37	1:55	12.74	9
SBM 3	12	290.50	39	2:10	13.43	10
SBM 4	12	290.50	41	2:02	14.11	6
Total	-	1162	159	-	87.36	32
Average	12	290.50	39.75	2:03	13.68	8

SBM: Shadguna Balijarita Makaradhwaja

**Table 3: Observations during heating of SBM (mean of four batches)**

Time (h)	Temperature setting (°C)	Temperature recorded (°C)	Observations
00:00	100	37	Switch on the furnace
00:30	150	102	Mild white fumes and sulfur aroma from the neck of the bottle
01:00	200	148	Mild yellowish fumes
02:00	250	251	Melting of <i>Kajjali</i> started and yellowish fumes continued
03:00	300	305	Yellowish depositions at neck
03:30	350	302	<i>Kajjali</i> -semi liquid form, yellowish fumes increased
04:00	350	347	<i>Kajjali</i> -molten and yellowish fumes increased
06:00	450	403	Yellowish fumes increased, stickiness was observed inside the glass bottle
06:30	450	452	Profuse dark yellowish fumes started
07:00	475	454	Fumes disappeared and reddish blue colored flame started
07:30	475	472	Flame increases gradually
08:00	500	479	Flame increases to about 4-5 inches height
08:30	500	501	Flame gradually decreased and sulfur deposits found at the neck of the glass bottle. Red glass bottom was observed
09:00	550	505	Mild bluish flames persisting at the neck of the bottle and red tinge at the bottom gradually increased
09:30	550	552	Flame disappeared, bottom of the glass bottle was found bright red, cold iron rod test and copper coin test were positive. Corking was done
10:00	600	553	Self-cooling
10:30	600	599	
11:00	600	598	
11:30	600	604	
12:00	Stop	599	

SBM: Shadguna Balijarita Makaradhwaja

**Graph 1: Temperature pattern for Shadguna Balijarita Makaradhwaja**

Total 4.49% weight gain was observed after completion of *Bhavana* process, that may be due to solid content of liquid media.

The purpose of providing layers of smeared cotton cloth is mainly to enhance heat resistance capacity to the glass bottle. To prevent spilling of *Kajjali*, it is to be filled up to 1/3<sup>rd</sup> part of glass bottle. It provides enough space for melting and boiling of *Kajjali* inside the glass bottle. During pilot study, spilling of *Kajjali* through the bottle during the moderate phase of heating was observed, if the quantity of *Kajjali* was more than 300 g. Looking into this, it is advisable to keep the quantity of *Kajjali* <300 g in a glass bottle of 750 ml capacity.

Electrical muffle furnace was used as a heating device. Researcher<sup>[13]</sup> cited that electrical muffle furnace is more

convenient than classical *Valuka Yantra* for the *Kupipakwa* preparation.<sup>[14]</sup> Initially mild white coloured sulfur fumes appeared through the neck of the bottle, while the density was increased with raised temperature. At 425°C, color of fumes were changed to reddish yellow. At 450°C, blue colored flame appeared through the neck of the bottle.

Four confirmative tests for *Kupipakwa Rasayana* were mentioned in *Rasashastra* texts that is, copper coin test, cold iron rod test, red bottom of glass bottle test and honeycomb structure test inside the bottle. Grayish white deposition over copper coin when placed over the neck of the bottle indicates sublimation of free mercury, while black deposition indicates free sulfur in the bottle. Grayish white deposition indicates time for sealing the mouth of the bottle, that prevent further loss of product. Red hot bottom of glass bottle is indicative of final stages of the procedure.

Breaking of glass bottle after corking may result due to free sulfur remains inside it. Average 39.75 g (13.68%) yield of *Makaradhwaja* was obtained from all SBM batches [Table 2]. Totally 12 hrs heat was given respectively to each batch until switching off of the heating device. The weight of *Bhavita Kajjali* for SBM was taken 290.5 in each batch. By considering the loss of *Kajjali* during its preparation and deduction of weight of gold, each batch of SBM contains only average 273 g of black sulfide of mercury or *Kajjali*. However, observed average quantity of the final product was 39.75 g for SBM, respectively. It designates average weight loss of 5.57 g that is, 12.64%.

## Conclusion

*Shadguna Balijarita Makaradhwaja* requires intermittent heating pattern, that is, mild heat (100–250°C) for 2.5 hrs, moderate heat (250–450°C) for 4.5 hrs and strong heat (450–600°C) for 5 hrs. It is concluded that increase in number of *Balijarana* increases the concentration of gold in sublimed *Makaradhwaja* which directly beneficial in therapeutic efficacy. Following this pattern, about 39.75 g (13.68%) yield can be obtained from 290.5 g of *Kajjali*.

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## हिन्दी सारांश

### षडगुण बलिजारित मकरध्वज के निर्माण का मानकीकरण

संजय बी. खेडेकर, प्रदिपकुमार प्रजापति

मकरध्वज आयुर्वेद कि एक प्रसिद्ध औषधि है। ग्रंथों में मकरध्वज निर्माण कि विभिन्न पद्धतियाँ वर्णित है। गंधक के पारद के साथ अनुपात के अनुसार तीन संदर्भ वर्णित है; द्विगुण बलिजारित मकरध्वज, त्रिगुण बलिजारित मकरध्वज और षडगुण बलिजारित मकरध्वज, कूपीपाक प्रक्रिया से मकरध्वज निर्माण में जटिलता संभावित है। अतः इस विषय अनुसार षडगुण बलिजारित मकरध्वज के निर्माण का मानकीकरण का यत्न किया है। षडगुण बलिजारित मकरध्वज का कुल चार बॅचेस में निर्माण किया। औसतम १३.६८% मकरध्वज प्राप्त हुआ। २९०.५ ग्राम कज्जली से षडगुण बलिजारित मकरध्वज निर्माण में क्रमाग्न आवश्यक है जिसमें मृदु अग्नि (१०० – १२०°से) २.५ घंटे, मध्यम अग्नि (२५० – ४५०°से) ४.५ घंटे और तीव्र अग्नि (४५० – ६००°से) ५ घंटे।