

STANDARD MANUFACTURING PROCEDURE OF NAGA BHASMA BY USING ARKA DUGDHA (LATEX OF *Calotropis procera*)

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Abstract

Standard manufacturing procedure (SMP) is the first and basic step towards standardization of any drug. In classics many methods are described to prepare a bhasma. So there is need to develop SMP of some commonly used method of bhasma preparation. Present work is based on development of SMP of Naga bhasma by using Arka dugdha as bhavana media. Naga bhasma was prepared in three batches. 300 g of Naga was used in each batch adopting the reference of Rasaratna samuchchaya 5/184. Freshly collected Arka dugdha was taken as media for levigation. Equal quantity of Manshila was added in 1st Puta followed by 1/20th part subsequently up to 10th Puta. Puta was given in Electric muffle furnace (EMF) at the temperature of 550^oC. The detail observations like change in weight, consistency, color, characteristic features of bhasma Pariksha and organoleptic characters after each Puta were noted till complete preparation of bhasma. Grey colored Naga bhasma was obtained after 10 Puta in EMF. Average 13.3 % weight gain was observed. Average 140.5 ml Arka dugdha was required for levigation in each Puta and from 2nd to 10th Puta.

Key words: Standard Manufacturing Procedure; Naga bhasma; Arka dugdha; *Calotropis procera*

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INTRODUCTION

The Ayurvedic drugs may be categorized in three groups viz. herbal, animal and metals / minerals.^[1] The metal / mineral category includes mercury, gold, copper, silver, tin, lead, iron, gems and precious stones etc. Metals are well known and used for therapeutic purpose since from ancient time i.e. since the time of Charaka Samhita.^[2] The pharmaceutical processing techniques and their internal use remained same for the long time without much changes and progress. From 8th to 9th century A.D. the beginning of Rasashastra had taken place in the field of Ayurveda. Many new pharmaceutical processing techniques along with many equipment and drugs were evolved and developed which have revolutionized Ayurvedic pharmaceutical technology to such an extent that metals could be converted to such a form which is considered to most suitable for its internal use. The converted form of metals is less toxic, highly absorbable and therapeutically very effective. Jarita Naga is considered as lead oxide (PbO), while Naga Bhasma is found as lead sulphide (PbS).^[3] There have been questions raised about quality, standardization and often about the safety of Ayurvedic medicines in recent past.^[4] Standardization of Rasaushadhis can be defined with the number of processes, involved in the production of a drug. The standard protocols are mentioned in the literature.^[5]

The selection of the processes for preparation of Naga Bhasma was done on the basis of the specific process mentioned in classical texts. While reviewing Rasashastra texts, various reference of Naga Marana are found with variation in respect of Jarana (polling) dravya, Maraka Dravyas, Bhavanas Dravyas (Levigation material) and number of Puta etc. However, each reference has its own importance of therapeutic efficacy. The collection of Arka dugdha (Latex of *Calotropis procera*) is not easy process.

Considering this fact present study was planned to develop the standard manufacturing procedure of Naga Bhasma prepared with Arka dugdha as bhavana media.^[6]

MATERIAL AND METHODS

Collection of raw material

Ashuddha Naga (Impure Lead), Ashuddha Manhshila (Arsenic disulfide), Tila taila (*Sesum indicum*) were procured from Pharmacy, Gujarat Ayurved University. Horse gram seeds (*Dolichos biflorus* Linn.) were purchased from local market of Jamnagar. Gomutra (cow urine) was procured from cow shed, Jamnagar. Kanji (sour gruel) and Takra (clarified butter milk) were prepared as per classical reference from Parada Vidyaniya^[7] and Sushurata Sutra^[8] respectively. The bhavana media Arka dugdha (*Calotropis procera*) were collected from local area in morning at 6 to 7 am.

Pharmaceutical procedure

Takra (butter milk), Kanji (sour gruel), Kulattha Kwatha (Decoction of *Dolichos biflorus*)^[9] and Churnodhaka (lime water)^[10] were prepared as per classical reference. Samanya Shodhana (general purification)^[11] of Naga was carried out using Dhalana principle (melting and pouring). Ashuddha Naga was melted in the Iron darvi and poured through the hole of Pitthara yantra which was already filled with tila taila. The process was repeated for two more times. The same process was repeated for remaining liquid media like Takra, Kanji, Go-mutra and Kulatha Kwatha. After completing this process, Vishsha shodhana (specific purification) process was carried by using Churnodaka as liquid media.^[12]

Shuddha Naga (purified lead) was made into Patras (thin leaf) through roll press machine. Then Shuddha Manshila (purified realgar) was

levigated with Arka Dugdha. Then paste of Manashila was smeared over the both side of Naga patras and kept for drying. After proper drying Naga Patras were kept in an earthen saucer, covered by another earthen saucer and junction was sealed by mud smeared cloth and allowed for drying. Then earthen saucer was subjected for 1st Puta through Horizontal muffle furnace at the temperature of 600°C which maintained for 1 hour. After self-cooling of the 1st Puta, materials were made into powder form and mixed with 1/20 part of Shuddha Manhashila and levigated with Arka Dugdha. Then round flat shaped Chakrikas were prepared and dried. After complete drying, the remaining process was repeated same as like 1st Puta. Total ten Putas were required to convert the lead into Bhasma.

OBSERVATIONS AND RESULTS

It was observed that the Bhasmas retained the original form even after Apunarbhava Pariksha confirming the good processing techniques. The Bhasma did not regain its metallic state, which is the rule for passing the test. The results were mentioned in Table 1 to Table 9.

DISCUSSION

There are two types of Naga mentioned in Ayurvedic classics viz. Kumara & Samala.^[13] But their differential characteristics and superiority regarding therapeutic utility is not mentioned in any classics. Raw Naga was observed to fulfill Ayurvedic like tested for Ayurvedic grahya (acceptable) parameters like quick melting, heavy, having bright black surface and gives black line on rubbing over white paper.^[14] The quantitative study shows the presence of Ca 0.0003%, Sn 131%, Sb 0.432%, As 0.0023, Cd 0.0007 and 99.80% lead. The minimum quantity of metal has to be taken for Shodhana purpose is 5 Pala (one Pala equal to 48 g) and maximum of 13 Pala is mentioned in classic.^[15]

The less quantity taken during the ancient period may be due to the Vaidyas himself prepare the medicine as per requirement to treat the patients. But now days due to commercialization more quantity is used for Shodhana purposes to meet the need. Present study to facilitate the standardization procedure it was decided to take 1 kg (Asudha Naga) each batch.

During the preparation anna (Rice) frothing was seen at initial stage but after proper cooking the rice, it subsided which may be due to heavy density. The physico-chemical properties like pH-3.4, colour, odour and taste are found, milky white, typical sour, sour acidic respectively found in Kanji. Prepared Takra was white, moderately thick liquid and slightly sour in taste with pH of 3.5. During preparation of Kwatha, frothing was observed in the initial stages which were subsided in later. Kulattha seeds were found soft in comparison to initial. Physico-chemical properties like colour, pH, and taste were found reddish brown, 6.5, and astringent in Kulattha Kwatha respectively. Liquid media eliminates the blemishes and detoxification of toxic substances.

Flame was caught from 2nd time of heating & quenching process in the Tila taila during Samanya Shodhana process which was not found during 1st heating & quenching process of Naga. It may be due to after 1st quenching the melted lead is mixed with oil and that oil may be the reason for catching of fire during the 2nd time heating process. Pungent smell, hissing sound and a rush of black fumes was observed after quenching in Tila Taila and bottom portion of iron ladle turned into yellow in color. Before first quenching in Takra, flame caught in Darvi (ladle) which may be oily substance of Tila taila. Some part of Naga was converted into yellowish powder form after each quenching; it may be due to oxide formation of lead. Melting time of Naga was gradually found increased after Shodhana in each media in 1st batch. (Table 2)

Table 1: Ingredients and their quantity for Naga Marana

Sr. no.	Ingredients	Batch		
		I	II	III
1 st Puta	Shuddha Naga Patra (g)	300	300	300
	Shuddha Manahshila (g)	300	300	300
	Arka Dugdha (ml)	200	200	200
2 nd Puta	Wt. of Naga after 1 st Puta (g)	372	367	370
	Shuddha Manahshila (g)	18.6	18.35	18.5
	Arka Dugdha (ml)	150	145	154
3 rd Puta	Wt. of Naga after 2 nd Puta (g)	368	364	362
	Shuddha Manahshila (g)	18.4	18.2	18.1
	Arka Dugdha (ml)	140	150	145
4 th Puta	Wt. of Naga after 3 rd Puta (g)	367	362	365
	Shuddha Manahshila (g)	18.3	18.1	18.25
	Arka Dugdha (ml)	135	145	140
5 th Puta	Wt. of Naga after 4 th Puta (g)	363	370	360
	Shuddha Manahshila (g)	18.1	18.5	18
	Arka Dugdha (ml)	130	140	135
6 th Puta	Wt. of Naga after 5 th Puta (g)	362	366	364
	Shuddha Manahshila (g)	18.1	18.3	18.2
	Arka Dugdha (ml)	125	135	130
7 th Puta	Wt. of Naga after 6 th Puta (g)	358	360	357
	Shuddha Manahshila (g)	17.9	18	17.85
	Arka Dugdha (ml)	125	140	125
8 th Puta	Wt. of Naga after 7 th Puta (g)	356	357	352
	Shuddha Manahshila (g)	17.8	17.85	17.6
	Arka Dugdha (ml)	120	125	130
9 th Puta	Wt. of Naga after 8 th Puta (g)	352	350	354
	Shuddha Manahshila (g)	17.6	17.5	17.7
	Arka Dugdha (ml)	115	130	120
10 th Puta	Wt. of Naga after 9 th Puta (g)	345	345	348
	Shuddha Manahshila (g)	17.25	17.25	17.4
	Arka Dugdha (ml)	120	140	128
	Wt. of Naga Bhasma after 10 th Puta (g)	338	340	342

Table 2: Average time taken for quenching of Naga during Samanya and Vishesha Shodhana

Batch	Average times required for melting of Naga (min)					
	Til Taila	Takra	Kanji	Gomutra	Kulattha Kwatha	Churnodaka
I	5.12	5.11	5.15	5.45	5.37	5.12
II	5.08	4.48	4.72	4.90	5.31	5.27
III	5.43	5.26	5.13	5.0	5.06	5.15

Table 3: Average pH value of different media utilized during Shodhana process

Liquid Media	pH before Shodhana	pH after Shodhana
Til taila	6.61	6.0
Takra	5.05	5.7
Kanji	3.2	3.30
Gomutra	7.45	7.45
Kulattha Kwatha	5.4	5.72
Churnodaka	10.73	10.94

Table 4: Weight of Naga before and after Samanya Shodhana

Batch	Tila Taila			Takra			Kanji		
	BS (g)	AS (g)	% change	BS (g)	AS (g)	% change	BS	AS	% change
I	1000	979.0	0.21	979.00	966	0.13	966	946	0.21
II	1000	980.3	0.19	980.3	965.6	0.14	965.6	943.5	0.22
III	1000	984.0	0.16	984	968.5	0.15	968.5	951.9	0.16
Avg.	1000	981.1	0.18	981.1	966.7	0.14	966.7	947.13	0.19

BS: Before shodhana; AS: After shodhana

Table 5: Weight of Naga before & after Samanya and Vishesha Shodhana

Batch	Samanya Shodhana						Vishesha Shodhana		
	Go-mutra			Kulattha Kwatha			Churnodaka		
	BS	AS	%change	BS	AS	% change	BS	AS	% change
I	946	931	0.15	931	918.3	0.12	918.3	904	0.14
II	943.5	934	0.95	934	919.3	0.14	919.3	907	0.12
III	951.9	942	0.99	942	933	0.09	933	916.4	0.16
Avg.	946.3	935	1.39	935.6	923.5	0.11	923.5	909.13	0.14

Table 6: Observations and results obtained during Marana of Naga (Batch I)

No. of Puta	Wt. of Chakrikas		Max. Temp. (°C)	Time required for attain the max. Temp. (min)	Chakrika consistency	Chandrika (luster)	Colour of Chakrika	Wt. of loss after Puta (g)
	Before Puta (g)	After Puta (g)						
1 st	605	372	600	45	Powder with some mass	-ve	Grayish	233
2 nd	372	368	600	45	hard	-ve	Grayish	04
3 rd	368	367	550	45	Soft	-ve	Grayish	1
4 th	367	363	550	45	Soft	-ve	Grayish	4
5 th	363	362	550	45	soft	-ve	Grayish	1
6 th	362	358	550	45	Soft	-ve	Grayish	4
7 th	358	356	550	45	soft	-ve	Gray	2
8 th	356	352	550	45	soft	-ve	Gray	4
9 th	352	345	550	45	soft	-ve	Gray	7
10 th	345	338	550	45	soft	-ve	Gray	7

-Ve = Chandrika absent

Shining of Naga was decreased after quenching in Kanji and Gomutra, while it was significantly decreased and blackish ash was observed floating over melted Naga after Shodhana in Kulattha Kwatha. The blackish ash may be due to burned particle of organic materials of Kulattha Kwatha. pH of all liquid media showed slight increase except the pH value of Gomutra which was unchanged. (Table 3)

It may be due to reaction (Hypothetical) between media and melted material during pouring. Hissing sound was heard while pouring of melted Naga in Churnodaka. It may be due to sudden change in temperature while pouring the melted lead in liquid media. Average time required for melting of Naga during Vishesha Shodhana process was 5.18 min.

Table 7: Observations and results obtained during Marana of Naga (Batch II)

No. of Puta	Wt. of Chakrikas		Max. Temp. (°C)	Time required for attain max. Temp. (min)	Chakrika consistency	Chandrika (luster)	Colour of Chakrika	Wt. of loss after Puta (g)
	Before Puta (g)	After Puta (g)						
1 st	606	367	550	40	Powder with some mass	-ve	Grayish	239
2 nd	367	364	550	40	hard	-ve	Grayish	3
3 rd	364	362	550	35	Soft	-ve	Grayish	2
4 th	362	370	550	35	Soft	-ve	Grayish	8
5 th	370	366	550	35	soft	-ve	Grayish Black	4
6 th	366	360	550	35	Soft	-ve	Grayish Black	6
7 th	360	357	550	35	soft	-ve	Gray	3
8 th	357	350	550	35	soft	-ve	Gray	7
9 th	350	345	550	35	soft	-ve	Gray	5
10 th	345	340	550	35	soft	-ve	Gray	5

Table 8: Observations and results obtained during Marana of Naga (Batch III)

No. of Puta	Wt. of Chakrikas		Max. Temp. (°C)	Time required for attain the max. Temp. (min)	Chakrika Consistency	Chandrika (luster)	Colour of Chakrika	Wt. of loss after Puta (g)
	Before Puta (g)	After Puta (g)						
1 st	603	370	550	45	Powder with mass	-ve	Grayish	233
2 nd	370	362	550	45	Hard	-ve	Grayish	8
3 rd	362	365	550	45	Hard	-ve	Grayish	3
4 th	365	360	550	45	Soft	-ve	Grayish	5
5 th	360	364	550	45	Soft	-ve	Grayish	4
6 th	364	357	550	45	Soft	-ve	Grayish	7
7 th	357	352	550	45	Hard	-ve	Grayish	5
8 th	352	354	550	45	Soft	-ve	Grayish	2
9 th	354	348	550	45	Soft	-ve	Grayish	6
10 th	348	342	550	45	Soft	-ve	Grayish	6

Table 9: Apunarbhava Pariksha of Naga Bhasma

Batch	Wt. of Bhasma	Wt. of Mitrapanchaka	Observations
I	2 g	10 g	No metallic luster or lumps
II	2 g	10 g	No metallic luster or lumps
III	2g	10 g	No metallic luster or lumps

The weight lost was observed after Samanya and Vissha Shodhana process. (Table 4 & 5) It may be due to few materials soluble in the liquid media during pouring and also may be due lose during heating process.

Manahshila was used as a maraka dravya for Naga (lead) in present study. Average 220.71 ml Ardraka Swarasa (Extract of ginger) was required to give each bhavana for 1 kg of Manashila.

Average 1545 ml Ardraka Swarasa was required for 7 times bhavana in all batches. Before the Shodhana, Manahshila was hard, dull orange color and lustrous. But after Shodhana it became soft, smooth, orange colour and lustrous. The weight of Manahshila was increased (23.56 g) after Shodhana. Increase in weight after levigation was due to the incorporation of solid contents from the levigating media. The amount of liquid media for levigation also depends on season, vigor during levigation and nature of material. The bhavana processes leads to the reduction of particle size of the materials.

Several methods are available for the preparation of Naga Bhasma in different classics. However, in the present study Marana of Naga was done using Manahshila and Arka dugdha as media. Collection of Arka Dugdha was very difficult, but it is one of the specific procedures mentioned in Rasaratna Samucchaya.

Each batch 300 g Shuddha Naga patra was taken for Marana process. Thin leaf of purified lead was prepared to facilitate the more surface area for the reaction with Manahshila. Average 193.33 ml Arka Dugdha was required for the first Bhavana. The average yield of Naga after 1st Puta was 369.66 g. After 1st Puta Naga Patras was easily converted into powder form may be due to the reaction of Naga and Manahshila at high temperature. From 2nd Puta powder of 1st Puta Naga was mixed with $\frac{1}{20}$ th part of Shuddha Manahshila. The average quantity of Manashila and Arka Dugdha for the second Bhavana were 18.68 g and 146.67 ml respectively. Average 46.08 g Manashila and 134.17 ml Arka Dugdha were required for the preparation of Naga Bhasma. Chandrika was found absent in Marita materials (from 1st Puta to 10th Puta). Average of 40 g was found to be increased which may be due to the presence of some inorganic materials incorporated during the Bhavana process and some part of arsenic converted into compound. It was observed that Chakrika were found hard after 2nd Puta at 600^oC in 1st

batch. So, temperature was decreased to 550^oC after 2nd Puta. Hence Chakrika became soft at this temperature. So for the remaining batches 550^oC temperature were given for the whole process. Chakrikas were soft in touch, easily breakable and not have any shining after 10 Putas. The bhasma pariksha like Varitaratwa, Rekapurnatwa, was passed after 3rd puta and Apunarbhava test were passed after 10 Putas.

CONCLUSION

Standardized Manufacturing Procedure in preparation of medicines is an essential requirement for good manufacturing practices as well as to insure the quality assurance and quantity of final product. Collection of Arka dugdha was a very tedious process but Naga bhasma prepared using Arka dugdha was found to be easily prepared within 10 Puta. This method could be adopted for further research works and for preparing Naga Bhasma in various pharmacies.

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