

Pharmaceutical Standardization of *Shweta Akika Bhasma* and *Pishti*

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Abstract: *Akika Pishti* is widely used in therapeutics to treat various disease conditions like *Hridaroga* (Cardiac disease) *Manoroga* (psychic disorders) and *Raktaja Vikara* (bleeding disorders). Some references found in classics also emphasized the use of *Akika Bhasma*. But till date no work has been carried out on pharmaceutical standardization of *Shweta Akika Bhasma* and *Pishti*. The present research work is aimed to establish the pharmaceutical standardization of *Shweta Akika Bhasma* and *Pishti*. Three batches of *Shweta Akika Bhasma* were prepared by purification of *Akika* followed by calcination as per the reference of Rastantrasaar and Siddhprayog Sangraha and three batches of *Shweta Akika Pishti* were prepared followed by levigation (*Bhavana*) as per the reference of Rastantrasaar and Siddhprayog Sangraha to develop standard parameters. *Shweta Akika Bhasma* with fixed quantity of cow dung cakes i.e., 10 *Shera* (9.321 kg) and *Shweta Akika Pishti* in terms of pharmaceutical standards i.e. light brown and grayish pink in color, 81.53 % and 153.33 % yield respectively along with reproducibility of fixed quality. The present study has ensured and standardized the method of preparation of *Shweta Akika Bhasma* and *Shweta Akika Pishti* according to the method explained in the classical literature.

Key Words: —*Shweta Akika, Bhasma, Pishti, pharmaceutical standardization.*

I. INTRODUCTION

Pharmaceutical standardization is essential for adoption of recommended pharmaceutical process for quality, safety and efficacy of the drug. Considering the advancement in the pharmaceutical technology, it is necessary to fix the standard parameters for the classical formulation by following the existing protocols. Henceforth, pharmaceutical standardization of *Bhasma* denotes the collection of authentic samples, ensuring the optimum manufacturing conditions such as purification, levigation, heating devices for incineration and attainment of the quality finished products, which directly effects on the therapeutic properties of drug.

Akika is a very familiar semiprecious stone in the world of stone and initiatory mentioned by the author of *Siddha Bheshaja Manimala* (19th century) [1].

Akika Pishti is widely used by *Vaidya* and *Hakim* in various disorders like *Hridaroga* (Cardiac disease), *Shiroroga* (headache due to vitiated *Dosha*), *Kasa* (cough), *Rakataja Vikara* (bleeding disorders), *Manoroga* (psychic disorders) and many more [2]. *Rakta*, *Shweta*, *Krishna*, *Shyama*, *Hareeta*, *Peeta* and *Neela* color of *Akika* were described in different *Rasagrantha*. Among them *Shweta Akika* is considered as the best by *Ayurveda Sara Sangraha* [3] and *API* [4] among all varieties of *Akika*. *Akika* is categorized under semiprecious stone and the calcination process of precious and semiprecious stone is not preferable in classics [5], [6], [7] Though the preparatory method of *Akika Bhasma* is mentioned in *Ayurvedic treatises*, it becomes enforced to discern whether *Bhasma* of precious and semiprecious stone should be prepared or not. Therefore, in present study an effort has been made to highlight the significance of pharmaceutical procedures and to develop the standard parameters of *Shweta Akika Bhasma* and *Pishti*. Till date no work has been carried out on Standard Manufacturing Process (SMP) of *Shweta Akika Bhasma* and *Pishti*.

Manuscript revised August 27, 2022; accepted August 28, 2022. Date of publication August 30, 2022.

This paper available online at www.ijprse.com

ISSN (Online): 2582-7898; SJIF: 5.59

II. MATERIALS AND METHODS

The whole pharmaceutical study was carried out in following steps;

- Procurement and authentication of the raw material
- Preparation of drug

Procurement and authentication of the raw material:

Shweta Akika was purchased from the market through authorized gem trader from Khambhat, Gujarat. After procurement, Akika was given for authentication at “Neel Gem Testing Laboratory” [ISO certified (9001-2008)], Ahmedabad, Gujarat. The laboratory authenticated and certified the sample as natural white agate on the bases of physical and optical parameters such as hardness, refractive index, specific gravity, fluorescence [figure 1] and solubility in concentrated Hydrofluoric acid. Flowers of *Gulab (Rosa Centifolia* Linn) were collected from the local market of Vadodara, Gujarat. Rose petals were identified and authenticated in Pharmacognosy department of Food and Drug Laboratory, Vadodara. *Go-Dugdha* (cow’s milk) was procured from the local market of Vadodara having *fssai* standards.

2.1 Preparation of drug

All the samples of *Shweta Akika Bhasma* and *Shweta Akika Pishti* were prepared in pharmaceutical laboratory of upgraded department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat.

To develop SMP, three batches of *Shweta Akika Bhasma* and *Shweta Akika Pishti* were carried out in following steps;

- Preparation of *Gulab Arka*
- Preparation of *Shweta Akika Shodhana* (SAS)
- Preparation of *Shweta Akika Bhasma* (SAB)
- Preparation of *Shweta Akika Pishti* (SAP)

First pilot batch was prepared as per the prepared proforma and findings obtained from that pilot batch; main batches were prepared by the adopting the same method to attain the reproducibility of that method.

2.2 Preparation of Gulab Arka

Gulab Arka was abundantly used throughout the preparation of *Shodhana*, *Pishti* and *Bhasma* of *Shweta Akika*. Henceforth preparation of *Gulab Arka* was requisite step for the present study. *Gulab Arka* was prepared as per the reference of API part II volume III. [i]

300 g fresh rose petals were washed properly and soaked overnight in 12.5 times water. Next day it was placed in a round bottom standard joint flask of 5 L capacities. The flask

was placed in a heating mantle and attached to distillation assembly. The temperature was set on 90°C at initial and maintained on 70 °C after boiling the liquid. Distillate was collected as *Gulab Arka* and stored in airtight containers. On the bases of observations of pilot batch, the requirement of *Gulab Arka* for 150 g of each batch size of *Shweta Akika Shodhana*, *Marana* and *Pishti* is depicted in table 1.

Table.1. Required quantity of Gulab Arka for three batches of SAS, SAB and SAP

Procedure	Description	Required quantity of Gulab Arka for pilot batch (ml)	Required quantity of Gulab Arka for one batch (ml)	Required quantity of Gulab Arka for 3 batches (ml)	Total required quantity of Gulab Arka
<i>Shweta Akika Shodhana</i>	21 times <i>Nirvapa</i>	2100 (300X21)	6300 (300X21)	18900	21000
<i>Shweta Akika Bhasma</i>	<i>Bhavana</i> for 1 st <i>Putra</i>	85X5 =425	85	255	680
<i>Shweta Akika Pishti</i>	7 days levigation	485.00	491.00	1473	1958
Total	-	3010	6880	20628	23638

In accordance with the requirement of *Gulab Arka*, total 13 batches were made by adopting the same procedure mentioned in pilot batch. Among them the data of three batches are enlisted in table no. 2. Total 24.375 L *Gulab Arka* was obtained from 3.9 kg of rose petals.

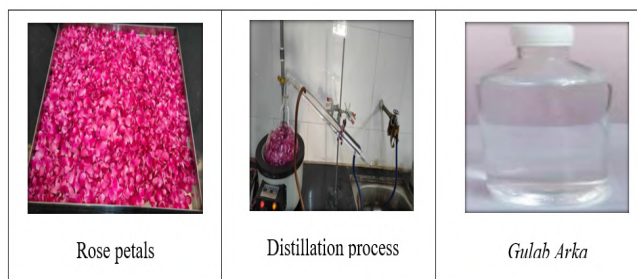


Fig.1. *Gulab Arka* preparation

2.3 Preparation of Shweta Akika Shodhana

A pilot study was carried out in order to have idea about the duration of the entire process as well as to identify the technical hitches that could be occurred during *Nirvapa* process i.e., fixed the temperature for red hot stage of *Akika*, vessels specifications and amount of *Gulab Arka* required for 21 times of *Nirvapa* process.

Shodhana of *Shweta Akika* was carried out by *Nirvapa* (heating and quenching) in *Gulab Arka* as per the reference of Rastantrasaar and Siddhprayog Sangraha [ii].

500 g of *Ashodhita Shweta* were heated up to red hot stage (between 490 °C - 500 °C) in an iron pan and quenched in *Gulab Arka* for 21 times. Liquid media was changed each time and taken in such amount that the material was properly immersed in the media (300 ml × 1 × 21 = 6300 ml) (6300 ml X 3 batches *Shweta Akika* = 18900 ml). The details of SAS (Batch-1) are depicted in table 3.



Fig.2. Different Stages of *Shweta Akika Shodhana*

2.4 Preparation of *Shweta Akika Bhasma*

150 g of *Shodhita Shweta Akika* powder was levigated with *Gulab Arka* for 6 hours by manually in a stone mortar. After 6 hours of trituration, uniform sizes of pellets of were prepared and allowed to complete dry. After drying, pellets were placed in an earthen *Sharava* and covered with another *Sharava*. *Sandhibandhana* was done by mud smeared cotton cloth and kept for drying. It was then subjected to *Putra*. The cow dung cakes were arranged from all sides in menztioned size of *Varahaputa* (18”x18”x18” lxbxh) [iii] with covering *Sharava Samputa* and ignited. After self-cooling, *Sharava Samputa* was taken out, collected the pellets and weighed. That procedure was repeated for 3 times by levigated with *Go – Dugdha*. After completion of 4th *Putra*, pellets were weighed and subjected to trituration in a stone mortar pestle to get a fine powder of it. The fine powder was stored in an airtight container. Total 4 *Putra* was given to complete the preparation of *Akika Bhasma*. Number of cow dung cakes used for *Akika Bhasma* preparation was one *Shera* i.e. 9.321 kg [iv] for each *Putra*. Total used quantity of cow dung cakes was 111. 85 kg (9.321 kg x 1 x 4 *Putra* x 3 batches *Shweta Akika Bhasma*).

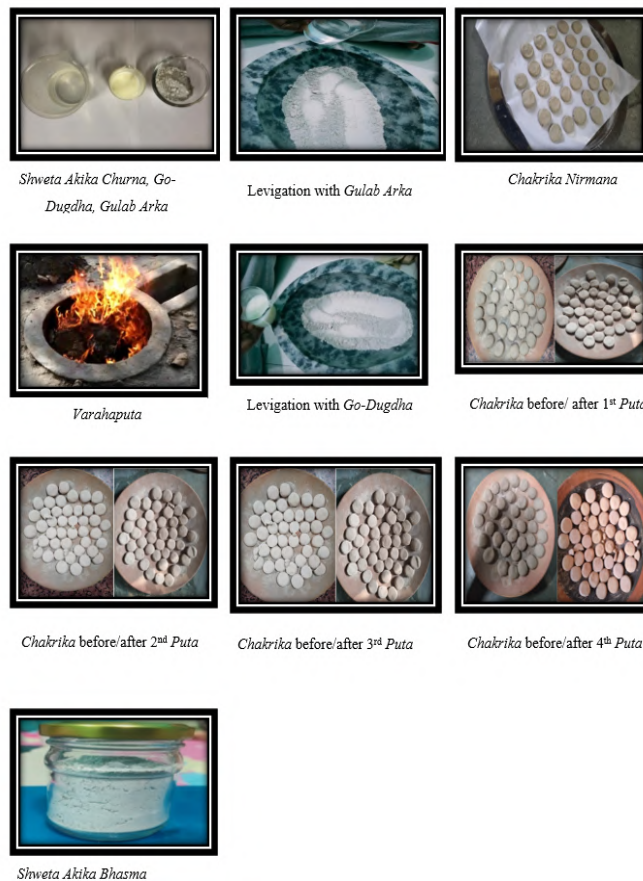


Fig.3. Different stages of *Shweta Akika Bhasma*

2.5 Preparation of *Shweta Akika Pishti*

150 g of *Shodhita Akika* powder was taken in a stone mortar and subjected to levigation with the help of pestle. Required amount of *Gulab Arka* was added to keep the mud like consistency and then levigation was done continuously for 6 hrs. This process was repeated for 6 days. After completion of levigation, the obtained material was dried properly and weighted and stored in air tight container.



Fig.4. Different stages of *Shweta Akika Pishti*

2.6 Observations and Results

During the preparation of *Gulab Arka*, water started boiling after 40 minutes and vapours were seen at the neck of the flask. *Arka* started to drain out after 50 minutes. Vapors started to condense and changed into liquid form when they passed through the condensing tube. After completion of distillation process, the aromatic smell came from *Arka*. Initially, the color of rose petals was reddish pink but after 40 minutes of boiling, they faded to brown.

The results of *Gulab Arka* are depicted in table 2.

Table.2. The result of *Gulab Arka Nirmana*

Sr. No.	Parameters	Batch-1	Batch-2	Batch-3	Average
1	Total time taken for preparation of <i>Gulab Arka</i> (hrs.)	9.00	9.00	9.00	9.00
2	Weight of fresh rose petals (g)	300	300	300	300
3	Quantity of water for distillation (ml)	3750	3750	3750	3750
4	Quantity of residue (g)	375	375	375	375
5	Quantity of remaining water (ml)	1875	1875	1875	1875
6	Final yield %	50	50	50	50
7	Final yield (ml)	1875	1875	1875	1875
8	Total loss of water (ml)	1875	1875	1875	1875
9	Total loss of water (%)	50	50	50	50
10	Reason of loss	Last portion may not contain the therapeutically essential substance			

During *Shodhana*, the material reacted to atmospheric oxygen and desired changes may take place due to intense heating. After heating, it was instantly quenched in the liquid media. Instant quenching is important because repeated immediate cooling after heating leads to breaking of the material. **In the raw material (*Akika*)**, *Akika* did not become red hot though the bottom of iron pan became red hot. No color change noticed in *Akika*, after heating in the between 490 °C- 500 °C. *Akika* was slightly brittle and less shiny after 21 times of quenching. The weight of *Akika* increased after quenching in *Gulab Arka* as a small amount of *Arka* remained in it. **In media**, As soon as, the material was quenched in *Gulab Arka*, typical crackling sound was heard with water vapours. A smell of *Gulab Arka* was observed after quenching. When the material was quenched in *Gulab Arka*, the temperature of liquid media was raised and the color became slightly whitish red. The details of *Shweta Akika Shodhana* are depicted in table 3.

Table.3. Details of *Shweta Akika Shodhana*

Sr. No.	Parameters	Batch-1	Batch-2	Batch-3	Average
1	Total time taken for <i>Akika Shodhana</i> (hrs.: min)	3.20	3.20	3.35	3.25
2	Initial quantity of <i>Ashodhita Akika</i> (g)	500	500	500	500
3	Temperature (°C)	331.19	328.52	329.42	329.71
	Flame (°C)	495.90	494.57	495.90	496.46
4	Quantity of <i>Gulab Arka</i> required for each quenching (ml)	300	300	300	300
5	Final quantity of <i>Shodhita Akika</i> after shade drying (g)	495	494	496	495
6	Total quantity of <i>Gulab Arka</i> required for 21 times of quenching	6300	6300	6300	6300
7	Final weight of <i>Shodhita Akika</i> (%)	99	98.8	99.2	99
8	Total loss (g)	5	6	4	5
9	Total loss (%)	1	1.2	0.8	1.00
10	Reason of loss	Due to quenching and filtering			
11	Remaining quantity of <i>Gulab Arka</i> after 21 times of quenching (ml)	4140	4200	4190	4147.66
12	Loss of volume of media after quenching	2160	2100	2110	2123.33
13	Total loss (%)	34.28	33.33	33.49	33.70
14	Reason of loss	Evaporation of <i>Arka</i> while quenching and filtering			

Powdering of *Akika* was prerequisite step in the manufacturing of *Shweta Akika Bhasma* and *Pishti*. This process is an intermediate process between *Shodhana* and *Marana* as well as for *Pishti Karana*. As *Shodhita Akika* was hard, it was quite difficult to make a powder of *Akika* in a mixer. After sieving, pink colored fine powder of *Shweta Akika* was obtained. The details of *Shodhita Akika* powdering are depicted in table no. 4.

Table.4. Details of *Shodhita Akika* powdering

Parameters	<i>Shodhita Shweta Akika</i> (Batch 1, 2 and 3)
Weight before powdering (g)	1485
Weight After powdering (g)	1453
Loss on powdering (g)	32.00
Percentage (%) w/w	2.15
Total time required for powdering (hrs.: min)	13.05

During *Akika Bhasma* preparation, on addition of *Gulab Arka* in powdered *Akika*, slight effervescences were occurred. It was very difficult to make pellet after levigation with *Gulab Arka* as proper binding was not possible. After drying, pellets were becoming little bit brittle so with due care they were put in *Sharava*. An average weight of each commercially made cow dung cake was around 170 g. Result of *Shweta Akika Bhasma* is depicted in table 5.

Table.5. Result of SAB

Sr. No.	Parameters	Batch-1	Batch-2	Batch-3	Average
1	Total time taken for RAB	12 days	13 days	12 days	12 days
2	Initial quantity of <i>Shodhita Shweta Akika Churna</i> (g)	150	150	150	150
3	Quantity of <i>Gulab Arka</i> (ml)	85	80	85	83.33
4	Quantity of <i>Go-Dugdha</i> (ml)	215	230	225	223.33
5	Final quantity of <i>Akika Bhasma</i> (g)	122	122	120	121.33
6	Final quantity of <i>Akika Bhasma</i> (%)	81.33	81.33	82.66	81.77
8	Total loss (g)	28	28	30	28.66
9	Total loss (%)	18.66	18.66	17.34	18.22
10	Reason of loss	<i>Putra procedure</i>			

During *Akika Pishti* preparation, on addition of *Gulab Arka* in powdered *Akika*, slight effervescences were occurred and aromatic fragrance was felt immediately. The color of *Shweta Akika* powder was changed light pink to creamy pink after adding *Gulab Arka* gradually and became darker after while no change was found in *Shweta Akika* powder. Lastly, a grayish pink and white colored *Pishti* was obtained from *Shweta* and *Shweta Akika* respectively which was triturated to make a fine powder. The observations during *Bhavana* of *Shweta Akika Pishti* are depicted in table 6.

Table.6. Observation of *Shweta Akika Pishti*

<i>Bhavana</i>	Weight of <i>Shodhita Shweta Akika Churna</i> after each <i>Bhavana</i> (g)			Quantity of <i>Gulab Arka</i> (ml) required in each <i>Bhavana</i>			Time taken for drying of material (hrs.)		
	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch	Batch
	-1	-2	-3	-1	-2	-3	-1	-2	-3
1	150	150	150	75	85	80	15	14	15
2	150	151	151	75	70	65	12	12	12
3	151	151	152	70	65	70	13	11	14
4	152	152	152	70	70	65	12	12	11
5	152	152	152	65	65	70	12	12	13
6	153	152	153	60	65	80	12	14	12
7	153	153	154	70	70	70	12	15	11
Average	151.57	151.57	152	69.28	70	71.42	12.57	12.85	12.57

The result of *Shweta Akika Pishti* is depicted in table 7.

Table.7. The result of *Shweta Akika Pishti*

Parameter	Batch-1	Batch-2	Batch-3
Initial weight (g)	150	150	150
Final weight (g)	153	153	154
Gain (g)	3	3	4
Gain (%)	2	2	2.66
Total quantity of <i>Gulab Arka</i> required (ml)	485	490	500
Total duration (hrs.)	42	42	42

Table.8. Classical parameters of *Shweta Akika Pishti*

Parameters	SAP		
	Batch- 1	Batch- 2	Batch- 3
<i>Rekhapatnava</i>	Positive	Positive	Positive
<i>Shlakshmatva</i>	Positive	Positive	Positive
<i>Mrudutva</i>	Positive	Positive	Positive
<i>Anjanasadrshatva</i>	Positive	Positive	Positive

III. DISCUSSION

The aim of present study was to establish to pharmaceutical standardization though SMP of *Shweta Akika Bhasma* and *Shweta Akika Pishti*. There is no description found in any *Rasagrantha* regarding the quantity of liquid media taken for quenching in *Nirvapa* procedure. Hence fore, the liquid media was taken in such amount that the material was properly immersed in the liquid media. Based on the inferences obtained from pilot study, 100 ml of *Gulab Arka* was required for each *Nirvapa* of 150 g *Akika*. Required quantity of *Gulab Arka* for *Shweta Akika Shodhana* (6300 X 3 batches = 18900 ml), for *Bhasma* (85 X 3 batches = 255 ml) and for *Pishti* (491 X 3 batches = 1473 ml)

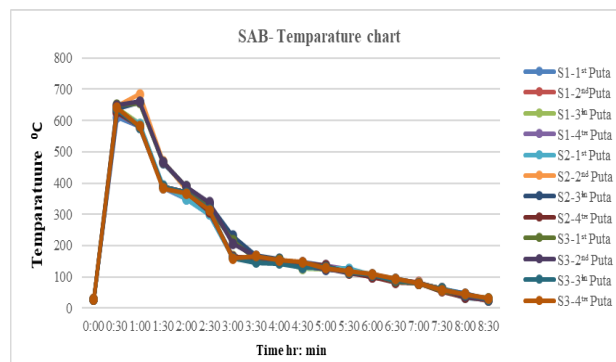
During *Akika Shodhana*, when the material was heated between 490 °C -500 °C, it did not become red hot but the bottom of iron pan became red hot. The temperature was also not exceeding to 500 °C and also the color of the material was remained the same. For that reason, the temperature for red hot stage was decided in between 490 °C -500 °C.

Numbers of trials were carried out to standardize the process of *Shweta Akika Bhasma* preparation. In classics, 1 to 4 *Gajaputa* is indicated for *Akika Bhasma* while *Kukkutaputa* has been mentioned by A.F.I./Bheshaja *Samhita/Rasodddharatantra*. Different references of *Akika Bhasma* has been mentioned where cow dung cakes are taken as a standard fuel and number of cow dung cakes and number of *Putra* as variables i.e. full of *Gajaputa*, 25 *Shera*, 20 *Shera*,

10 *Shera* cow dung cakes and 1 to 4 *Gajaputa* respectively. Total four pilot batches were conducted in classical *Putra* by using different amount of fuel i.e. full of *Gajaputa* (48 kg i.e. 252 Nos.), 25 *Shera* (23,302 kg i.e.123 Nos.) and 20 *Shera* (18.642 i.e.90 Nos.) kg in the pit of *Gajaputa* 27"x 27"x 27" (lxbxh) [v] and It was observed that the peak temperature was **937.5 °C, 865.25 °C, 837 °C** for at an average 45 minutes after ignition and self- cooling time was found 12 hours, 10 hours and 9 hours respectively. The color and brittleness of pellets were having desired characteristics i.e. soft and brittle but after 2nd, 3rd and 4th *Putra*, again the pellets were burnt and became hard. So, further pilot batch was carried out. In 4th pilot batch 10 *Shera* (9.321 kg) cow dung cakes were used in the pit of *Varahaputa* of 18"x18"x18" (lxbxh). It was found that having less number of cow dung cakes in a large size pit would cause heat loss from surroundings. So it was decided to prepared 4th batch in the pit of *Varaha* by taking 10 *Shera* cow dung cakes. An average peak temperature was observed **749.5 °C** at 40 minutes after ignition and time taken for self-cooling was found 8.30 hours. 6.222 kg (~ 35 Nos.) cow dung cakes were placed beneath and 3.111 kg (~ 15 Nos.) cow dung cakes were placed above the *Sharava Samputa*. The color and brittleness of pellets were having desired characteristics i.e. soft and brittle after 1st, 2nd, 3rd and 4th *Putra* and desired characteristics of *Bhasma* were attained. 5th pilot batch was carried out in EMF at 600°C because in EMF once the desired temperature set, the automated temperature control system maintains the temperature throughout the procedure. Desired characteristics of *Bhasma* were attained, after completion of all 4 *Putra*.

Findings obtained by adopting both classical *Putra* and EMF methods, *Varahaputa*, filled with 1 *Shera* (9.333 kg ~50 Nos.) cow dung was taken as standard for preparation of RAB. The optimized temperature and duration of self-cooling for the preparation of *Shweta Akika Bhasma* was 751.95 °C and 8.30 hours for classical *Putra* and 600 °C and 40 hours in Electric Muffle Furnace respectively. The required fuel was 9.321 kg cow dung cakes filled in pit having size of 18"x18"x18" for classical *Putra*.The average quantity of *Gulab Arka* used for levigation before 1st *Putra* was 83.33 ml while *Go-Dugdha* was 223.33 ml (for 2nd +3rd + 4th *Putra*) for *Shweta Akika Bhasma*. In preparation of *Shweta Akika Bhasma* higher of loss was observed after 1st *Putra* in three batches was 4.00 %, 4.67 %, 5.33 %, total loss observed after completion of 4 successive *Putra* was 18.66 %, 18.66 % and 20.00 %, Yield was 122 g (81.33 %), 122 g (81.33 %) ; 120 g (82.66 %) respectively. The reason of loss may be due to *Putra* procedure.

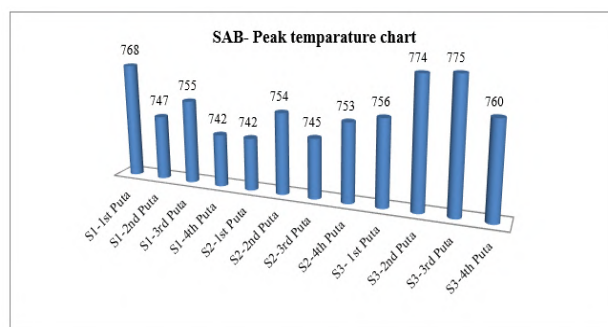
The temperature of *Putra* during *Marana* of *Akika* was recorded at regular intervals of 15 minutes for 8.30 hours only for an outline idea of temperature.



Graph 1: Showing temperature chart of *Shweta Akika Bhasma*

The peak temperature was observed between 775 °C – 728 °C SAB preparation. It was observed after average 43.16 minutes and retained static for 12-15 minutes.

The highest peak temperature for all three batches of SAB is depicted in graph below;



Graph 2: Showing peak temperature chart for *Shweta Akika Bhasma*

During *Shweta Akika Pishti* preparation, no color change found in of *Akika* powder, after adding *Gulab Arka* for SAP. Lastly, white colored *Pishti* was obtained after completion of trituration.

In the preparation of *Shweta Akika Pishti*, total time taken for three batches was 21 working days and consequence 126 hours, total quantity of *Gulab Arka* used were 485 ml, 490 ml and 500 ml during the entire preparation, Yield was found 153 g, 153 g, 154 g which indicates weight gain 2 %, 2 %, 2.66 % after completion of levigation respectively.

Shweta Akika Bhasma and *Pishti* were of light brown colored and white colored respectively. Average comparative yield percentage of *Shweta Akika Bhasma* and *Pishti* were 81.53% and 102.22% respectively. The average yield percentage was increased during *Bhavana*, as the active principles of the

liquid media impregnate to the material while in *Putra*, only the inorganic part of the active principles remains in a very minute amount, as herbo-mineral mixture is incinerated in closed vessel; nano-oxide particles converted into a more favourable oxidation for human consumption. [vi]

IV. CONCLUSION

The first step in standardizing every medicinal product is pharmaceutical standardization. The pharmaceuticals in Ayurvedic preparation approaches should be used to consider current ideas and techniques. In consideration of pharmaceutical study; *Shweta Akika Pishti* was found easier than *Akika Bhasma* in terms of preparatory method and an average comparative yield. Results of the present study ensure the reproducibility of the pharmaceutical procedures, and those can be followed in *Shweta Akika Bhasma* and *Pishti* successfully.

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