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RESEARCH ARTICLE

Pharmaceutical Postulates for Standard Operative Procedures to Prepare SAHAJ VATI

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ABSTRACT

Obesity is an important contributor of various non communicable disorders like diabetes, heart disease, osteoarthritis etc. in developed and developing country. In *Ayurvedic* science numerous herbs, metals and minerals are available for management of obesity as single agent or compound formulations. For the management of obesity, we selected *Shilajeet*, *Guggul*, *Haridra* and *Chitrak* form vast literature of *Ayurveda* and prepare *vati* named as *Sahaj vati* and develop standard operative process for their preparation. Before preparation of *Sahaj vati*, *Shodhan* of *Shilajeet* and *Guggul* was done and two batches of *Sahaj vati* was prepared having *Shilajeet, Guggul, Haridra* and *Chitrak* as main ingredients and seven *bhavana* of *Agnimantha* with slight modification of processing technology and tablets & *vati* was prepared for batch I and batch II respectively. In this way three samples of each batch were prepared. After *Shodhan*, 32.96 % and 72.80% of s*uddha Shilajeet* and *suddha Guggul* was obtained from raw materials and after completion of process 1.052, 1.060 & 1.054 Kg and 0.559, 0.564, 0.572 Kg of *Sahaj vati* was prepared for batch I & II respectively. In this way total 3.166 and 1.695 Kg of *Sahaj vati* was prepared from 3.00 Kg of raw material in batch I and II respectively.

Key words: Obesity, *Ayurvedic* science, *Shilajeet, Guggul, Haridra* and *Chitrak, Sahaj vati.*

INTRODUCTION

Obesity is recognized as a global problem by experts of United Nations, Food and Agricultural Organization and WHO Collaborating Centers as well as advisers from the International Obesity Task Force (IOTF) [1]. It causes global burden of disease, disability including many life-threatening chronic non-communicable diseases such as heart disease, type-2 diabetes, hypertension, stroke and certain cancers etc. [2] Its prevalence has increased with alarming speed over the past twenty years. In the year 2000 more than 300 million people worldwide were obese and it is now projected that by 2025 up to half the population of the United States will be obese if current trends are maintained [3].

In *Ayurvedic* Classics a lot of herbs, metals and minerals like *Vacha, Guggul, Haridra, Tamra bhasma, Lauha bhasma* and *Shilaijeet* etc. are reported for management of obesity as single therapeutic agent [4,5]. Here an attempt has been done to develop compound formulation by taking references from classical manuscripts indicated for management of obesity. For this purposes we prepared *vati* named as *Sahaj vati* by selecting *Shilajeet* [6], *Guggul* [7], *Haridra* [8] and *Chitrak* [9] as main ingredients and *Agnimantha* [10] as *bhavana dravya* among the vast literature of *Ayurveda* science (**Table 1**). In the wake of the present surge of increased global curiosity regarding safety and efficacy of *Rasaaushadhies* (herbo-mineral Formulations) there is an imminent need to pay attention to the establishment of standard operating procedure (SOP). To develop SOP of for *Sahaj vati*, each step of the process was considered as an independent procedure, an attempt was made to validate each step. For this minimum of three samples of each batch was prepared.

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Table 1: Showing ingredients of *Shaja vati* along with their Indication

Ingredient of *Shaja vati*	Botanical name/English name	Parts/Form used	Indications	References
Shilajeet	*Black Bitumen*	*Suddha*	*Sthaulya*	Charak. Charak Sahmita with Charak chandrika Hindi commentary by Bramhanand Tripathi 21/24 Chaukhambha Surbharti Varanasi 2003 p 404
Guggul	*Commiphora mukul*	*Suddha*	*Medo roga*	Charak. Charak Sahmita with Charak chandrika Hindi commentary by Bramhanand Tripathi Sutra Sthan 25/40 Chaukhambha Surbharti Varanasi 2003
Chitrak	*Plumbago Zeylanica*	*Mool*	*Lekhan Karshan*	Charak. Charak Sahmita with Charak chandrika Hindi commentary by Bramhanand Tripathi 4/3 Chaukhambha Surbharti Varanasi 2003 p77
Haridra	*Curcuma longa*	*Kanda*	*Sthaulya*	Vagbhatt. Astang Hriday with vidhyotini hindi commentary by Atridev Gupta sutra sthan 14/26 Chaukhambha prakashan Varanasi 2012 p 138
Agnimantha	*Premna obtusifolia*	*Kanda Sar*	*Sthaulya*	Gosh R, Ghosh S, Maity LN.Therapeutic efficacy of Agnimanth (Premna *obtusifolia* R.Br.) in obesity IJTK 2009;8:369-71

COLLECTION AND AUTHENTICATION

All the ingredients of *Sahaj Vati* except *Guggul* were procured from Gola Dinanath, Local market of Varanasi and *Guggul* was procured from Jaipur, Rajasthan.

MATERIALS AND METHODS

Sahaj Vati was prepared in two batches (Batch I and Batch II) having same ingredients *Shilajeet*, *Guggul*, *Chitrak* and *Haridra* by the seven *bhavana* of *Agnimantha kwatha* with slight variation of their pharmaceutical processing. Before preparation of *Sahaj vati*, *Shodhan* of *Shilajeet* and *Guggul* was done [11,12] and coarse as well as fine powder of *Chitrak* & *Haridra* was prepared with help of pulviser. Batch I was prepared with mixture of *suddha Shilajeet, suddha Guggul* and fine powder of *Haridra* & *Chitrak* by seven *Bhavana* of *Agnimantha Kwatha* in mechanical *kharal* and tablets were prepared. Batch II was prepared in two steps, in first step we prepared *Kwatha* of coarse powder of *Haridra* and *Chitrak* and *suddha Shilajeet* and *Guggul* was dissolve in it and kept for drying. After complete drying seven *bhavana* of *Agnimantha kwatha* was given to this mixture in mechanical *kharal* and *vati* was prepared. In this way three samples were prepared of each batch.

RESULTS

After *Shodhan*, 32.96 % and 72.80% of *Shilajeet* and *Guggul*, was obtained from *Shilajeet* stone and *asuddha Guggul* respectively (**Table 2**). In Batch I, total three liters (1.50 liters for 1st and 0.250 liter from 2nd to 7th) of *Agnimantha kwatha* was consumed for *bhavana* of *Sahaj Vati* and 1.052, 1.060 & 1.054 Kg of *Sahaj vati* was prepared respectively for three samples (**Table 3**). During steps I of batch II, 1.10, 1.00 and 1.150 liters of *Haridra* & *Chitrak kwatha* was obtained respectively for three samples (**Table 4**). In Batch II, 0.537, 0.545 and 0.542 kg of intermediate product was obtained after completion of step I and 1.625 liters (0.750 liters for 1st and 0.125 liter from 2nd to 7th) of *Agnimantha kwatha* was consumed in preparation of *Sahaj vati*. After completion of step II, 0.559, 0.564, 0.572 Kg of *Sahaj vati* was prepared for three samples (**Table 5 & 6**).

Table 2: Showing details about *Shodhan of Shilajeet* and *Guggul*

Name of Drugs	Initial weight	Principle	Media used	Quantity of Media	Duration	Final weight	Yield %
Shilajeet Stone	4.890 kg	*Prakshalana*	Water	42 L	32 days	1.612 kg	32.96
Asuddha Guggul	2.5 Kg	*Swedan*	*Triphala and Guduchi Kwatha*	11 L	32 days	1.820 Kg	72.8

Table 3: Showing details of Pharmaceutical study of Batch I of *Sahaj vati*

Sample	Ingredients	Quantity (gm)	Principle	Duration	Final Yield
A	S. *Shilajeet* S. *Guggul* *Haridra* (F.P.) *Chitrak* (F.P.)	250 250 250 250	*Bhavana* of *Agnimanth Kwatha* (3L (For seven B)	26 days	1.052 kg
B	S. *Shilajeet* S. *Guggul* *Haridra* (F.P.) *Chitrak* (F.P.)	250 250 250 250	*Bhavana* of *Agnimanth Kwatha* (3L (For seven B)	28 days	1.060 kg
C	S. *Shilajeet* S. *Guggul* *Haridra* (F.P.) *Chitrak* (F.P.)	250 250 250 250	*Bhavana of Agnimanth Kwatha* (3L (For seven B)	33 days	1.054 kg

F.P.: Fine powder, S.: Suddha

Table 4: Showing details of *Kwatha* preparation involve in pharmaceutical study of batch II

Sample	Ingredients	Quantity (gm)	Water	Quantity: Water ratio	Duration (hrs)	Final volume of *Kwatha*
A	*Chitrak* (C.P.) *Haridra* (C.P.)	250 250	8	1:8	6	1.10 L
B	*Chitrak* (C.P.) *Haridra* (C.P.)	250 250	8	1:8	6	1.00 L
C	*Chitrak* (C.P.) *Haridra* (C.P.)	250 250	8	1:8	6	1.150 L

C.P.: Coarse powder

Table 5: Showing details of preparation of Intermediate product involve in pharmaceutical study of batch II

Sample	Ingredients	Quantity	Process	Duration	Final yield (Kg)
A	*Kwtaha* of *Chitrak* & *Haridra* *S. Shilajeet* *S.Guggul*	1.10L 250 gm 250 gm	Dissolution & drying	10 days	0.537
B	*Kwtaha* of *Chitrak* & *Haridra* *S. Shilajeet* *S.Guggul*	1.00L 250 gm 250 gm	Dissolution & drying	11 days	0.545
C	*Kwtaha* of *Chitrak* & *Haridra* *S. Shilajeet* *S.Guggul*	1.150L 250 gm 250 gm	Dissolution & drying	11 days	0.546

Table 6: Showing Step II of Batch II of Pharmaceutical study of *Sahaj Vati*

Sample	Ingredients/Intermediate Product	Quantity	Process	Duration (Days)	Final Yield
A	I.P. (having *kwatha* / extract of *Chitrak* & *Haridra* and S. *Shilajeet* & S. *Guggul)*	0.517	*Bhavana of Agnimatha Kwatha*- 1.625 L (For seven *Bhavana*)	44 days	0.559 kg
B	I.P. (having *kwatha* / extract of *Chitrak* & *Haridra* and S. *Shilajeet* & S. *Guggul)*	0.519	*Bhavana of Agnimatha Kwatha*- 1.625 L (For seven *Bhavana*)	32 days	0.564 kg
C	I.P. (having *kwatha* / extract of *Chitrak* & *Haridra* and S. *Shilajeet* & S. *Guggul)*	0.522	*Bhavana of Agnimatha Kwatha*- 1.625 L (For seven *Bhavana*)	28 days	0.572

I.P.: Intermediate Product

Table 7: Showing solid content of *Haridra* and *Chitrak*

Name of *Dravya*	Quantity of *Dravya*	Quantity of water	Ratio (*Dravya*: water)	Solid Content	Duration
Haridra	100 gm	800 ml	1:8	10 gm	20 hrs
Chitrak	100 gm	800 ml	1:8	11gm	20 hrs
Agnimantha	100 gm	800 ml	1:8	03.5 gm	08 hrs

DISCUSSION

It was observed that 32.96% and 72.8% of *Shilajeet* and *Guggul* (Table 2) was obtained respectively after *Shodhan* process. *Shilajeet* is thick exudates ooze from the mountain during summer season and after exudation, it flow on the surface from where other substances may also incorporated in it before converting in to solid form (*Shilajeet* stone). During collection of *Shilajeet* some stone particle, soil & vegetation of that region may also collected with *Shilajeet*. In *Shodhan* process, *Shilajeet* stone was broken in to small particle, dissolve in to hot water and set aside for twenty four hours, after that it was decanted in second container, this process was successively repeated up to five times. It is reported that *Shilajeet* easily dissolves in water without leaving any residue [13] so that second container mainly have dissolve *Shilajeet* with less insoluble matter which may be due to handling and after successive process up to five times only *Shilajeet* goes in to fifth container. And after complete drying of liquid of fifth container, pure *Shilajeet* was obtained.

Guggul, the gum-resin exudates of *Commiphora mukul*, is extracted by the method of tapping, in this method an incision is made in the bark of the plant and gum exudates is collected as it oozes out of the bark. Generally it is collected by the tribal people using the traditional method i.e. they give several deep incisions on the stem to get maximum yield so that there may be possibility of other part of plant such as bark, leaves etc present in it. In *Shodhan* of *Guggul*, *swedan* was done in *dola yantra* having *Triphala Guduchi kwatha* and during *swedan* process *Guggul* dissolve in *Triphala Guduchi kwatha* goes in to medium from *pottali* through dissolution while insoluble matter remain in the *pottali*, in this way *suddha Guggul* was obtained in *Triphala Guduchi Kwatha* after complete drying.

There are two types of solid-state synthesis i.e. high-temperature solid-state synthesis and mechanochemical synthesis. In the former powdered reactants are mixed and reacted in an oven or furnace at a sufficiently high temperature to cause reaction, usually without melting the reactants. This method is mainly restricted to the synthesis of inorganic compounds (e.g. *Bhasma*) that are stable at the high temperatures. [14] and later involve mechanical grinding of the dry reactants without heating (apart from any heating that results from the conversion of the mechanical

energy of grinding into heat), is suitable for reactions involving organic compounds. During drug designing, we were thinking that which process is suitable of pharmaceutical processing of *Sahaj vati* having mainly organic ingredient and after scrutinizing the Ayurvedic literature, it was observed that process of *bhavana* is suitable for preparation of *Sahaj vati*. And process of *bhavana* is much nearer to mechnochemical synthesis or Mechanochemistry in contemporary science, a branch of chemistry concerned with chemical and physicochemical transformations of substances in all states of aggregation produced by the effect of mechanical energy' [15] i.e. dealing with ultra-fast chemical reactions between solids and surrounding gaseous or liquid molecules under mechanical forces [16.] In mechanochemical reactions, small quantity of liquid is deliberately added to the reaction mixture and presence of small amounts of ''appropriate'' solvents, demonstrating a significant improvement in the rate of product formation [17]. It is reported that very small amounts of added liquid can dramatically accelerate and even enable mechanochemical reactions between solids and particle size reduction, uniform distribution occur due to this process. After that we had decided that *Sahaj vati* was prepared by *bhavana* of *agnimanth kwatha* (organic liquid) for both batches after that tablet and *vati* was prepared for batch I and II respectively.

It was observed that 1.052, 1.060 and 1.054 kg of *Sahaj vati* was obtained from 1.00 kg of raw materials (*Suddha Shilajeet, Suddha Guggul, Haridra*, and Chitrak) for each samples. Thus there was increase of 0.52, 0.060 and 0.54 kg for three samples of batch I respectively. This increase was due to *bhavana* of *Agnimatha kwatha* and from the (**Table 7**), it was observed that as 100 gm of *Agnimanth kwatha* content 3.5 gm of solid contents. Total 1.850 kg of *Agnimatha kwatha* was used for *bhavana* of batch I and it put down 64.75 gm of solid content so that theoretically 64.75 gm should be increase in weight after process but due to pharmaceutical processing there was 12.75, 4.75 and 10.75 gm theoretical loss occur respectively for three samples of Batch I.

Sahaj vati of Batch II was prepared in two steps, in first steps intermediate product was prepared by dissolving s*uddha Shilajee*t and *Guggul* in *kwatha* of *Haridra* and *Chitrak*. From table 4 it was observed that *kwatha* prepared by total 500 gm of *Haridra* and *Chitrak* was used for dissolution of 500 gm of *suddha Shilajeet* and *Guggul* and their weight has been increase by 37, 45 and 42 gm respectively for three samples of batch II (Table 5). But when we go through (Table 7), it showed that 200 gm of *Haridra* and *Chitrak* was produce 21 gm of solid content so the basis of table 7, 550 gm of *Haridra* & *Chitrak* produced 51.5 gm solid contents and it may be added in intermediate product but there are theoretically 14.5, 6.5 and 9.5 gm loss occur at step first. During steps II, 22, 22 and 26 gm weight gain was observed from intermediate product for three samples this increase was possible due to addition of *Agnimantha kwatha* during *bhavana*. From table it was observed that 100 gm of *Agnimanth kwatha* content 3.5 gm of solid contents (Table 7) and 850 gm of *Agnimantha kwatha* was used for *bhavana* of three samples, so that theoretically increase of 29.75 gm may occur in each sample but due to processing 7.75. 7.75 and 3.75 theoretical loss take place for three samples.

STANDARD OPERATIVE PROCEDURE

1.612 kg *suddha Shilajeet* was obtained from .890 kg of *Shilajeet* stone by *shodhan* process. In this process 24 liter of water was used and *shodhan* was completed in 32 days. Out of 32 days, 9 days were used for *shodhan* process and 23 days for drying of decanted liquid in oven at 45^0C.

1.820 Kg *suddha Guggul* was obtained from 2.5 kg of *asuddha Guggul* by *swedan* process. For *swedan*, 15 liter of *Triphala-Guduchi kwatha* was used and completed by 16 hours of heating at temperature of 80 ^{0}C. After that semi solid *Guggul* was placed in oven at 45 ^{0}C for 28 days. 15 liter of *Triphala-Guduchi Kwatha* was prepared by 13 hours of heating at temperature of 100 ^{0}C from 3.6 Kg of *Triphala Churna* & 1.8 kg of *Guduchi* with 32 liter of water.

In batch I, 1.060 Kg of *Sahaj vati* was prepared having ingredients *Suddha Shilajeet, Suddha Guggul, Chitrak* and *Haridra* of 250 gm each and 3 liter *of Agminatha kwatha* used as *bhavana drava* for seven *bhavana*. 3 liter of *Agnimantha kwatha* was prepared from 1.85 kg of *Agnimantha churna* with 30 liter water and completed in 16 hours at temperature 100 ^{0}C. 13 hours was taken for each *bhavana* in this way total 90 hrs was taken for seven *bhavana*. After that semi solid mixture was placed in oven at 45 ^{0}C for 19 days, in this way total 29 days were used for completion of process.

Batch II was prepared in two steps, in first step 1.10 lit of *Haridra-Chitrak kwatha* was prepared

by using 250 gm of *Haridra* & 250 gm of *Chitrak* and 8 liter and completed by 7 hours of heating of at 100 ^{0}C. 250 gm of *Guggul* & 250 gm of *Shilajeet* were dissolved in it and placed in oven at 45 ^{0}C for 10 days in this way 0.542 kg of intermediate product was obtained. In second steps, intermediate product was subjected to *bhavana* of 1500 ml of *Agnimatha kwatha* for seven *bhavana* and 18 hours were taken for each *bhavana* in this way total 126 hours was taken for seven *bhavana*. 1500 ml of *Agnimatha kwatha* was prepared by taking 950 gm of *Agminatha kwatha* with 13.5 liter water at temperature of 100 ^{0}C and after that 10 days were taken for preparation, in this way total 37 days were used for completion of process.

CONCLUSION

Sahaj vati was having ingredient *sudha Shilajeet* and *Guggul*, *Chitrak* and *Haridra* prepared by seven *bhavana* of *Agnimanth kwatha* in two batches (three samples for each) with slight modification of processing. There are 52, 54 and 60 gm weight gain in three samples of batch I and weight gain of 37, 45 and 42 gm for three samples in Batch II.

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