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Standardization of Bindu Ghrita

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ABSTRACT:

One of the major contributions of Ayurveda is the dosage form called Sneha Kalpana where ghrita and taila are processed in such a way that all the phytochemicals from the plant parts are transferred to the lipid media, mostly the ones which are lipid soluble. The process of making Sneha Kalpana is divided into two steps; the first is Sneha Murchchhana and the second is Sneha Paka. Sneha Murchchhana is performed to remove doshas from the lipid media while Sneha Paka is the preparation of medicated ghrita or taila (Sneha Kalpana). The product obtained after the process of Sneha paka is known as Siddha ghrita or Siddha taila. There are various formulations of Siddha ghrita and Siddha taila given in the Ayurveda text. Bindu Ghrita is one of the formulations of ghrita, mentioned in Ayurveda texts like Chakradatta, Sharangadhara Samhita, Bhaishajya Ratnavali, Gadanigraha and Yoga Ratnakara. The word Bindu suggests its therapeutic use indicating the number of *Bindus* applied on the *Nabhi* (umbilicus) which is equal to the number of Virechana Vega (purgations). Internal use of Bindu Ghrita is also suggested in some texts. Bindu Ghrita is used to treat Udara rogas mainly in Jalodara (Ascites). Its other indications are as Kushtha, Aadhmana, Mandaagni, Gulma etc. There have been very few works done on this formulation, and no work on the standardization of Bindu Ghrita has been undertaken till date. This study focuses on the pharmaceutical as well as analytical standardization of Bindu Ghrita as per the reference of Sharangadhara Samhita and is one of the first studies reported on its standardization.

Keywords – Sneha Kalpana, Bindu Ghrita, Jalodara, Virechana Vega, Murchchhana, Udara roga.

INTRODUCTION

The fundamental objective of Ayurveda is the maintenance of health i.e. "*Swasthasya Swasthaya Rakshanam*" and curing diseases i.e. "*Aturasya Vikara Prashamanam*"¹. *Bhaishajya Kalpana* is one of the branch of Ayurveda that deals with the pharmaceutical preparation of Ayurveda formulations. *Sneha Kalpana* is one of the unique dosage forms of Ayurveda which is explained in *Bhaishajya Kalpana*.

Sneha Kalpana is medicaments prepared from Sneha i.e. lipid material. Sneha siddhi is the process of making



oleaginous medicaments. While preparing *Sneha Kalpana* we have to consider three factors, these are *Kalka dravya*, *Sneha dravya* and *Drava dravya*. *Kalka dravya* is the paste of herbal ingredients, *Sneha dravya* is any lipid (Usually *taila* and *ghrita*) and *Drava dravya* could be *Ksheera*, *Kwatha* or water i.e. liquid media. These three are taken in a definite proportion and are subjected to a heating pattern which is unique for the *Sneha siddhi* process.

Lipid soluble drugs have better Pharmacokinetic action in Sneha Kalpana form compared to Kwatha or other watersoluble dosage forms because lipid-soluble substances readily permeate into the cell membrane due to their fatsoluble nature. Bindu Ghrita is one of the Sneha Kalpana, which is mentioned in texts like Chakradatta. Sharangadhara Samhita, Bhaishajya Ratnavali, Gadanigraha and Yoga Ratnakara. This ghrita is named Bindu because of its therapeutic dose which causes its unique action. Local application of one bindu of Bindu Ghrita on Nabhi will result in one Virechana Vega and so on, i.e. a number of bindu will cause an equal number of Virechana Vegas. This unique property is responsible for the name *Bindu*. One *Bindu* is approximately about 0.5ml.² Bindu Ghrita is indicated in a broad spectrum of diseases, mostly the ones caused by the malfunctioning of Agni. Diseases like Udara roga, Kushtha, Adhmana, Mandagni and Gulma etc. are therapeutic indications of Bindu Ghrita.

Till date no studies about the Standardization of *Bindu Ghrita* were carried out, therefore considering the wide array of therapeutic activities of *Bindu Ghrita* and the unavailability of data on standardization of the same, it was found necessary to standardize *Bindu Ghrita*. Considering all the above-mentioned factors the present study was planned accordingly.

MATERIALS & METHODS

The study was mainly carried out in two different stages

- · Pharmaceutical Study
- Analytical Study

[A] Pharmaceutical Study

The pharmaceutical study consists of

1. Preparation of coarse powder of ingredients

- 2. Ghrita Murchchhana
- 3. Preparation of Bindu Ghrita (3 batches)

1. Preparation of coarse powder of ingredients

Collection of Raw Materials -

All the raw materials were procured from the pharmacy of the National Institute of Ayurveda, Jaipur. Except for Shankhini (replaced with Shankhapushpi), Satala (Var. Euphorbia tirucalli), Dantiphala (Jayapala), Koshataki, Devdali, Nilini, Aparajita, Hemkshiri were procured from raw drugs supplier from Maharashtra and fresh Matulunga, Snuhi Ksheera, Arka Ksheera were procured from a local gardener from Jaipur and identified by the expert of Dravyaguna department of NIA Jaipur. Before undergoing any pharmaceutical process there was the need for careful inspection of raw materials to detect foreign matters like sand, dust and seeds etc. The foreign materials were separated by the hand picking and sieving process. Then they were stored in an airtight glass container and used as per requirement.

Physical impurities were removed from the herbal drugs and drugs were sun-dried and coarse powder was made using laboratory-based Mortar and Pestle. The *Bindu Ghrita* was prepared using the reference mentioned in *Sharangadhara Samhita*. Three samples of *Bindu Ghrita* were prepared in the Drug Manufacturing Laboratory of the Department of *Rasashastra* and *Bhaishajya Kalpana*, NIA Jaipur. Physico-chemical study and Analytical study were performed in the Drug Testing Laboratory of NIA Jaipur and S.R. laboratory Jaipur. (Ayush certified laboratory)

2. Ghrita Murchchhana

The reference used for *Ghrita Murchchhana* was taken from *Bhaishajya Ratnavali*, Principle followed in the process was *Sneha Paka* principle itself.

 Table 1 Showing Ingredients of Ghrita Murchchhana³

Out of all the drugs mentioned in table 1, coarse powder of drugs numbered 2-7 were taken and added with *Matulunga Nimbu Swarasa* (Fresh Fruit Juice) and mixed properly in a mortar pestle. A required quantity of water was added till the *Kalka* was properly formed.

After the formation of *Kalka*, *Go-ghrita* (2.5Kg) was heated to make it free from moisture. The temperature achieved during the process was around 100°C, this heating process took 20 mins to make the entire amount of *ghrita* free from moisture. After this *go-ghrita* was kept aside for self-cooling. When the temperature of *go-ghrita* was around 70°C, *Kalka* was added to it. *Kalka* was added slowly in the *ghrita* and stirred continuously. After this process mentioned quantity of water (10 litres) was added in this. The heating was started and was continued till the *Sneha Siddhi Lakshanas* were achieved. Heating was discontinued once *ghrita* started showing all *Sneha Siddhi Lakshanas*.⁴ *Ghrita* was kept aside for self-cooling (70°C) and was filtered through a double-layered Muslin cloth. For all three batches of *Bindu Ghrita*, the required amount of *Murchchhita go-ghrita* was prepared in one batch.

The final product i.e. *Murchchhita ghrita* (2328g with 6.88% loss) was weighed and kept in a PET jar once it was at room temperature. (Fig. 1)

3. Preparation of *Bindu Ghrita*

The reference used in the preparation of *Bindu Ghrita* is from *Sharangadhara Samhita Madhyam Khanda*, *Sneha Kalpana Adhyaya*. The principle used in this process was *Sneha Paka*.

 Table 2
 Showing Ingredients of Bindu Ghrita for each

 sample⁵

Drugs numbered from 2 - 20 in table 2 were cleaned and *yavakut churna* i.e. coarse powder was prepared. The process was done separately for each ingredient. For making *Kalka*, coarse powder of all drugs was added with a small quantity of water to achieve a *Kalka* (Paste) like appearance. Later *Murchchita go-ghrita* was taken into a stainless_steel vessel and it was heated just to make it moisture free. (Temperature achieved 100°C)

Then *Kalka* was added slowly with continuous stirring. After the addition of *Kalka*, *ghrita* temperature was noted around 70°C. Later to this water, *Snuhi Ksheera* and *Arka Ksheera* were added in the mentioned quantity. The temperature was again fallen down to 50°C. The mixture was heated till all the water was evaporated. This was indicated by the appearance of *Sneha Siddhi Lakshanas*. *Phena Shanti*, the appearance of *Varti* and absence of cracking sound in the *Ghrita* and *Kalka* when exposed to flame are the *Sneha Siddhi Lakshana*. After the appearance of these *Lakshana*, the heat was discontinued. After a few minutes, the prepared *Bindu Ghrita* was filtered using a double-layered Muslin cloth and stored inside a PET jar after self-cooling. (Fig. 2)

In a similar way, a second sample and the third sample of *Bindu Ghrita* were prepared. The three samples were coded as BG-1, BG-2 and BG-3 respectively in this study.

Table 3 Showing the weight loss of 3 Samples of BinduGhrita in Sneha Paka

[B] Analytical Study

Tests were carried out as per the protocol for testing ASU drugs which included Organoleptic parameters, Physicochemical parameters like Viscosity, Specific gravity etc. and other tests like Heavy metal analysis, Aflatoxins & Microbial analysis. HPTLC of the samples was also carried out.

Organoleptic Test -

Table 4Results of Organoleptic characters of BG-1, BG-2 and BG-3

Physico-chemical and Miscellaneous Test⁶ –

Table 5Results of the Physico-chemical andMiscellaneous parameters of Bindu Ghrita Samples

RESULTS AND DISCUSSIONS

Ayurveda formulations like Bindu Ghrita are not yet standardized in API and AFI. There was an immense need to standardize this formulation using Physico-chemical or Analytical parameters. The word Bindu suggests its therapeutic use indicating the number of bindus (drops) applied on the Nabhi (umbilicus) which is equal to the number of Virechana Vega (purgations). Bindu Ghrita one among the rare formulations were external application of the medicament can cause purgations in the patients probably due to a combination of powerful purgative drugs like Danti, Jayapala, Hemakshiri, Snuhi Ksheera etc. Internal use of Bindu Ghrita is also suggested in some texts. Bindu Ghrita is used to treat Udararogas mainly Jalodara (Ascites). Its other indications are Kushtha, Aadhmana, Mandaagni, Gulma etc.

In the present study, *Bindu Ghrita* was prepared according to the reference of *Sharangadhara Samhita*. *Murchchhana* was done prior to *Sneha paka* to remove *Ama dosha* which can be considered as unwanted components in the raw *ghrita*, like intermediate chemical constituents, dissolved gases, adulterants and moisture present in raw *ghrita* or developed due to long time storage. During *Sneha paka Mandagni* (i.e. 60-80°C) was maintained throughout the procedure in order to prevent the evaporation of active principles, to avoid adhering of *Kalka* on the bottom of the vessel as well as to provide sufficient time for the active principles to get incorporated into *ghrita*.

Phena Shanti, absence of frothing is one of the Sneha Sidhi Lakshanas which denotes completion of the process of Sneha paka. Ghrita is a saturated fatty acid with a single bonded structure. On heating, it undergoes hydrolysis. Once the water content evaporates it results in subsiding of froth in the ghrita. Absence of crackling sound and appearance of Varti indicate the absence of moisture content in the prepared ghrita. In the present study an average loss of 9.33% was observed which may be probably due to the absorption of ghrita by the kalka part. Normally the colour of ghrita depends on the constituents present in the ghrita, the colour of all three samples was found yellowish brown. The odour was typical aromatic which was seen in all three samples. After paka, the odour of samples leads to aromatic due to the addition of Kalka

dravyas and Drava dravyas.

Minimal variations were found in the Physico-chemical parameters of all the three samples. Viscosity was in the range 35.75cP to 37.50cP, Specific gravity was found to be 0.9450 to 0.9595, Refractive index was 1.480 to 1.485, Iodine value between 27.80 to 30.75, Acid value found in the range 0.04 to 0.06, Peroxide value was between 3.50 to 3.98, Saponification value came out between 273.96 to 296.50, Ester value was 273.92 to 296.45 and the total fatty matter was 96.75 to 97.75. Rancidity was absent in all three samples. Heavy metals & aflatoxins found in all three samples were within permissible limits. Microbial analysis shows that all three samples have microbial count within normal limits. HPTLC report of samples BG-1, BG-2 & BG-3 show a large number of spots, which denotes that samples have a large number of Phytoconstituents. (Fig.3) This indicates the presence of Phytoconstituents in all multiple ingredients added in the preparation of Bindu Ghrita. HPTLC provides qualitative information on the main constituents of the drug. In the present study, methanolic extract of the sample was used and the solvent system was toluene and ethyl acetate in the ratio of 9:1 respectively. For determination of the TLC plate methanolic H₂SO₄ was used. Samples of Bindu Ghrita were analyzed on different wavelengths 254 nm, 366 nm and 510 nm. BG-2 shows the maximum number of spots in visible light. The presence of these spots could be due to the addition of various Kalka dravyas and Drava dravyas. But due to the absence of any standards, the specific compound could not be separately identified. The scanning data shows different spots visualized get confirms the chemical nature and distribution pattern in the specified mobile phase.Table 6 Results of HPTLC Finger Print data of BG-1, BG-2 and BG-3

CONCLUSION

The Physico-chemical parameters are important for the quality control of ASU formulations. The results of this study may be used as reference standards for *Bindu Ghrita*

and will also be helpful in further studies of similar kind.

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S.No	Name	Latin Name	Part Use	Quantity
1	Go-ghrita	Clarified Butter	-	2.5Kg
2	Haritaki	Terminelia chebula	Fruit	156.25g
3	Vibhitaki	Terminelia bellerica	Fruit	156.25g
4	Amalaki	Embelica officinalis	Fruit	156.25g
5	Musta	Cyprus rotandus	Rhizome	156.25g
6	Haridra	Curcuma longa	Rhizome	156.25g
7	Matulanga Nimbu	Citrus medica	Swarasa (Fresh Fruit Juice)	156.25g
8	Water	-	-	10 Ltr.

 Table 1 Showing Ingredients of Ghrita Murchchhana

Table 2 Showing Ingredients of Bindu Ghrita for each sample

S.No.	Name of Dravya	Latin Name	Part Use	Quantity
1	Go-ghrita (Murchchhita)	Clarified Butter	-	768g
2	Chitraka	Plumbago zeylanica	Root	12g
3	Shankhapushpi	Convolvulus pluricaulis	Panchanga	12g
4	Haritaki	Terminalia chebula	Fruit	12g
5	Kampillaka	Mallotus philipinesis	Phala raja	12g
6	Shweta Trivrita	Operculina terpethum	Root	12g
7	Krishna Trivrita	Operculina terpethum	Root	12g
8	Vriddhadaru	Argyreia nervosa	Root	12g
9	Aragvadha	Casia fistula	Fruit Pulp	12g
10	Danti	Baliospermum montanum	Root	12g
11	Dantiphala	Croton tiglium	Seed	12g
12	Koshataki	Luffa acutangular	Fruit	12g
13	Devdali	Luffa echinate	Fruit	12g

14	Nilini	Indigofera tinctoria	Whole Plant	12g
15	Aparajita	Clitoria ternatea	Whole Plant	12g
16	Satala	Euphorbia tirucalli	Whole Plant	12g
17	Pippalimoola	Piper longum	Root	12g
18	Vidanga	Embelia ribes	Fruit	12g
19	Kutaki	Pichrorrhiza kurroa	Root	12g
20	Hemkshiri	Argemona maxicana	Whole Plant	12g
21	Snuhi Ksheera	Euphorbia nerifolia	Latex	288g
22	Arka Ksheera	Calotropis procera	Latex	96g

Table 3 Showing the weight loss of 3 Samples of Bindu Ghrita in Sneha Paka

Sample	Date of Commencement	Date of Completion	Initial weight of Murchchhita Ghrita	Weight of <i>Bindu Ghrita</i> after <i>Paka</i>	Loss of <i>Ghrita</i>	% Loss	Mean of Loss (in %)
BG-1	27/01/2022	29/01/2022	768g	683.52g	84.48g	11.00%	9.33 %
BG-2	05/02/2022	07/02/2022	768g	708.48g	59.52g	7.75%	
BG-3	11/02/2022	13/02/2022	768g	696.58g	71.42g	9.30%	

Table 4 Results of Organoleptic characters of BG-1, BG-2 and BG-3

S.N	Organoleptic Character	Normal Go- Ghrita	Murchchhita Go- ghrita	SAMPLE-1 (BG-1)	SAMPLE-2 (BG-2)	SAMPLE-3 (BG-3)
1	Colour	Light yellow	Yellowish (Dark Yellow)	Yellowish Brown	Yellowish Brown	Yellowish Brown
2	Odour	Characteristic of <i>Go-ghrita</i>	Characteristics of Kalka dravya specially Haridra	Aromatic	Aromatic	Aromatic
3	Consistency	Semisolid	Semiliquid	Liquid	Liquid	Liquid
4	Appearance	Oily	Oily	Oily Viscous	Oily Viscous	Oily Viscous

S. NO	Parameters	BG – 1	BG – 2	BG – 3
1	Viscosity	35.75cP	37.50cP	36.75cP
2	Specific gravity	0.9595	0.9450	0.9545
3	Refractive Index	1.480	1.485	1.482
4	Rancidity	Absent	Absent	Absent
5	Iodine Value	28.50	27.80	30.75
6	Acid Value (mg KOH/g)	0.06	0.04	0.05
7	Peroxide Value	3.50	3.98	3.95
8	Saponification Value (mg KOH/g)	274.52	273.96	296.50
9	Ester Value	274.46	273.92	296.45
10	Total fatty matter	96.75	96.95	97.75
11	Heavy Metals (mg/Kg or ppm) Lead (Pb) Arsenic (As) Cadmium (Cd) Mercury (Hg)	1.08 0.21 BLQ (LOQ 0.01) BLQ (LOQ 0.01)	1.38 0.16 BLQ (LOQ 0.01) BLQ (LOQ 0.01)	0.93 0.17 BLQ (LOQ 0.01) BLQ (LOQ 0.01)
12	Total Aflatoxins (mg/Kg or ppm) Aflatoxin B1 Aflatoxin B2 Aflatoxin G1 Aflatoxin G2	BLQ (LOQ 0.05) BLQ (LOQ 0.05) BLQ (LOQ 0.05) BLQ (LOQ 0.05)	BLQ (LOQ 0.05) BLQ (LOQ 0.05) BLQ (LOQ 0.05) BLQ (LOQ 0.05)	BLQ (LOQ 0.05) BLQ (LOQ 0.05) BLQ (LOQ 0.05) BLQ (LOQ 0.05)
13	Microbial Analysis Total Bacterial Count Total Fungal Count	<10cfu/gm <10cfu/gm	<10cfu/gm <10cfu/gm	<10cfu/gm <10cfu/gm

Table 5 Results of the Physico-chemical and Miscellaneous parameters of Bindu Ghrita Samples

Table 6 Results of HPTLC Finger Print data of BG-1, BG-2 and BG-3

Sample 254nm		366nm	510nm	
BG – 1	16 spots visualize	9 spots visualize	10 spots visualize	
BG – 2	14 spots visualize	8 spots visualize	13 spots visualize	
BG – 3	14 spots visualize	10 spots visualize	10 spots visualize	







Pharmaceutical Process of Bindu Ghrita



Figure 9