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Pharmaceutico-Analytical Standardization of *Bhagottar Gudika*: A Herbomineral Formulation

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ABSTRACT
Pharmaceutical standardization is essential to ensure the safety, efficacy, and reproducibility of Ayurvedic formulations. The present study focuses on *Bhagottar Gudika* (BG), a classical herbo-mineral formulation described in *Bhaishajya Ratnavali* (15/127–29), which lacks standardized analytical data. BG was prepared in three batches using purified mercury (*Parada*), purified sulphur (*Gandhaka*), and powdered herbal drugs including *Pippali*, *Haritaki*, *Bibhitaki*, *Vasamoola*, and *Bharangi twak*, with *Babbula patra swarasa* as the *bhavana dravya*. Standard pharmaceutical procedures such as *Shodhana*, *Mardana*, and *Bhavana* were performed following classical texts. The prepared samples were evaluated using organoleptic, physico-chemical, and microbiological parameters as per the guidelines of the *Ayurvedic Pharmacopoeia of India* and CCRAS. Analytical results revealed uniformity in hardness, friability, disintegration time, pH, ash values, and extractive values among the three batches, all within pharmacopoeial limits. Microbial load was also within permissible ranges, confirming safety. The findings establish preliminary standardization parameters for BG, which can serve as reference values and a fingerprint profile for future research. This study highlights the importance of integrating classical Ayurvedic methods with modern analytical tools to ensure quality, safety, and reproducibility of traditional formulations.

Keywords: *Bhagottar Gudika, pharmaceutical standardization, herbo-mineral formulation, Ayurveda, quality control*

Introduction

Pharmaceutics is the science of practical experience which involves preparing medicines from raw drugs. To prepare a palatable, convenient dosage form, which can be administered easily in to the body, some modifications are required through specialized techniques called "Pharmaceutical Processes", or *Samskaras* in *Ayurveda*. The Pharmaceutical study is the study by which a drug formulation has design with optimum pharmacokinetics, stability, delivery and patient acceptance. *Ayurvedic* system of medicine should be considered the pioneer concerning the pharmaceutical processing and therapeutic application of metals. Also in order to ensure the quality control, quality assurance and safety for an *Ayurvedic* drug it is necessary to introduce technological advancements and apprehensions of modern science. To standardize the drug it is necessary to validate it on the basis of modern analytical parameters.
Considering the herbo-mineral compound "*Bhagottar Gudika" (Bhaishjya Ratnawali* 15/127-29) has no standard data available till date. Hence, the present study has been carried out with aims and objectives to develop analytical profile of "*Bhagottar Gudika"* by assessing its organoleptic as well as physico-chemical parameters including hardness, disintegration time, pH, loss on drying, ash values, UV-Vis. Spectrophotometry, HPTLC etc.

AIMS & OBJECTIVES

To prepare three samples of *Bhagottar Gudika*(BG) as per the reference of Bhaishjya Ratnawali
To analyze the prepared samples on various standard parameters

MATERIAL & METHODS

Collections of raw materials:-
All the raw drugs of *Bhagottar Gudika* were procured from the pharmacy of NIA, Jaipur, and raw drugs which were unavailable at pharmacy like *Vasamoola and Babbula Patra* were collected from the periphery and identified by the experts of the P.G. Department of *Dravyaguna Vigyan*, NIA, Jaipur, tested analytically and compared with the standards available in Ayurvedic Pharmacopoeia of India(API); then only utilized for this formulation.

Shodhana* of *Parada* and *Gandhaka
Shodhana of *Parada* was as per the standard reference given in *Ras Tarangini* as given in Table 1. Shodhana of *Gandhaka* was done as per the standard reference given in API as given details also in Table 1. Then *dwiguna gandhaka kajjali* was prepared as given in Table 2.

Preparation of Fine Powders of Herbal Drugs
Crude drugs i.e. *Pippali, Haritaki, Bibhitaki, Vasamoola and Bharangitwaka* were weighed individually. By careful inspection, foreign matters like dust, sand etc. were removed. Then the entire ingredients were cleaned by cloth dusting. Cleaned drugs were pounded separately in the *Ulukhala yantra.* Then they were powdered using the mixer grinder and sieved through 85 no. mesh size. The fine powders thus obtained were weighed separately and stored in air tight plastic bags for further pharmaceutical use. The details of losses are given below in Table 3.

Preparation of *Bhagottar Gudika*:-
- This formulation prepared as per the reference of *Bhaishjya Ratnawali 15/127-9*.
- All the ingredients were weighed as per the requirement.
- At first 15g *kajjali* is taken in *khalva yantra* then each ingredient was mixed in the *khalva yantra* as order given in reference shloka with increasing quantity of drug i.e. 15g Pippali Churna, then 20 g Haritaki Churna, then 25g Bibhitaki Churna, then 30g Vasamoola Churna and 30 g Bharangi Twaka Churna making mixture 140g in total.
- Then *bhawana* was given with *Babbula Patra Swarasa* 21 times. The amount of *swarasa* kept on decreasing with every *bhawana* because of herbal contents absorbing moisture which was not possible to dry completely. After some *bhawana,* the *swarasa* amount was stable.
- After completion of 21 *bhawana*, it was dried completely and powdered. Then honey was added to the mixture and mixed well to form 1 *masha* pills.
- For the purpose of standardization, "*Bhagottar Gudika"* was prepared in three batches with the same reference and procedure.

Analytical Study
The Test parameters were taken according to "Protocol for Testing of Ayurvedic, Siddha and Unani medicines", Govt. of India, Dept. of Ayush, Ministry of Health and Family Welfare, Pharmacopoeial Laboratory for Indian Medicines, Ghaziabad; Ayurvedic Pharmacopoeia of India, 2008 Dept. of Ayush, Govt. of India, and "Laboratory Guide for the Analysis of Ayurvedic and Siddha Formulations", CCRAS, Dept. of Ayush, Govt. of India, 2010.

RESULTS

Table 1: Showing the details of Parada & Gandhaka Shodhana

S.N.	*Dravya*	Weight before *Shodhana* (g.)	After *Shodhana*			Reference of *Shodhana*
			Weight (g.)	Yield (%)	Loss (%)	
1	*Parada*	200	159.8	79.9	21.1	R.T. 5/27-29
2	*Gandhaka*	200	172	86	14	AFI Part-I, App- II pg. no. 363

Table 2: Showing the details of *kajjali* Preparation

Quantity of Shudhha Parada	Quantity of Shudhha Gandhaka	Time of Total Mardana till nischandratva	Amount of kajjali obtained	Loss
80g	160g	13 hours	230g (95.83%)	10g (4.17%)

Table 3: Showing weight of herbal drugs before and after powdering.

S.No.	*Dravya*	Before removing foreign matter and powdering (g.)	After removing foreign matter and powdering		
			Weight (g.)	Yield (%)	Loss (%)
1	*Pippali*	270	225	83.33	16.67
2	*Haritaki*	208	190	91.35	8.65
3	*Bibhitaki*	223	204	91.48	8.52
4	*Vasamoola*	269	200	74.35	25.65
5	*Bharangi*	269	240	89.22	10.78

Table 4: Comparative statement showing the results during the preparation of *Bhagottar Gudika's* three samples.

S.No.	Sample Code	Initial wt. of total contents (g.)	Weight after Bhawana (g.)	%increase in wt. after Bhawana (g.)	Wt. of final product (g.)	Total wt. increased	Wt. gain (%)
1.	BG 1	140g	168g	20%	255g	115g	82.14%
2.	BG 2	140g	172g	22.86%	261g	121g	86.43%
3.	BG 3	140g	171g	22.14%	257.5g	117.5g	83.93%

Table 5: Showing the results of analytical tests of three samples of *Bhagottar Gudika*

Sr . No.	Parameter	BG-1	BG-2	BG-3
Organoleptic Characters				
1.	Appearance	Round shaped uncoated *vati*	Round shaped uncoated *vati*	Round shaped uncoated *vati*
2.	Colour	Black	Black	Black
3.	Taste	*Kashaya, Amla, Katu*	*Kashaya, Amla, Katu*	*Kashaya, Amla, Katu*
4.	Odour	Characteristic	Characteristic	Characteristic
Physico-chemical Parameters				
5.	Hardness (kg/cm^2)	4.5	4.7	4.0
6.	Friability	0.1%	0.1%	0%
7.	Disintegration Time	21 min.	23 min.	20 min.
8.	pH(10%aqueos solution)	5.0	4.8	4.8
9.	Loss on Drying	8.65%	9.35%	7.95%
10.	Total Ash	7.17% w/w	8.45% w/w	7.50% w/w
11.	Acid-insoluble ash	2.47 % w/w	3.12 %w/w	2.64 % w/w

12.	Water soluble ash	5.45% w/w	6.12% w/w	6.25% w/w
13.	Alcohol-soluble extractive	8.42 % w/w	7.92% w/w	7.86% w/w
14.	Water-soluble extractive	34.40% w/w	37.40 % w/w	33.20 % w/w
Microbiological Analysis(cfu/g)				
15.	Total Aerobic Microbial count	80	90	110
16.	Total Fungal count	<10	<10	<10

DISCUSSION

1. **PARADA SHODHANA:-**

The *Shodhana* of *Parada* was carried out as per the reference of *Rasa Tarangini* 5/27-29. In *Shodhana* process, mercury and lime powder were kept in a *Khalva Yantra* & *Mardana* (rubbing) was started and mixed well, the mixture had turned blackish in colour. Rubbing was done for 24 hrs as written in *Ras Tarangini* to do *mardana* for 3 days. Then mercury is separated from the mixture of lime powder, by squeezing it through a two folded cloth. This mercury was again kept in the *Khalva Yantra* and rubbed with an equal part of garlic and half part of *Saindhava Lavana*. After that the colour of the mixture had turned into black and mercury was divided into very fine globules. At this stage mixture washed with hot water and mercury collected by squeezing through a two folded cloth.

After *Shodhana*, the yield of *Shuddha Parada* was 78.9 % and loss of weight was 21.1 % (42.2 g.) is due to procedural loss during *Mardana(Hansa Gati, Dhoom Gati, Adrishya Gati)*, washing process(*Jal Gati*) and purification(*Malgati*).

3. **GANDHAKA SHODHANA :-**

The *Shodhana* of *Gandhaka* was carried out as per the reference of AFI Part-I, Appendix- II, pg. no. 363 (*Rasamrita* 2/3). Prior to *Shodhana, Gandhaka* was converted into coarse powder. It ensures easy melting of *Gandhaka* in the vessel. The cloth used for straining purpose should be smeared with *Goghrita*. It will ensure less loss during pouring of molten *Gandhaka.* After than hot milk was poured in a vessel and the *Goghrita* smeared cloth was tied covering its mouth. Iron pan (*Kadhai*) was kept on mild heat and *Goghrita* was put into it. When the *Goghrita* melted, *Gandhaka* powder was put into it. On melting, *Gandhaka* was immediately poured into the milk through the cloth. *Gandhaka* was thus filtered. The vessel containing the milk was also slightly stirred so that to obtain a uniform consistency of *Gandhaka*. It had collected at the bottom of the vessel containing *Godugdha*. After the completion of the process, *Gandhaka* was washed with warm water and dried well. This process was repeated for 3 times with changing *Godugdha* every time. The *Gandhaka* was washed with warm water, then dried well and powdered. After *Shodhana*, the yield of *Shuddha Gandhaka* was 86% and loss of weight 14% (28g) is due to repeated heating and procedural loss during filtering and washing process.

4. **DWIGUNA GANDHAKA KAJJALI NIRMANA:-**

The preparation of *Kajjali* was carried out as per the reference of *Rasa Tarangini* 6/107. *Samanya Sodhita Parada*(80g) and *Suddha Gandhaka*(160g) was taken in mentioned quantity and triturated in *Khalva Yantra*. Trituration was continued till the *Kajjali* became completely Jet black in colour & obtained *Nischandratva*. For confirmation of *Nischandratva* a pinch of *Kajjali* was added to a drop of water on palm and rubbed gently so as to trace out the free mercury particles. The yield of *Kajjali* was 95.83% and loss of weight 4.17 % (10 g.) is due to procedural loss during *Mardana.*

5. **Preparation of fine powders of Herbal Drugs(*Pippali, Haritaki, Bibhitaki, Vasamoola* and *Bharangitwaka).***

After cleaning and *Shodhana* process all the herbal drugs were powdered by using *Ulukhal yantra,* grinder and then they were allowed to pass through 85 no. mesh size. The total percentage of loss for *Pippali, Haritaki*, *Bibhitaki, Vasamoola* and*Bharangi* are shown in table below. This loss was due to the removal of foreign matter from crude drug as well as due to procedural loss in grinding and in sieving process.

6. Preparation of Babbula Patra Swarasa

Babbula patra are dry in nature and contain very less water content, so it was not possible to obtain its *swarasa* only by grinding and squeezing them. Hence this swarasa was made as per the reference of *Sharangadhar Samhita Madhyam Khanda* 1/2. 100g *Babbula Patra* were washed properly and then kept overnight in ss vessel with double quantity of water i.e. 200ml. Then next day these leaves were taken into the grinder and then crushed with water. After that this mixture was squeezed through cloth to extract *swarasa*. *Swarasa* was collected into measuring glass. Green coloured 250 ml *swarasa* was obtained with the contents added from the leaves.

A) PHARMACEUTICAL PROCESS:-

Preparation of *Bhagottar gutika*:-

- This formulation prepared as per the reference of *Bhaishjya Ratnawali 15/127-9*.
- All the ingredients were weighed as per the requirement.
- At first 15g *kajjali* is taken in *khalva yantra* then each ingredient was mixed in the *khalva yantra* as order given in reference *shloka* with increasing quantity of drug i.e. 15g Pippali Churna, then 20 g Haritaki Churna, then 25g Bibhitaki Churna, then 30g Vasamoola Churna and 30 g Bharangi Twaka Churna making mixture 140g in total.
- Then *bhawana* was given with *Babbula Patra Swarasa* 21 times. The amount of *swarasa* kept on decreasing with every *bhawana* because of herbal contents absorbing moisture which was not possible to dry completely. After some *bhawana,* the *swarasa* amount was stable.
- After completion of 21 *bhawana*, it was dried completely and powdered. Then honey was added to the mixture and mixed well to form 1 *masha* pills.
- For the purpose of standardization, "*Bhagottar gutika"* was prepared in three batches with the same reference and procedure.
- Increase in weight after *bhawana* is due to addition of total solid content from the *babbula patra swarasa*.
- Then addition of honey is also responsible for the total increase in weight in the final mixture.

Organoleptic Characters

Regarding Organoleptic characters, the colour of "*Bhagottar gutika*" is black. It is smooth in touch due to its herbal ingredient powder and honey as binding agent. Its appearance is round shaped uncoated *vati*, taste is *Kashaya, Amla, Katu. Kashaya rasa* may be due to *Babbula Patra Swarasa bhawana* whose main rasa is *kashaya*. *Amla* may be due to *Haritaki* and *Vibhitaki* & *Katu* may be due to *Pippali* and *Vasa*. Characteristic Odour may be odour developed with mixing of different drugs.

Hardness of the tablet

The hardness of tablet depends upon the nature of material and quantity of excipients used during the preparation of formulation. Hardness is related to the bioavailability of any drug. Hardness of 4 kg/cm^2 is suitable for handling and 6 kg/cm^2 or more would produce highly compact nature. (Laboratory Guide book for the analysis of Ayurveda and Siddha Formulations, CCRAS.)

Hardness of all the three samples is within range after drying of vati.

Friability test

Friability test determines the physical strength of tablet which shows its ability to withstand the abrasion in packing, handling and transporting. Percentage of friability should not be more than 0.8%. That means the drug can be easily transported without any special packing. This test also shows that the physical strength of BG was within normal limit.

Disintegration time

Disintegration time (D.T.) is related with bioavailability of any drug. It is performed to find out that in how much time the tablet disintegrates at thermostatically maintained temperature of 37^{0}C. This one is important because the dissolution rate depends upon D.T. which ultimately affects the rate of absorption and physiological availability of the drug in blood stream. Normally, D.T. for uncoated tablet is 30 minutes.

So, the result shows that D.T. of all the samples are within limit.

pH(10% aq.)

The pH value is one of the main factors influencing the quality of medicine. It always controls many chemical and microbiological reactions. This value conventionally represents the acidity or alkalinity of an aqueous solution and important from the point of view of stability or physiological suitability of drug.
All the three samples of BG were acidic in nature.

Loss on Drying

Moisture content should be low to prevent degradation of product. Excess of moisture in drug encourage the microbial growth, presence of fungi or insects and leads to deterioration following hydrolysis. To estimate the moisture content sample was dried at 105^0 C for 3 hrs.
The result showed that LOD of BG-2 was slightly more in BG-1 it maybe because, it retained some more moisture content.

This showed that LOD of all the three samples under the normal limit (not more than 14%w/w at 105^0c) according to Pharmacopoeia standard for *Ayurvedic* Formulation, CCRAS.

Total Ash

Ash value depends on the presence of inorganic substances in the material. Ash value is the criteria to judge the identity and purity of crude drug. The residue remaining after the ignition is called as Ash which generally contains some inorganic salts derived from the sample but some adulteration maybe added from the sand and soil to the material.
The above data indicate that the total ash of BG-2 is little more than BG-1 & 3 and it may be due to the presence of inorganic impurities like silica.

Acid Insoluble Ash

Acid Insoluble Ash (AIA) is a part of total ash insoluble in dil. HCl. It is recommended for certain drugs because of presence of siliceous materials are determined by it.
Above data showed that AIA was little more in BG-2 and it may be due to the presence of silica in minute quantity in it. All the three samples of BG had the AIA percentage within the normal limit according to Pharmacopoeial standards for *Ayurvedic* Formulation, CCRAS.

Water Soluble Ash

Percentage of Water Soluble Ash of Sample BG-1was 5.45%w/w that of Sample BG- 2 was 6.12% w/w and of Sample BG-3 was 6.25% w/w. So, the mean value of Water Soluble Ash was 5.94w/w. This showed that the ash of BG-3 was slightly more soluble in water compared to the other samples.

Alcohol Soluble Extractive

The determination of extractable matter refers to the amount of constituents in a given amount of medicinal plant material extracted with solvents. In present work, alcohol and water (distilled water) were used to determine the extractive values.
The result showed that the values of Alcohol soluble extractive for all the three samples of BG were close to each other with slightly more value in BG-1.

Water Soluble Extractive

The Water Soluble Extractive values indicate that water soluble constituents present in the sample. Water Soluble Extract of all the raw drugs are within limits when matched with API standard monographs. The results showed that the values of water soluble extractive for BG- 1, 2 and 3 were very close to each other.

Microbiological analysis

From there origin, herbal drugs normally contaminated with microorganisms from soil, air and water. Sometimes, microorganisms potentially pathogenic to human maybe present. So it is necessary to estimate total Microbiological count of any pharmaceutical product.

Microbiological Analysis showed that all the three samples had microbial count within normal limit, as per API. So, all the three samples were not harmful and safe for therapeutic purpose.

CONCLUSION

Bhagottar Gutika (BG) is a *Kharaliya Rasayana*, while preparing this formulation, *bhavana dravya* i.e. *babbula patra swarasa* was added after adding each ingredient of BG in *khalva yantra* and a total 21 *bhawana* were given. 140g initially taken mixture of all ingredients weighed 168g, 172g, 171g after *bhawana* and 255g, 261g and 257.5g after *vati* formation in samples BG-1, BG-2 and BG-3 respectively. Final weight of all the three samples of BG were more than the total initial weight of ingredients. The reason was may be due to the moisture, total solids of *Bhawana dravya* and honey used while manually preparing the *Vati*. The data of analytical tests showed that the results of all the three samples of *Bhagottar Gutika* i.e. BG-1, BG-2, BG-3 were slightly more or less close to each other. So these may be regarded as the standard analytical values/results for the *Bhagottar Gutika* and may be used as a fingerprint for further studies.

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