ORIGINAL ARTICLE

Pharmaceutical standardisation of "*Balachaturbhadrika Sharkar*" prepared using different sweeteners

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Abstract

Aim: With an aim to prepare an efficacious and palatable dosage form for common childhood disorders, a standard operating procedure for pharmaceutical preparation of "*Balachaturbhadrika Sharkara*" using different sweeteners, i.e., sugar, honey, jaggery, and stevia, has been developed in the present research work. **Materials and Methods:** A pilot-scale study has been carried out by various experiments to generate data for optimization of the sugar concentration and method of preparation, which are physically and chemically stable. Four samples of *Balachaturbhadrika Sharkara* were prepared using all four sweetening agents and the sand process for standard of *Balachaturbhadrika Sharkara* was set as a quality specification for the same. **Results and Disucssion:** The optimal sugar concentration for sugar, jaggery, and honey came out to be 66.7% and 6.7% for stevia, as per the results of the pilot study. All the samples had a dark brown appearance except the stevia-based sample. Early completion of *Sharkara* preparation occurs with stevia, with the sample being colorless as well as odorless. **Conclusion:** Among all the four samples, syrup prepared with stevia is low in calorific value and can also be useful for diabetes patients.

Key words: *Balachaturbhadrika Sharkara,* standardisation, sweeteners, *Sharkara*

INTRODUCTION

As quoted by *CharakaAcharya,* the drugs to be administered to children should possess *Madhura* and *Kashaya Rasa*. It is commonly seen that *Churna, Vati, Guti, Kwatha,* etc. are not palatable to children. *Churna* is a solid type of dosage form that is very commonly preferred by the *Vaidyas.* However, administration of *Churna* is not always an easy task because the taste of *Churna* lingers in the mouth for a long time and causes nausea in patients. The shelf life of *Churna* is very short, up to 2 months. In general, this dosage form is administered with some adjuvants (*Anupana*) to avoid its entry into the trachea through the buccal cavity. It is very difficult to administer *Churna* to children, and semi-unconscious patients as it may clog the trachea. Among modern dosage forms, syrup and suspension are the forms that can overcome almost all the demerits of *Churna* without much deviation from *Ayurvedic* principles of pharmaceutics.[1]

Balachaturbhadra Churna is one of the most commonly used formulations described by A*charyaChakradatta* in *Jwaratisara*. It is a homogenous mixture of fine powders of *Ghana* (*Cyperusrotundus*), *Krishna* (*Piper longum*), *Aruna* (*Aconitum heterophyllum*), and *Shringi* (*Pistaciaintegerrima*).[2] The drugs selected for the

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Received: 08-07-2023
Revised: 20-08-2023
Accepted: 30-08-2023

present study, when combined, become very *Tikta*. Thus, it was the biggest challenge to figure out how to make this drug combination most palatable and to formulate this compound drug into syrup form by using different sweetening agents, viz. sugar, honey, jaggery, and stevia (non-caloric). Though the market is flooded with herbal juices and other such liquid preparations, but no research or developmental work has been carried out in this regard to date. This work is an effort to contribute to this fast-growing demand in the market. Considering the above facts, an attempt has been made with the following aims and objectives:

- To prepare an efficacious and palatable dosage form for common childhood diseases
- To prepare *"Balachaturbhadrika Sharkara*" using different sweetening agents, i.e., sugar, honey, jaggery, and stevia
- To explore a standard "pharmaceutical protocol" the for preparation of *Balachaturbhadrika Sharkara* as per the reference of IP.

MATERIALS AND METHODS

Four samples of *Balachaturbhadrika Sharkara* were prepared using different sweeteners as per the optimum sugar concentration obtained from the results of the pilot study**.** Before the development of *Balachaturbhadrika Sharkara,* a pilot study was carried out to generate data for optimization of the sugar concentration and method of preparation, which are physically and chemically stable. Points taken into consideration were sugar concentration, crystallization, palatability, consistency and fermentation.

Firstly, *Balachaturbhadrika Decoction* (*Kwatha*), as per the ingredients listed in Table 1, was prepared as per the conventional method of *Kwatha* preparation. Afterward, various samples of *Balachaturbhadrika Sharkara* using sugar, jaggery, honey, and stevia were prepared**.** As per the results of the pilot study listed in Tables 2-5, the optimum sugar concentration for sugar, jaggery, and honey came out to be 66.7%, but when the quantity of stevia was added at 66.7%, the decoction got frothy. As 1 g of stevia is equal to 10 g of sugar, its optimum concentration came out to be 6.7%.

Table 1: Ingredients of *Balachaturbhadrika Churna*

S. No	Dravya	Latin name
1	Ghana	*Cyperusrotundus*
2	Krishna	*Piper longum*
3	Aruna	*Aconitum heterophyllum*
4	Shringi	*Pistaciaintegerrima*

Main Pharmaceutical Study

Procurement and preparation of raw drugs

The raw drugs were procured from the local suppliers in Haridwar. Sugar, honey, and "organic jiggery," devoid of chemicals, were taken by local confectioners, and Stevia powder from a sweet brand was bought online from natural mantra.com. All the drugs were cleaned properly so that physical impurities or adulterants remained and subjected to shade drying until a constant weight was obtained. Properly dried drugs were then subjected to size reduction with the help of a Pulveriser. *Madhu* (honey) was subjected to chemical tests to confirm its purity.

Preparation of Kwatha

The natural circulation evaporation (*Kwathana*) method was the basic principle followed. The *Yavakuta Churna* (mesh size 44) of the *Kwathadravyas* was mixed with the mentioned quantity of water in a stainless steel cauldron and subjected to an overnight soaking of 12 h to allow the imbibition of the menstrum inside the tissues of the drug so as to escape entrapped air. The next day, constant mild heat was applied to the cauldron with continuous stirring to facilitate the evaporation and reduce the volume of the *Kashaya* (Galenical) to 1/8th of the initial volume of water. After a desirable reduction in volume, the *Kwatha* was strained with double-folded cotton cloth and collected in a separate vessel for further processing. The residue that remained above the cloth was discarded.[3]

Preparation of Balachaturbhadrika Sharkara

The prepared decoction was taken in a stainless steel vessel after filtration. Then a weighted amount of the respective sweetener was added to the filtered decoction. The process was prepared on low heat with continuous stirring until the sweetener was completely dissolved into the decoction. Then the solution was filtered 2 times through stainless steel strainers. The concentration of sugar was measured by using a sugar refractometer. This filtrate was collected and stored at room temperature in airtight, amber-colored glass bottles properly labeled as per Rule 161 of the Drugs

Table 2: Sugar based *Balachaturbhadrika sharkara*

Reference	(*Kwathya Dravyas*)	Water	Reduced upto	Sugar	Sugar concentration	Crystallization
Dravyagunavigyaniyamuttrardh 2/56	100 g	800 mL	100 mL	200 g	70%	Seen on 7th day
Indian Pharmacopoeia	100 g	800 mL	100 mL	66.7 g	66.7%	Not seen

Table 3: Jaggery based *Balachaturbhadrika sharkara*

Reference	*Kwathya Dravyas*	Water	Reduced upto	Jaggery	Sugar concentration	Crystallization
Self- formulated	100 g	800 mL	100 mL	100 g	59%	Not seen
	100 g	800 mL	100 mL	200 g	68%	Not Seen

Table 4: Honey based *Balachaturbhadrika sharkara*

Reference	*Kwathya Dravyas*	Water	Reduced upto	Honey	Sugar concentration	Crystallization
Self- formulated	100 g	800 mL	100 mL	100 g	Below 48%	Not seen
	100 g	800 mL	100 mL	200 g	58%	Not seen
	100 g	800 mL	100 mL	300 g	63%	Not seen
	100 g	800 mL	100 mL	400 g	67%	Not seen

Table 5: Stevia based *Balachaturbhadrika Sharkara*

Reference	*Kwathya Dravyas*	Water	Reduced upto	Stevia	Palatability	Crystallization
Self- formulated	100 g	800 mL	100 mL	66.7 g	Foam was seen/more sweeter	No Seen
	100 g	800 mL	100 mL	6.7 g	As per palatability	Not Seen

Table 6: Practical details of *Balachaturbhadrika sharaka* preparation

Sweetener used	(*Kwathya Dravyas*)	Water	Reduced upto	Quantity of sweetener	Sugar concn	Crystallization
Sugar	2000 g	16 L	2000 mL	1.334 Kg	66.7%	Not seen
Jaggery	1000 g	8 L	1000 mL	2000 g	66.7%	Not seen
Honey	560 g	4480 mL	560 mL	2240 g	66.7%	Not seen
Stevia	2000 g	16 L	2000 mL	134 g	6.7%	Not seen

Table 7: Preparation chart of *Balachaturbhadrika Sharaka*

Results	Sugar	Jaggery	Honey	Stevia
Time taken for preparation of *Balachaturbhadrika* decoction	2.4 h	1 h 30 min	45 min	2.4 h
Time taken for preparation of *Balachaturbhadrika Sharkara*	2 h	1h	40 min	15 min
Final quantity of *Sharkara* obtained	2 L	2 L	2 L	2 L
Percentage of *Sharkara* obtained	100%	200%	400%	100%

and Cosmetics Act 1940 and Rules 1945. Continuous stirring of the decoction was done to avoid burning, and the temperature was maintained between 60°C–70°C. *Sharkara* was filtered through the strainer in a lukewarm condition.

Observations and Results

Tables 6 and 7.

DISCUSSION

For quality assurance of the finished product, it is necessary to evaluate, compare, and discuss the data compiled after several repetition of the same procedure to generate a standard protocol for any formulation.[4] Syrups are liquid preparations of drugs containing a sufficient quantity of sucrose, either to preserve them or to make their administration more comfortable. In the present study, the *Balachaturbhadrika Churna* was prepared into *Sharkara* form by maintaining its sucrose percentage at 66.7 g/100 mL as per the reference given by the Indian Pharmacopoeia. The ratio of jaggery in the syrup has been taken from *vatikalpana*; the use of a double quantity of jaggery gives 66.7% sugar in the syrup. Keeping the same object of sucrose concentration in concern, honey was mixed 4 times more than decoction. As stevia is a non-caloric sweetener, its concentration is maintained according to its palatability and sweetness concentration compared to sugar. During *Sharkara* preparation, as per findings of Table 6, all the samples had a dark brown color, except the stevia-based samples. Specific odours of honey and jaggery were observed in the samples, the other two being odorless.

Preparation of *Kwatha*

The net effect of the boiling, besides the extraction of the aqueous soluble principles, is to render higher molecules or polysaccharides fit for microbial action, eliminate unwanted microorganisms, coagulate or precipitate complex proteins, eliminate excess dissolved oxygen in the solution, and reduce the water activity of the drug, i.e., the free water available within them, which makes the drug susceptible to contaminants.[4] The basic fundamentals told by various *Acharyas* regarding the preparation of *Kwatha* stand testimony to the extraction principles established now. *Yavakuta Churna* (coarse powder-mesh size 44) of *Kwatha Dravyas* was taken so as to facilitate proper extraction of water-soluble constituents. Mass transfer theory suggests that the maximum surface area should be obtained by reducing the drug to individual cells, but in practice, this is not possible because a prolonged size reduction process is likely to lead to decomposition of constituents or loss of volatile materials, and a suspension of extremely fine particles would be very difficult to separate in the final stages. In general, the appropriate degree of size reduction will cause some of the cells of the drug to be broken and provide a particle size to assist penetration of the solvent and escape of soluble matter. Overnight soaking was done to facilitate the imbibition of the menstrum inside the tissues of the drug, which allows the entrapped air to escape and resist the flow of menstruation. The duration of soaking should be decided according to the weather, as excess duration may lead to unwanted microbial growth. Mild heating with a peak temperature maintained around 92°C was applied for proper extraction and to reduce the chances of degradation of the active constituents due to hydrolysis. As the convection current set up by heating at a low temperature for a longer period does not produce sufficient movement of the liquid, continuous mechanical stirring is needed to facilitate the natural circulation of evaporation.

The stability data on any dosage form includes selected parameters that together form the stability profile, which forms the basis for assigning storage conditions and shelf life to pharmaceutical products.[5] The conservation of herbal product attributes during storage is censorious for undertaking therapeutic activity.[6] According to one research, the shelf life of all *Sharkara* has been reported to be approximately 9 years, and the one prepared with Stevia is 3 years.[7] It has been observed that if we prepare the syrup with honey, the cost of the syrup increases. Sodium benzoate is a food-grade, safe preservative that is recommended in food products. Sugar is itself a good preservative, but when it is added in the percentage of 66.7% w/v as per the Indian Pharmacopoeia, there is no need to add the preservatives. Jaggery also works as a preservative at a concentration of 66.7% w/v as depicted in Table 7. The use of honey in diabetes has been validated by biomedical science, which is a well-established fact as per Ayurveda.[8] Four times as much honey gives 67% sucrose in the syrup; a concentration of sugar below 66.7% in the syrup can develop fermentation.[9]

CONCLUSION

The accomplishment of the pharmaceutical preparation of all four samples of *Balachaturbhadrika Sharkara* using four different sweeteners, viz., sugar, jaggery, honey, and stevia, was elaborated in the present research work. As per the results of the pilot study, the optimum sugar concentration for sugar, jaggery, and honey came out to be 66.7%, but in the case of stevia, its optimum concentration came out to be 6.7%. All the samples had a dark brown-colored appearance, except the stevia-based sample. Early completion of *Sharkara* preparation occurs with stevia, with the sample being colorless as well as odorless. Syrup prepared with stevia is low in calorific value and can also be useful for diabetes patients.

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Source of Support: Nil. **Conflicts of Interest:** None declared.