AYU

Access this article online
Website: www.ayujournal.org
DOI: 10.4103/0974-8520.190698
Quick Response Code:

Pharmaceutical Standardization

Pharmaceutical standardization of *Kamsaharitaki* granules

Nidhi Khemuka, Galib R.[1], Biswa Jyoti Patgiri[1], Pradeep Kumar Prajapati[1]

Department of Rasashastra and Bhaishajya Kalpana, Govt. Ayurved College, Jabalpur, Madhya Pradesh, [1]Department of Rasashastra and Bhaishajya Kalpana Including Drug Research, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India

Abstract

Introduction: *Kamsaharitaki Avaleha* is a well-known ayurvedic preparation. Considering certain inconveniences of *Avaleha*, an attempt has been made to convert it into granules that are convenient in handling, dispensing, and storage. **Aim:** To convert *Kamsaharitaki Avaleha* into granules form and develop standard manufacturing procedure. **Materials and Methods**: Seven pilot batches were prepared to fix the ratio of formulation composition. The procedure was repeated for 14 times to ensure the process validation. **Results:** Converting into granules in presence of jaggery and *Haritaki* pulp is found to be difficult. Replacing these two with *Khanda Sharkara* and *Haritaki* powder yielded desired characteristics of granules. **Conclusion:** This modified proportion of ingredients can be considered as standard in preparing *Kamsaharitaki Avaleha* granules. As no manufacturing and physicochemical properties are available for *Kamsaharitaki* granules; the current findings can be considered as standard for future studies.

Key words: Granules, *Kamsaharitaki Avaleha*, *Khanda Paka*, standardization

Introduction

Conversion of formulations into various dosage forms to achieve added benefits keeping intact the therapeutic properties has gained momentum in recent past that has great importance in the market. In addition, standardization, quality control, and shelf life of final products are also other major issues. Shelf life of the formulation always depends on the pharmaceutical procedure and nature of the formulation. Granules are convenient in handling, dispensing, and storage.[1] Considering this, it has been planned to convert *Kamsaharitaki Avaleha*[2] into granules and develop standard manufacturing procedure (SMP).

Materials and Methods

All the herbal drugs and honey were procured from the Pharmacy, Gujarat Ayurved University, Jamnagar. *Yavakshara* was prepared in the Department of Rasashastra and Bhaishajya Kalpana, Institute for Postgraduate Teaching and Research in Ayurveda, Jamnagar. *Khanda Sharkara* (sugar candy) and *Guda* (jaggery) were procured from local market of Jamnagar. All the herbal drugs were authenticated in Pharmacognosy Laboratory of the institute. Formulation composition of granules is placed at Table 1.

Pharmaceutical procedure

Preparation of Churna (powder)

Dried herbal drugs (*Haritaki*, *Sunthi*, *Pippali*, *Maricha*, *Twak*, *Ela*, and *Patra*) were powdered individually in a mixer and sieved through #72 to obtain fine powders. *Yavakshara* was prepared by *Yava Panchanga*.[3]

Preparation of Kwatha (decoction)

Three hundred and eighty-four grams of coarse powder of *Dashamoola* was taken in a stainless steel container of 5 L capacity. Three thousand and seventy-two millilitre of potable water was added to it and allowed to soak overnight. Next day morning, the contents were subjected to heat and stirred continuously throughout the process till the volume

Address for correspondence: Dr. Nidhi Khemuka, Lecturer, Department of Rasashastra and Bhaishajya Kalpana, Govt. Ayurved College, Jabalpur - 282 002, Madhya Pradesh, India.
E-mail: dr.nidhi_ag@yahoo.com

How to cite this article: Khemuka N, Galib R, Patgiri BJ, Prajapati PK. Pharmaceutical standardization of *Kamsaharitaki* granules. Ayu 2015;36:416-20.

Table 1: Formulation composition of *Kamsaharitaki* granules

Ingredients	Botanical name/English name	Parts used	Quantity for *Avaleha*	Quantity for granules
Dashamoola Kwatha				
Bilva	*Aegle marmelos* Corr.	Dried roots	3072 ml *Kwatha*	768 ml
Agnimantha	*Premna integrifolia* Linn.			
Shyonaka	*Oroxylum indicum* Vent.			
Patala	*Stereospermum suaveolens* DC.			
Kashmarya	*Gmelina arborea* Linn.			
Kantakari	*Solanum xanthocarpum* Schrad. and Wendl.			
Brihati	*Solanum indicum* Linn.			
Gokshura	*Tribulus terrestris* Linn.			
Shalaparni	*Desmodium gangeticum* DC.			
Prasniparni	*Uraria picta* Desv.			
Other ingredients				
Haritaki	*Terminalia chebula* Retz.	Fruit pulp	1200 g	162 g powder
Guda	Jaggery	-	4800 g	-
Sharkara	Sugar candy			1200 g
Shunthi	*Zingiber officinale* Roxb.	Dried rhizome	48 g	12 g
Marica	*Piper nigrum* Linn.	Dried fruit	48 g	12 g
Pippali	*Piper longum* Linn.	Dried fruit	48 g	12 g
Twak	*Cinnamomum zeylanicum* Blume.	Dried stem bark	48 g	12 g
Ela	*Elettaria cardamomum* Maton.	Dried seed	48 g	12 g
Patra	*Cinnamomum tamala* Ness.	Dried leaves	48 g	12 g
Yavakshara	Alkaline substance of *Hordeum vulgare* Linn.	Water soluble ash of plant	12 g	3 g
Madhu	Honey	-	384 g	96 g

Table 2: Preparation of *Haritaki Churna*

Batches	Quantity taken (g)	Powder obtained (g)	Powder (%)	Seed (g)	Seed (%)	Loss (g)	Loss (%)
1	300	165	55	117	38	135	45
2	300	162.6	54.2	118	39.33	137.4	45.8
3	300	160.4	53.5	120	40	139.6	46.53
4	300	160	53.33	118	39.33	140	46.67
5	300	164	54.67	116	38.67	136	45.33
6	300	163	54.3	115	38.33	137	45.7
7	300	159	53	118	39.33	141	47
8	300	162.2	54.06	120	40	137.8	45.94
9	300	161.3	53.77	116.5	38.83	138.7	46.23
10	300	163	54.3	115	38.33	137	45.7
11	300	162	54	118	39.33	138	46
12	300	163	54.3	114.5	38.16	137	45.7
13	300	162.5	54.17	119	39.66	137.5	45.83
14	300	161	53.67	120.5	40.16	139	46.33
Average	300	162	54	117.5	39.17	138	46

reduced to a quarter i.e., 768 ml. Throughout procedure of *Kwathana* (boiling), the temperature was maintained in between 85- 95°C. It took 4 h to prepare the *Kwatha*.

Preparation of granules

The general method of preparation emphasized for *Khanda Paka*[4] is followed for the preparation of *Kamsaharitaki* granules (KHG). Ingredients of granules were same as *Avaleha*.[5] Seven pilot batches were prepared for fixing the proportion of formulation. Out of these, initial six batches prepared with *Guda* and *Haritaki* were pulp failed to get converted into granules. They were replaced with *Khanda Sharkara* and *Haritaki* powder in seventh pilot batch. It fulfilled the desired characteristic features of granules. This ratio of ingredients was adopted in further 14 batches of granules to ensure the process validation of KHG.

For granules prepared *Dashamoola Kwatha* (768 ml) was shifted into a stainless steel vessel and was added with 1200 g of *Khanda Sharkara*. The contents were heated at 90–95°C until complete dissolution of *Khanda Sharkara*. This solution was filtered through a clean cotton cloth to separate undissolvable impurities (if any) and further heated until appearance of *Avaleha Siddha Lakshanas*. At this stage, the vessel was removed from the fire and stirred continuously. When the temperature of the contents was reduced to 56–60°C *Madhu* and fine powders of *Haritaki* and later *Prakshepa Dravyas* were added with thorough stirring to get a homogenous blend. The blended mass was passed through #10 sieve to obtain granules and kept for drying at room temperature. The dried granules were packed in airtight container [Figure 1].

Figure 1: Preparation of *Kamsaharitaki granules*; (a) *Dashamoola Kwatha Dravya* soaked, (b) *Dashamoola Kwatha* preparation, (c) filtration of *Dashamoola Kwatha*, (d) sugar candy, (e) *Paka* of *Dashamoola Kwatha* and sugar till *Avaleha Siddhi*, (f) one thread stage of *Paka*, (g) four thread stage, (h) *Apsu Majjana*, and *Pratitastu na Shiryate*, (i) honey, (j) addition of *Haritaki* and *Prakshepa Dravyas* gradually, (k) passing through sieve (l) packaging of granules in airtight container

Observations and Results

Seven pilot batches were prepared for converting *Avaleha* into granules. Preparing granules of *Kamsaharitaki Avaleha* by classical reference is not possible. *Khanda Sharkara* and *Haritaki* powder were used in the place of jaggery and *Haritaki* pulp to prepare granules. Average 54% *Haritaki Churna* detained and percentage yield of *Prakshepa Dravyas* (*Sunthi*, *Pippali*, *Maricha*, *Twak*, *Ela*, and *Patra*) were found 78.70%, 83.60%, 84.67%, 84.70%, 62.60%, and 82.50%, respectively. During the procedure of granules, the temperature was maintained in between 90°C and 100°C and observed *Darvipralepa* at 93°C, *Tantumatvam* at 94°C, *Apsumajjanam* at 94°C and *Sthiratvam* at 95°C. Average yield was found 1497.5 g. It took 7.5 h to complete the preparation of granules. Details of powdering of herbal drugs, results of pilot batches and final batches, and chief desired characteristics of KHG are placed at Tables 2–6, respectively.

Discussion

The proportion of *Dashamoola* and water for the preparation of *Dashamoola Kwatha is* not specified in the text. Considering the *Madhyama* character (moderate hardness) of *Dashamoola*; eight times of water was added, boiled, and reduced to a quarter.[6] The quantity of *Prakshepa Dravya* to be added is also not specified in the text; Ayurvedic Formulary of India (AFI) reference is followed for this. In an attempt to convert *Avaleha* into granules, seven pilot batches of KHG were prepared. Initial attempt (KHGp1) with classical proportion of ingredients did not yield desired characteristics. It was converted into lump. It may be due to the stickiness of *Guda* (*jaggery*). Decreased proportion of *Guda* (half and one-fourth to classical proportion) in KHGp2 and KHGp3 also formed into lump. In the other two pilot batches (KHGp4, KHGp5) instead of *Guda*, *Khanda Sharkara* (sugar candy) was used as the sweetening base with the same ratio of *Kamshaharitaki Avaleha*. However, failed to convert in to granules, it may be due to using of *Haritaki* pulp.

Table 3: Preparation of *Prakshepa Dravya Churna*

Prakshepa Dravya	Weight of raw drug (before removing physical impurities)	Weight of raw drug (after removing physical impurities)	Weight of *Churna*	Percentage yield
Shunthi (g)	500	477.0	375.5	78.70
Pippali (g)	600	578.8	483.9	83.60
Maricha (g)	600	575.0	486.9	84.67
Twak (g)	600	588.8	498.7	84.70
Ela (g)	600	587.0	367.5	62.60
Patra (g)	600	203.0	167.5	82.50

Table 4: Results obtained during preparation of pilot batches of *Kamsaharitaki* granules

Batch	*Dasha-Moola Yava-Kuta* (g)	Water (ml)	*Kwatha* (ml)	*Khanda Sharkara*/ *Guda* (g)	*Haritaki* (g)	Total quantity of *Prakshepa Dravya* (g)	*Madhu* (g)	Yield (g)
KHGp1	188	1500	375	600 g *Guda*	80g powder	37.5	48	694
KHGp2	188	1500	375	300 g *Guda*	80g powder	37.5	48	720
KHGp3	188	1500	375	150 g *Guda*	80g powder	37.5	48	730
KHGp4	188	1500	375	600 g *Khanda Sharkara*	90g pulp	37.5	48	750
KHGp5	188	1500	375	600 g *Khanda Sharkara*	90g pulp	37.5	48	700
KHGp6	188	1500	375	150 g *Guda*	80g powder	37.5	48	714
KHGp7	188	1500	375	600 g *Khanda Sharkara*	80g powder	37.5	48	726

K: *Kashaya*, M: *Madhura*, C: *Katu*, KHG: *Kamsaharitaki* granules

Table 5: Results obtained during preparation of final batches of *Kamsaharitaki* granules

Batch	*Dashamoola Yavakuta* (g)	Water (ml)	*Kwatha* (ml)	*Khanda Sharkara* (g)	*Haritaki powder* (g)	Total quantity of *Prakshepa* (g)	*Madhu* (g)	Yield (g)
KHG 1	375	3000	750	1200	162	75	96	1500
KHG 2	375	3000	750	1200	162	75	96	1500
KHG 3	375	3000	750	1200	162	75	96	1496
KHG 4	375	3000	750	1200	162	75	96	1520
KHG 5	375	3000	750	1200	162	75	96	1506
KHG 6	375	3000	750	1200	162	75	96	1420
KHG 7	375	3000	750	1200	162	75	96	1502
KHG 8	375	3000	750	1200	162	75	96	1490
KHG 9	375	3000	750	1200	162	75	96	1514
KHG 10	375	3000	750	1200	162	75	96	1480
KHG 11	375	3000	750	1200	162	75	96	1510
KHG 12	375	3000	750	1200	162	75	96	1516
KHG 13	375	3000	750	1200	162	75	96	1520
KHG 14	375	3000	750	1200	162	75	96	1490
Average	375	3000	750	1200	162	75	96	1497.5

KHG: *Kamsaharitaki* granules

In KHGp6, *Haritaki* powder was used instead of *Haritaki* pulp and proportion of *Guda* was used ¼ but was also not converted into granules. All these six pilot batches yielded lump like product difficult to convert into granules with characteristic flavour. In the seventh batch, (KHGp7) jaggery and *Haritaki* pulp were replaced with *Khanda Sharkara* and *Haritaki* powder, respectively. This was easily converted into granules. Finally, these ingredients and ratio were considered in the preparation of further 14 batches to ensure the process validation.

Four thread consistency of sugar syrup was prepared to obtain desired characteristics of granules. As most of the *Praksepa Dravya* contains volatile principles, they were added in increments at the end of the procedure with constant stirring to get homogenous blend and to prevent volatilization. Honey was added at 60°C just before adding the powders for getting the perfect consistency of granules.

Conclusion

Converting *Avaleha* into granules help in fixing the dose, easy to administer, and also increases the shelf life. The pilot batches reveal that *Khanda Sharkara* and *Haritaki* powder should be used instead of jaggery and *Haritaki* pulp while preparing granules. As there is no standard published data on

Table 6: Chief desired characteristics of *Kamsaharitaki* granules

Siddhi Lakshana	Time of appearance after addition of sugar candy (min)	Temperature (°C)
Darvipralepatva	After 130	93
Tantumatvam - 1 thread	After 140	94
Apsumajjanam	After 160	94
2 thread	After 170	95
Patitastu na Shiryate	After 190	95
4 thread	After 200	95
Sthiratvam	After 195	95
Addition of *Prakshepa*		
Madhu	After 230	60
Powder	After 235	56-60

this formulation, a comparison is not possible and the current observations may be referred in future studies.

Financial support and sponsorship
IPGT and RA, Gujarat Ayurved University, Jamnagar, Gujarat.

Conflicts of interest
There are no conflicts of interest.

References

1. Paneliya AM, Patgiri B, Galib R, Bedarkar P, Prajapati PK. Pharmaceutical development of granules of vasa avaleha. Ann Ayurvedic Med 2013;2:16-21.
2. Acharya YT, editor. Charaka Samhita of Agnivesha, Chikitsa Sthana. Ch. 12, Ver. 50-52. Reprint Edition. Varanasi: Chaukhamba Prakashan; 2004. p. 366.
3. Shastri AD, editor. Sushruta Samhita of Sushruta, Sutra Sthana. Ch. 11, Ver. 13. Reprint Edition. Varanasi: Chaukhamba Sanskrit Sansthan; 2003. p. 47.
4. Vyas Harikrishna B. Shastri Sankardaji Pade, Aryabhishak, Bhrihatapaka Samgraha. 29th ed. MumbaiSastu Sahitya Vardhaka Karyalaya; 2009. p. 758-9.
5. Annonymous. The Ayurvedic Formulary of India, Part-I. New Delhi: Department of Indian System of Medicine and Homoeopathy, Ministry of Health and Family Welfare GOI; 2001. p. 40.
6. Shastri P, editor. Sharangadhara Samhita of Sharangadhara, Madhayama Khanda. Ch. 9, Ver. 3, Reprint Edition. Varanasi: Choukhambha Orientalia; 2002. p. 212.

हिन्दी सारांश

कंसहरीतकी कणिका का औषधीय मानिकीकरण

निधी खेमुका, गालिब आर., बिस्वाज्योति पटगिरी, प्रदीपकुमार प्रजापति

कंसहरीतकी अवलेह एक सुपरिचित औषधी है। अवलेह निर्माण में आने वाली असुविधा को ध्यान में रखते हुए यह प्रयास, इसे कणिका रूप मे परिवर्तित करने हेतु किया गया है। अवलेह कल्पना को कणिका रूप मे परिवर्तित करने का प्रयास अतिरिक्त लाभ की प्राप्ति के उद्देश्य से किया गया है। कणिका रूप मे औषधि का प्रबंधन एवं संचयन अधिक सुविधाजनक है, यह ध्यान मे रखते हुए कणिका रूप में औषधि का परिवर्तन किया गया है। सात प्रायोगिक वर्ग का निर्माण संघटको के अनुपात निर्धारण हेतु किया गया है। प्रक्रम के पुष्टीकरण हेतु इस प्रक्रिया को चौदह बार दोहराया गया हैं। गुड एवं हरीतकी की लुगदी के उपयोग की स्थिति में कणिका निर्माण एक कठिन प्रक्रिया है। इसे खण्ड शर्करा एवं हरीतकी चूर्ण से स्थानान्तरित करने पर अभीष्ट लक्षणों की प्राप्ति होती है।

घटकों का यह परिवर्तित अनुपात कणिका निर्माण हेतु मानक के रूप में किया जा सकता है। कंसहरीतकी कणिका उपलब्ध नही हैं अतः वर्तमान निष्कर्ष निकालने में इसके मानिकीकरण हेतु सुरिचारणीय है।