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.

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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.

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.                   |            |                      |                       |
| Shalapami                    | Desmodium gangeticum DC.                    |            |                      |                       |
| Prasnipami                   | 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 tamalasess.                      | 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       |
For granules preparedDashamoola 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°CMadhu 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].

**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 (Shunthi, 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. 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 Kamsaharitaki Avaleha. However, failed to convert into granules, it may be due to using of Haritaki pulp.

| 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           |
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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

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.

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

| Batch | Dasha-Moola Yava-Kuta (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        | 1506     |
| KHG 5 | 375                      | 3000       | 750         | 1200                | 162                 | 75                              | 96        | 1420     |
| KHG 6 | 375                      | 3000       | 750         | 1200                | 162                 | 75                              | 96        | 1502     |
| KHG 7 | 375                      | 3000       | 750         | 1200                | 162                 | 75                              | 96        | 1490     |
| KHG 8 | 375                      | 3000       | 750         | 1200                | 162                 | 75                              | 96        | 1514     |
| 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

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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
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Conflicts of interest
There are no conflicts of interest.

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Table 6: Chief desired characteristics of Kamsaharitaki granules

| Siddhi Lakshana | Time of appearance after addition of sugar candy (min) | Temperature (°C) |
|-----------------|--------------------------------------------------------|-----------------|
| Darvipralepatva | 130                                                     | 93              |
| Tantumatvam     | 140                                                     | 94              |
| 1 thread        |                                                        |                 |
| Apsumajanam     | 160                                                     | 94              |
| 2 thread        | 170                                                     | 95              |
| Tantumatvam     | 190                                                     | 95              |
| Shriratvam      | 200                                                     | 95              |
| 4 thread        | 195                                                     | 95              |
| Tantumatvam     | 230                                                     | 60              |
| Shriratvam      | 235                                                     | 56-60           |

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