PRELIMINARY QUALITY CONTROL PARAMETERS OF KAMSAHARITAKI AVALEHA AND ITS GRANULES.

Nidhi Khemuka, Galib R., B.J Patgiri, PK Prajapati
Department of RS and BK, IPGT & RA, Gujarat Ayurved University Jamnagar, India. 561008.
Corresponding authors Email: dr.nidhi-_ag@yahoo.com

Abstract:

Introduction: Kamsaharitaki Avaleha (KHA) is an important Ayurvedic formulation containing Dashamoola and Haritaki as main ingredients and Trikatu, Trijata, Yavakshara as the other. Development of new dosage forms without diluting the basic principles of Ayurveda is the need in current scenario for their global acceptance. Avaleha form has few difficulties such as problems in transportation, fixing of unit dose, chances of microbial growth etc. Considering these inconveniences and to convert it into a dose form with additional advantages; an attempt has been made to convert Kamsaharitaki Avaleha into granules and develop preliminary physico-chemical profile of both formulations. Materials and Methods: Raw materials have been collected from Pharmacy, Gujarat Ayurved University, Jamnagar, and utilized after proper authentication. Avaleha and granules were prepared in Rasashastra and Bhaishajya Kalpana zab, Institute for Post Graduate Teaching and Research in Ayurveda, Jamnagar. The samples were subjected to relevent physico-chemical parameters. Results: The differences in the physico-chemical profile of Kamsaharitaki Avaleha and Kamsaharitaki granules are insignificant. Licrobial count and Heavy metal analysis were within prescribed limits. This indicates quality and safety of both the products.

Key words: Chromatography, Granules, Kamsaharitaki, Microbial overload, Quality.

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Introduction: Kamsaharitaki Avaleha (KHA) is a polyherbal semi-solid formulation, described by Acharya Charaka in disorders like Swayathu (inflammation), Swasa (Asthma), Jwara (Fever), Arochaka (Anorexia). Dashamoola and Haritaki are the main ingredients and Trikatu, Trijata, Yavakshara are the Prakshepa dravyas (condiments). Avaleha was prepared by using Jaggery as base with addition of honey.[1] Formulation composition with proportion is placed at table 1.

Avaleha (confection) form has some demerits like more possibilities of microbial growth, difficult to transport etc. To overcome these problems and to prepare superior dosage form; attempts have been made to develop Kamsaharitaki granules. Preliminary physico-chemical profiles of Kamsaharitaki Avaleha (KHA) and Kamsaharitaki granules (KHG) are not reported till date. Considering this; it has been attempted to develop preliminary physico-chemical profile of KHA & KHG.

Materials and Methods

KHA and KHG were prepared by following standard guidelines. Ingredients and their ratio are same in both the formulations but sugar candy and Haritaki powder were used in place of Jaggery and Haritaki pulp respectively in KHG. Both samples were packed in sterile glass containers (200ml capacity) and subjected to relevant physico-chemical studies in order to develop preliminary analytical profile.

Organoleptic characters: appearance, colour, odour and taste of both the formulation were noted.

Stationary Phase used in High Performance Thin Layer Chromatography (HPTLC) [13] is MERCK - TLC / HPTLC Silica gel 60 F254 on Aluminum sheets and Mobile Phase is - Toluene: Ethyl acetate: Formic acid (10: 3: 1). Anisaldehyde sulphuric acid reagent was used as spray reagent.

**Observations and Results**

Comparative organoleptic characters of KHA and KHG are depicted in Table 2. Physico-chemical characters of KHA and KHG are shown in Table 3. Microbial count of KHG is less than KHA. Microbial counts of both samples are depicted in table 4. Heavy metal analysis of both samples is shown in table 5. The findings of HPTLC at254nm, 366nm and visible light were depicted in table 6. (Plate-1) spots in KHA, 7 spots in KHG were visible in short wave (uv 254 nm). In long wave (uv 366 nm) 6 spots in KHA & 5 spots in KHG were visible and after spraying 6 spots were visible in both samples.

**Discussion**

Considering the changing scenario of the society, conversion of classical dosage forms into new forms that are more palatable, easily absorbable and having shelf life becomes the need of hours. At the same time, one cannot compromise with the desired therapeutic effects. In the current attempt; it has been attempted to convert KHA into granules. Granules are convenient in handling, dispensing, and storage and increase the acceptability of a product, as the granules are free from moisture content, less chance of microbial contamination is expected. Granules also mask bitter taste of drugs and thus increase palatability.

In physico-chemical analysis, organoleptic tests are very important because palatability of a drug is dependent upon these characters. Both drugs were aromatic and have similar taste (astringent and bitter). *Avaleha* was brownish black in colour while granules were creamish brown. This Difference may be because of addition of sugar and *Haritaki* powder in granules.

There was insignificant difference in the preliminary physico-chemical parameters but moisture percentage of granules is less (1.96%) than KHA (15.60%). The reason may be semisolid consistency of *Avaleha* that contains considerable portion of moisture.

PH (1% aqueous solution) shows that both samples were acidic in nature. As tannin is weak acidic nature, [14] the acidic pH of final product may be due to rich tannin content in final product. There was increase of water soluble extractive in KHG (84.97%) than KHA (72.42%), which depicts more bio availability of granules than *Avaleha*. Total microbial count, Heavy metal analyses were within the permissible limits.[15]

**Conclusion**

The differences observed in preliminary physico-chemical parameters of both the drugs are insignificant. These values are nearer to the standards laid down in API. Few parameters like moisture content, total fat content, total solid content, tannins, HPTLC are not mentioned in API. Hence the observation of these parameters can’t be comparable. Absence of microbial contamination and Heavy metals provide the quality and safety aspects of the formulation.

**Acknowledgement**

Authors duly knowledge the Ysu research lab for their kind co-operation and support.

**References:**


Source of Support : Nil
Conflict of Interest : None
Table 1: Formulation composition of Kamsaharitaki Avaleha (KHA)

<table>
<thead>
<tr>
<th>Sl.No.</th>
<th>Ingredients</th>
<th>Botanical Name / English name</th>
<th>Parts used</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dashamoola</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i</td>
<td>Bilva</td>
<td>Aegle marmelos Corr.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>ii</td>
<td>Agnimantha</td>
<td>Premna integrifolia Linn.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>iii</td>
<td>Shyonaka</td>
<td>Oroxylum indicum Vent.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>iv</td>
<td>Patala</td>
<td>Stereo spermumsuaveolens DC.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>v</td>
<td>Kashmari</td>
<td>Gmelina arborea Linn.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>vi</td>
<td>Kantakari</td>
<td>Solanum xanthocarpum Schrad. &amp; Wendl.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>vii</td>
<td>Brihati</td>
<td>Solanum indicum Linn.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>viii</td>
<td>Gokshura</td>
<td>Tribulus terrestris Linn.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>ix</td>
<td>Shalaparni</td>
<td>Desmodium gangeticum DC.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>x</td>
<td>Prasniparni</td>
<td>Uvaria picta Desv.</td>
<td>Dried Root</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Haritaki</td>
<td>Terminalia chebula Retz.</td>
<td>Dried Fruit pulp</td>
<td>1200 g (100 no.)</td>
</tr>
<tr>
<td>3</td>
<td>Guda</td>
<td>Jaggery</td>
<td>-</td>
<td>4800 g (1 Tula)</td>
</tr>
<tr>
<td>4</td>
<td>Trikatu</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i</td>
<td>Shunthi</td>
<td>Zingiber officinale Roxb.</td>
<td>Dried Rhizome</td>
<td>48g (1 Pala)</td>
</tr>
<tr>
<td>ii</td>
<td>Marica</td>
<td>Piper nigrum Linn.</td>
<td>Dried Fruit</td>
<td>48g (1 Pala)</td>
</tr>
<tr>
<td>iii</td>
<td>Pippali</td>
<td>Piper longum Linn.</td>
<td>Dried Fruit</td>
<td>48g (1 Pala)</td>
</tr>
<tr>
<td>5</td>
<td>Trijata</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i</td>
<td>Twak</td>
<td>Cinnamomum zeylanicum Blume.</td>
<td>Dried Stem bark</td>
<td>48g (1 Pala)</td>
</tr>
<tr>
<td>ii</td>
<td>Ela</td>
<td>Elettaria cardamomum Maton.</td>
<td>Dried Seed</td>
<td>48g (1 Pala)</td>
</tr>
<tr>
<td>iii</td>
<td>Patra</td>
<td>Cinnamomum tamala Ness.</td>
<td>Dried Leaves</td>
<td>48g (1 Pala)</td>
</tr>
<tr>
<td>6.</td>
<td>Yavakshara</td>
<td>Alkaline substance of Hordeum vulgare Linn.</td>
<td>Water soluble ash of plant</td>
<td>12 g (1 Pala)</td>
</tr>
<tr>
<td>7</td>
<td>Madhu</td>
<td>Honey</td>
<td>-</td>
<td>384 g (½ Prastha)</td>
</tr>
</tbody>
</table>

Table 2: Comparative Organoleptic Characters of KHA & KHG

<table>
<thead>
<tr>
<th>Parameters</th>
<th>KHA</th>
<th>KHG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Semisolid, homogenous material</td>
<td>Dry, heterogenous</td>
</tr>
<tr>
<td>Colour</td>
<td>Brownish black colour</td>
<td>Creamish brown</td>
</tr>
<tr>
<td>Odour</td>
<td>Aromatic</td>
<td>Aromatic</td>
</tr>
<tr>
<td>Taste</td>
<td>Bitter &amp; Astringent</td>
<td>Bitter &amp; Astringent</td>
</tr>
</tbody>
</table>
Table 3: Physico-Chemical profiles of KHA & KHG at different intervals

<table>
<thead>
<tr>
<th>Parameters</th>
<th>KHA</th>
<th>KHG</th>
<th>API %</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH (1% w/v)</td>
<td>4.68</td>
<td>4.37</td>
<td>3.96-4.08</td>
</tr>
<tr>
<td>Moisture (%)</td>
<td>15.60</td>
<td>1.96</td>
<td></td>
</tr>
<tr>
<td>Total Ash (%)</td>
<td>2.74</td>
<td>1.69</td>
<td>&lt;2%</td>
</tr>
<tr>
<td>Acid insoluble Ash (%)</td>
<td>0.10</td>
<td>0.07</td>
<td>&lt;0.13</td>
</tr>
<tr>
<td>Alcohol Soluble Extractive (%)</td>
<td>57.96</td>
<td>28.28</td>
<td>&gt;74%</td>
</tr>
<tr>
<td>Water Soluble Extractive (%)</td>
<td>72.42</td>
<td>84.97</td>
<td>&gt;70%</td>
</tr>
<tr>
<td>Total Fat content (%)</td>
<td>0.066</td>
<td>0.21</td>
<td></td>
</tr>
<tr>
<td>Total Solid Content (10% soln.)</td>
<td>6.0</td>
<td>9.0</td>
<td></td>
</tr>
<tr>
<td>Total Sugar Estimation (%)</td>
<td>61.53</td>
<td>54.15</td>
<td></td>
</tr>
<tr>
<td>Tannin (%)</td>
<td>5.231</td>
<td>9.42</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Microbial growth in KHA & KHG

<table>
<thead>
<tr>
<th>Parameters</th>
<th>KHA</th>
<th>KHG</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total plate count (cfu/g)</td>
<td>72x10^2</td>
<td>66x10^2</td>
<td>&lt; 100 CFU/g</td>
</tr>
<tr>
<td>Total fungal count (cfu/g)</td>
<td>Absent</td>
<td>Absent</td>
<td>&lt;100 CFU/g</td>
</tr>
<tr>
<td>E. coli</td>
<td>Absent</td>
<td>Absent</td>
<td>Absent per 10g</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Absent</td>
<td>Absent</td>
<td>Absent per 10g</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Absent</td>
<td>Absent</td>
<td>Absent per 10g</td>
</tr>
<tr>
<td>SalmonellaSpp.</td>
<td>Absent</td>
<td>Absent</td>
<td>Absent per 10g</td>
</tr>
</tbody>
</table>

cfu: Colony Forming Units

Table 5: Heavy metals in KHA & KHG

<table>
<thead>
<tr>
<th>Heavy metals</th>
<th>KHA</th>
<th>KHG</th>
<th>Permissible limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead (Pb)</td>
<td>ND</td>
<td>ND</td>
<td>10ppm</td>
</tr>
<tr>
<td>Cadmium (Cd)</td>
<td>ND</td>
<td>ND</td>
<td>0.3ppm</td>
</tr>
<tr>
<td>Arsenic (As)</td>
<td>1.965ppm</td>
<td>ND</td>
<td>ppm</td>
</tr>
<tr>
<td>Mercury (Hg)</td>
<td>ND</td>
<td>0.012ppm</td>
<td>1ppm</td>
</tr>
</tbody>
</table>

Ppm: parts per million, ND: Not Detected

Table 6: HPTLC Plate / Chromatograms for KHA/KHG

<table>
<thead>
<tr>
<th>@254nm</th>
<th></th>
<th>@366nm</th>
<th></th>
<th>@Visible</th>
</tr>
</thead>
<tbody>
<tr>
<td>KHA</td>
<td>KHG</td>
<td>KHA</td>
<td>KHG</td>
<td>KHA</td>
</tr>
<tr>
<td>0.10</td>
<td>0.12</td>
<td>0.16</td>
<td>0.18</td>
<td>0.16</td>
</tr>
<tr>
<td>0.18</td>
<td>0.22</td>
<td>0.25</td>
<td>0.25</td>
<td>0.30</td>
</tr>
<tr>
<td>0.28</td>
<td>0.42</td>
<td>0.33</td>
<td>0.33</td>
<td>0.52</td>
</tr>
<tr>
<td>0.55</td>
<td>0.52</td>
<td>0.43</td>
<td>0.43</td>
<td>0.60</td>
</tr>
<tr>
<td>0.61</td>
<td>0.60</td>
<td>0.55</td>
<td>0.53</td>
<td>0.67</td>
</tr>
<tr>
<td>-</td>
<td>0.61</td>
<td>0.80</td>
<td>0.78</td>
<td>0.78</td>
</tr>
</tbody>
</table>
Plate no. 1:

KHA at 254nm

KHA at 366nm

KHA at visible

KHG at 254nm

KHG at 366nm

KHG at visible