INTRODUCTION

Aushadhi is one of the important tools to fulfill the aim of the Ayurveda, i.e. to maintain the health of an individual and to cure the patients. Aushadhi generally comprises formulations prepared by the single or multiple drugs. These formulations are classified as primary and secondary Kalpana. Primary Kalpana include Panchavidha Kashaya Kalpana (Swarasa, Kalka, Kwatha, Hima, and Phanta).

Secondary formulations include preparations developed by using Panchavidha Kashaya Kalpana as an ingredient. Secondary formulations were developed to enhance the shelf life, palatability, safety, efficacy, and bioavailability of the drugs. Moreover, it also helps to reduce the dose of the ingredients. Vati Kalpana is the widely accepted secondary formulation because it is a unit dosage form which consists of polyherbal or herbomineral drugs. Eladi gutika is an example of Vati Kalpana which is a polyherbal formulation with multidimensional therapeutic activities including hiccup, vertigo, intoxication, fever, and rheumatism.

OBJECTIVE: The present study was designed to formulate Eladi gutika and standardized according to the protocol. The analysis of formulation was based on organoleptic, physicochemical, qualitative parameters, and high-performance thin-layer chromatography (HPTLC).

RESULTS AND DISCUSSION: The results revealed that the prepared formulation complying with all standards of the vati and gutika. HPTLC study has shown the presence of many phytoconstituents in the formulation.

CONCLUSIONS: The standards for the prepared gutikas were established by evaluating six batches for different parameters. Results of the physicochemical parameters were 7.66 ± 0.20%, 8.18 ± 0.20%, 2.81 ± 0.23%, 0.48 ± 0.03%, 1.33 ± 0.10%, 46.98 ± 0.67%, and 50.64 ± 1.07% for pH, loss on drying, total ash, acid insoluble ash, water soluble ash, water-soluble extractive value, and alcohol soluble extractive value, respectively.

KEY WORDS: Eladi gutika, high-performance thin-layer chromatography, standardization

ABSTRACT

Introduction: The World Health Organization and Ministry of AYUSH, India, collaboratively establishing protocols or monographs for the global acceptance of traditional medicines. Standardization confirms the identity, quality, purity, and efficacy of drugs and formulations. Therefore, continuous efforts of Ayurvedic Pharmacopeia Committee and Pharmacopoeial Laboratory for Indian Medicines have resulted in the publication of several monographs for the standardization of Ayurvedic drugs and formulations. However, yet standards of many Ayurvedic formulations are not available. One such formulation is Eladi gutika. It is a polyherbal formulation with a wide array of therapeutic activities including hiccup, vertigo, intoxication, fever, and rheumatism.

Objective: The present study was designed to formulate Eladi gutika and standardized according to the protocol. The analysis of formulation was based on organoleptic, physicochemical, qualitative parameters, and high-performance thin-layer chromatography (HPTLC).

Results and Discussion: The results revealed that the prepared formulation complying with all standards of the vati and gutika. HPTLC study has shown the presence of many phytoconstituents in the formulation.

Conclusions: The standards for the prepared gutikas were established by evaluating six batches for different parameters. Results of the physicochemical parameters were 7.66 ± 0.20%, 8.18 ± 0.20%, 2.81 ± 0.23%, 0.48 ± 0.03%, 1.33 ± 0.10%, 46.98 ± 0.67%, and 50.64 ± 1.07% for pH, loss on drying, total ash, acid insoluble ash, water soluble ash, water-soluble extractive value, and alcohol soluble extractive value, respectively.

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INTRODUCTION

Aushadhi is one of the important tools to fulfill the aim of the Ayurveda, i.e. to maintain the health of an individual and to cure the patients. Aushadhi generally comprises formulations prepared by the single or multiple drugs. These formulations are classified as primary and secondary Kalpana. Primary Kalpana include Panchavidha Kashaya Kalpana (Swarasa, Kalka, Kwatha, Hima, and Phanta).

Secondary formulations include preparations developed by using Panchavidha Kashaya Kalpana as an ingredient. Secondary formulations were developed to enhance the shelf life, palatability, safety, efficacy, and bioavailability of the drugs. Moreover, it also helps to reduce the dose of the ingredients. Vati Kalpana is the widely accepted secondary formulation because it is a unit dosage form which consists of polyherbal or herbomineral drugs. Eladi gutika is an example of Vati Kalpana which is a polyherbal formulation with multidimensional therapeutic activities including hiccup, vertigo, intoxication, fever, and rheumatism. Ayurvedic Formulary of India (AFI) provides a standard formula for the preparation of Eladi gutika. However, the standard evaluation parameters have not been discussed yet. Standardization confirms the identity, quality, purity, and efficacy of drugs and formulations. Hence, there is a need for standardization and evaluation to obtain a quality product. Therefore, continuous efforts of Ayurvedic Pharmacopoeia Committee and Pharmacopoeial Laboratory for Indian Medicines have resulted in the publication of several monographs for the standardization of Ayurvedic drugs and formulations. However, yet standards of many Ayurvedic formulations are not available.

The standardization parameters have been performed according to the Protocol for Testing of Ayurvedic, Siddha and Unani medicines for Vati and Gutika.

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MATERIALS AND METHODS

Collection of Plant Material

Yastimadhu (Glycyrrhiza glabra), Tvak (Cinnamomum zeylanicum), Tejpatta (Cinnamomum tamala), Ela (Elettaria cardamomum), Pippali (Piper longum), Munnaka (Vitis vinifera), and Madhu (Apis melifera) were procured from the local market of Sundar Nagar, Himachal Pradesh, whereas Kharjura (Phoenix dactylifera), Mishri (Rock candy), and Ghita were procured from the local market of Phagwara, Punjab. The drug was authenticated from the Department of Botanical and Environmental Sciences, Guru Nanak Dev University, Amritsar.

Preparation of Eladi Gutika

The collected plant material was washed with water and shade dried. The evaluation of raw materials was done and compared with the standard values from Ayurvedic Pharmacopoeia of India. Total six batches of Eladi gutika were prepared to standardize the process and the formulation.\(^5\) Ingredients, their ratios, and process\(^6\) were same for all the batches. Ingredients of Eladi gutika are given in Table 1.

Before process

Preparation of powders

Yastimadhu, Ela, Tvak, Tejpatta, Mishri, and Pippali were finely powdered individually and sieved through the mesh no. 85. Then, powders were taken in the required quantity as mentioned in Table 2. The same procedure was followed for the powdering of other batches. The observations of the process are mentioned in Table 3.

Preparation of paste

The paste of Munnaka and Kharjura was prepared separately and taken in the quantity as mentioned in Table 2. The same method was followed to prepare pastes of other batches. The observations of the process are mentioned in Table 4.

During process

Mixing of powdered drugs

The powdered drugs were homogeneously mixed by serial dilution and kept aside for further process.

Mixing of powdered drugs with pastes

The prepared pastes were evenly mixed together as per the ratio. Then, a mixture of powders was added and mixed homogeneously.

Trituration with honey

Prepared mixture was triturated with the honey till the consistency of bolus became hard. The observations of the process are mentioned in Table 5.

Preparation of gutika

Gutikas were prepared manually as described in the classical texts as per their dose.

After process

Prepared gutika was kept at the room temperature after drying, stored in airtight container for the further use.

Analysis of Eladi gutika

All batches of the formulation were subjected to organoleptic, physicochemical, qualitative, and high-performance thin-layer chromatography (HPTLC) study to develop standards for the Eladi gutika.

Table 1: Ingredients of Eladi gutika

<table>
<thead>
<tr>
<th>Common name</th>
<th>Scientific name</th>
<th>Part used</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yastimadhu</td>
<td>Glycyrrhiza glabra</td>
<td>Roots</td>
<td>8</td>
</tr>
<tr>
<td>Ela</td>
<td>Elettaria cardamomum</td>
<td>Seeds</td>
<td>1</td>
</tr>
<tr>
<td>Tvak</td>
<td>Cinnamomum zeylanicum</td>
<td>Bark</td>
<td>1</td>
</tr>
<tr>
<td>Munnaka</td>
<td>Vitis vinifera</td>
<td>Fruits</td>
<td>8</td>
</tr>
<tr>
<td>Tejpatta</td>
<td>Cinnamomum tamala</td>
<td>Leaves</td>
<td>1</td>
</tr>
<tr>
<td>Pippali</td>
<td>Piper longum</td>
<td>Fruits</td>
<td>4</td>
</tr>
<tr>
<td>Kharjura</td>
<td>Phoenix dactylifera</td>
<td>Fruits</td>
<td>8</td>
</tr>
<tr>
<td>Madhu</td>
<td>Apis melifera</td>
<td>-</td>
<td>8</td>
</tr>
<tr>
<td>Mishri</td>
<td>Rock candy</td>
<td>-</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 2: Quantity of ingredients to prepare the Eladi gutika

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Part used</th>
<th>Different batches of Eladi gutika (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>Yastimadhu</td>
<td>Roots</td>
<td>48</td>
</tr>
<tr>
<td>Ela</td>
<td>Seeds</td>
<td>6</td>
</tr>
<tr>
<td>Tvak</td>
<td>Bark</td>
<td>6</td>
</tr>
<tr>
<td>Tejpatta</td>
<td>Leaves</td>
<td>6</td>
</tr>
<tr>
<td>Pippali</td>
<td>Fruits</td>
<td>24</td>
</tr>
<tr>
<td>Mishri</td>
<td>-</td>
<td>48</td>
</tr>
<tr>
<td>Kharjura</td>
<td>Fruits</td>
<td>48</td>
</tr>
<tr>
<td>Madhu</td>
<td>-</td>
<td>48</td>
</tr>
<tr>
<td>Munakka</td>
<td>Fruits</td>
<td>48</td>
</tr>
</tbody>
</table>

Table 3: Observation of powdering of raw materials

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Yastimadhu</th>
<th>Tvak</th>
<th>Ela</th>
<th>Tejpatta</th>
<th>Mishri</th>
<th>Pippali</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial weight (g)</td>
<td>80</td>
<td>15</td>
<td>30</td>
<td>20</td>
<td>55</td>
<td>45</td>
</tr>
<tr>
<td>Final qty (g)</td>
<td>51.55±1.12</td>
<td>8.36±0.58</td>
<td>12.63±0.89</td>
<td>12.06±0.45</td>
<td>51.31±0.31</td>
<td>33.03±0.91</td>
</tr>
<tr>
<td>Loss (g)</td>
<td>28.55±1.24</td>
<td>6.43±0.50</td>
<td>17.23±0.87</td>
<td>8±0.48</td>
<td>3.63±0.38</td>
<td>12.19±0.90</td>
</tr>
<tr>
<td>Yield (%)</td>
<td>64.73±1.34</td>
<td>56.84±3.23</td>
<td>42.58±2.93</td>
<td>59.35±1.36</td>
<td>93.07±0.41</td>
<td>73.35±1.99</td>
</tr>
</tbody>
</table>
Organoleptic evaluation of formulation
The individual batch of the formulation was evaluated for its organoleptic parameters including color, odor, taste, and texture. The observations are mentioned in Table 6.

Physiochemical evaluation of raw drugs and formulation
The prepared batches of the formulation were evaluated based on physiochemical parameters, namely pH, loss on drying, total ash, acid insoluble ash, water-soluble ash, alcohol soluble extractive value, water-soluble extractive value, and weight variation. The results and observations of the parameters are mentioned in Table 7.

Qualitative analysis
The qualitative analysis of prepared batches was done by performing tests for alkaloids, tannins, flavonoids, carbohydrates, glycosides, steroids, starch, reducing sugar, non-reducing sugar, and monosaccharides. The results of the parameters are mentioned in Table 8.

Thin-Layer Chromatography (TLC) Analysis
TLC is an important or easy technique for the qualitative and quantitative analysis of the compound or herbal drugs. It consists of two phases one is a stationary phase and another is mobile phase. The solvent system for TLC taken is toluene:ethyl acetate:formic acid (9.2:9.2:1.5).

HPTLC Analysis
HPTLC is the advanced form of TLC used for the qualitative and quantitative analysis by enhancing the separation and resolution of the compounds. The fine particle size of stationary phase ensures the better efficiency of the separation and resolution in HPTLC. The preparation of samples of the formulations and chromatographic conditions of the HPTLC as the solvent system is toluene:ethyl acetate:formic acid (9.2:9.2:1.5).

RESULTS AND DISCUSSION
Standardization is quality assurance for the establishment of a constant compound profile and biological activities of quality products. It is one of the important aspects to maintaining the quality and safety of the herbal drugs and the formulation to attain the desired efficacy. The World Health Organization specific guidelines for the assessment of the safety, efficacy, and quality of herbal medicines as a prerequisite for global harmonization are of utmost importance. TLC and HPTLC fingerprint profiles were also used for fixing standards for the Ayurvedic formulations.

In the preparation of Eladi gutika, the classical method was used. This preparation and evaluation parameters are not available. Therefore, in the present study standards for the preparation and evaluation of Eladi gutika were developed. The raw materials were evaluated and compared to standards for ensuring the quality of raw materials. Six batches of the formulation were prepared and evaluated.
were prepared and evaluated for the development of standards.

In the preparation of Eladi gutika, the quantity of ingredients is mentioned in Tables 2–4. 138 g of finely powdered drugs were homogeneously mixed with 96 g of paste drugs. Then, it was subjected to trituration with 48 g of honey for 15 min. The average quantity of obtained bolus was 224.18 ± 1.79 g, and the average percentage yield was 79.35 ± 0.63 g [Table 5]. Then, it was converted into gutika by rolling between hands and kept for drying before storage. The dose of gutika as per AFI is 4 g.

Pharmaceutical analysis of each batch of the formulation was performed using organoleptic, physicochemical, and qualitative tests. The organoleptic characteristics were found same for all the batches [Table 6]. Physicochemical parameters were evaluated for all the batches using the methods described in the Ayurvedic Pharmacopoeia of India. Average results of pH, loss on drying, total ash, acid insoluble ash, water soluble ash, water-soluble extractive value, and alcohol soluble extractive value were 7.66 ± 0.20%, 8.18 ± 0.20%, 2.81 ± 0.23%, 0.48 ± 0.03%, 1.33 ± 0.10%, 46.98 ± 0.67%, and 50.64 ± 1.07%, respectively. Gutikas of all batches were passed in weight variation test [Table 7]. According to the IP/BP the tablet whose average weight is 250 mg or more, than the 5% deviation is the acceptance criteria.[20] However, disintegration, friability, and hardness of gutika were not evaluated due to the large size of the gutika.

Qualitative analysis of formulation revealed the presence of alkaloids, tannins, flavonoids, carbohydrates, glycoside, starch, reducing sugar, and non-reducing sugar may be due to the presence of many herbal drugs. Moreover, these phytoconstituents may also responsible for its multidimensional therapeutic activities [Table 8].

Chromatographic profile of formulation was developed by TLC and HPTLC. In TLC of formulation 4 Rf [Figure 1a], i.e., 0.08, 0.081, 0.90, and 0.95 was found [Table 9] whereas, HPTLC profile of formulation revealed the presence of 10 Rf [Figure 1b] including 0.07, 0.14, 0.32, 0.42, 0.49, 0.65, 0.72, 0.77, 0.84, and 0.91 [Table 10].

**CONCLUSION**

Gutikas were prepared manually as per the classical texts. The standards for the prepared gutikas were established by evaluating six batches for different parameters. Results of the physicochemical parameters were 7.66 ± 0.20%, 8.18 ± 0.20%, 2.81 ± 0.23%, 0.48 ± 0.03%, 1.33 ± 0.10%, 46.98 ± 0.67%, and 50.64 ± 1.07% for pH, loss on drying, total ash, acid insoluble ash, water soluble ash, water-soluble extractive value, and alcohol soluble extractive value, respectively. Gutikas were passed in the weight variation test. Qualitative analysis of formulation revealed the presence of alkaloids, tannins, flavonoids, carbohydrates, glycoside, starch, reducing sugar, and non-reducing sugar. Chromatographic study revealed that its rich in the phytoconstituents.

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