Standardization of marketed ayurvedic formulation: Lavangadi vati

Nutan M Dudhal, Dr. Kiran A Wadkar, Dr. Manish S Kondawar, Sachin G Lokapure and Tukaram N Mane

Abstract
Ayurveda is time-tested, trusted worldwide plant-based system of medicines and consists of various Ayurvedic formulations such as Asava, Arista, Ghruta, Taila, Churna, Bhasma, Vati, Gutika, Kwatha and much more. Medicines prepared in the form of tablets or pills are known as vati and Gutika. Traditionally Lavangadi Vati is an Ayurvedic formulation and popularly used for the treatment of asthma, cough, and fever. Three different batches of lavangadi vati of same formulation i.e. Baidyanath lavangadi vati was compared with standard laboratory prepared with Lavangadi vati. All the parameters tested for the Lavangadi vati were found within the limit. All formulations free from the organoleptic evaluation, microbial contamination and other parameters like extractive value, Ash value, moisture content, phytochemical screening, weight variation, hardness, disintegration, arsenic was performed.

Keywords: Standardization, lavangadi vati, ayurveda

1. Introduction
Herbal medicines consist of plant or its part to treat injuries, disease or illnesses and are used to stop and treat diseases and ailments or to promote health and healing. It is a drug or preparation made from a plant or plants and used for any of such purposes. Herbal medicines are the oldest form of healthcare known to mankind \[1\]. In old times, Vaidhyas used to treat patients on the individual basis and prepare drug according to the requirement of the patient. But the scenario has changed now; herbal medicines are being manufactured on the large scale in pharmaceutical units. World Health Organization has set specific guidelines for the evaluation of the safety, efficacy, and quality of herbal medicines \[1\]. Due to lack of infrastructures, skilled manpower reliable methods, and strict regulatory laws, most of these manufacturers produce their product on a very uncertain basis \[2\]. The Ayurvedic system of medicine mainly uses herbs, herbal products, in the form of churna, extracts, kashayas, asavas, aristas etc. These formulations usually contain more than one type of herb or herbal products. Very often raw materials are being collected from different geographical sources and at different seasons. Hence the amount of active constituents present in the sample material varies and its effects are likely to reflect in the final product \[2\]. Nature has bestowed our country with an enormous wealth of medicinal plants; therefore India has often referred to as the Medicinal Garden of the world. In this regard, India has a unique position in the world, where a number of recognized indigenous systems of medicine viz., Ayurveda, Siddha, Unani, Homeopathy, Yoga, and Naturopathy are being utilized for the health care of people \[3\]. Herbal drugs have been used since ancient times as medicines for the treatment of a range of diseases. Medicinal plants have played a key role in world health. In spite of the great advances observed in modern medicine in recent decades, plants still make an important contribution to health care. The recent global recovery of interest in herbal medicines has led to an increase in the demand for them. The need of the hour is to evolve a systematic approach and to develop well-designed methodologies for the standardization of herbal raw materials and herbal formulations \[4\]. Medicines prepared in the form of tablets or pills are known as vati and Gutika. These are made of one or more drugs of plant, animal origin. Traditionally Lavangadi Vati is popularly used for the treatment of asthma, cough, and fever \[5\]. For the preparation of Lavangadi vati following herbal drugs clove, black paper, bibhitaki, black catechu, acacia, was used.

Keywords: Standardization, lavangadi vati, ayurveda
2. Materials and Methods

2.1. Collection, identification and authentication of raw materials

Required plant material collected from the local region, and plant authenticated from the botany department. The collected plant was shade-dried. Three different batches of same manufacturers of Lavangadi vati were purchased from local Ayurvedic medicinal shop from the Sangli.

2.2. Preparation of Lavangadi Vati (Tablet) [6]

Preparation of granules

Grind all the ingredients in mortar pestle to a fine powder & triturate with the formed decoction, a semisolid paste will be formed. Then Formed damp mass & pass through sieve No.12. The granules were obtained kept for drying.

Evaluation of prepared granules

Granules evaluated by using following parameters, moisture content, tapped density, bulk density, Hausner’s ratio, Angle of repose, Carr’s index, porosity.

Preparation of Lavangadi vati:

preparation and evaluation of granules were done successfully. Moisture content was 2.3%, bulk density and tapped density was 0.58gm/ml and 0.62gm/ml respectively. Carr's index and Hausner’s ratio was found within good flowability range. The angle of repose found within the good range and porosity was found 6%.

Preparation of Lavangadi vati:

Preparation of sample solution of extracted Lavangadi Vati

A stock solution of Lavangadi Vati was prepared by dissolving 10mg of extracted Lavangadi Vati in 10ml of methanol. It is soluble in methanol so volume making done by methanol, to get a solution containing 1000 μg/ml.

Preparation of working standard solution of Catechin:

A stock solution of Catechin was prepared by dissolving 10mg of Catechin up to 10 ml of Methanol, to get a stock solution containing 1000μg/ml of Catechin.

Preparation of standard stock solution of Catechin:

Dissolving 10mg of Catechin up to 10 ml of Methanol, to get a stock solution containing 1000μg/ml of Catechin.

Sample preparation

Preparation of working standard solution of Catechin:

A standard stock solution of Catechin was prepared by dissolving 10mg of Catechin up to 10 ml of Methanol, to get a stock solution containing 1000μg/ml of Catechin.

Preparation of Lavangadi Vati (Tablet) [6]

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A stock solution of Lavangadi Vati was prepared by dissolving 10mg of extracted Lavangadi Vati in 10ml of methanol. It is soluble in methanol so volume making done by methanol, to get a solution containing 1000 μg/ml.

3. Result and Discussion

The herbal drugs require for the preparation of lavangadi vati was collected from the local market and authenticated from Dr. M. D. Wadmare sir, H. O.D. Dept. of Botany, KWC College, Sangli. Four different batches of Baidyanath Lavangadi Vati were procured from local market. By using the same formula Lavangadi Vati was prepared in Laboratory. And hence parameters of the same have been studied.

Preparation and evaluation of granules were done successfully. Moisture content was 2.3%, bulk density and tapped density was 0.58gm/ml and 0.62gm/ml respectively. Carr's index and Hausner’s ratio was found within good flowability range. The angle of repose found within the good range and porosity was found 6%.

Organoleptic evaluation of prepared granules for Lavangadi vati.

The friability for sample MK-1, MK-2, MK-3 and LB was found to be 0.64%, 0.29%, 0.42% and 0.42% respectively. The hardness of sample MK-1, MK-2, MK-3 and LB was found to be 3.15, 3.1, 3.2, and 4 respectively. Disintegration time for sample MK-1, MK-2 MK-3 and LB was found to be 3.43, 3.43, 3.47 and 3.48 min respectively limit for the uncoated tablet was 15min. Weight variation of sample MK-1, MK-2, MK-3, and LB was found to be 0.29%, 0.42% and 0.42% respectively.

Four different batches of similar preparation that is ‘Baidynath Lavangadi Vati’ were procured from local market & by using same formula lavangadi vati prepared in the laboratory. Organoleptic properties of Lavangadi Vati were similar i.e. brown color, aromatic, and pungent taste. The only difference was that lab prepared vati was blackish brown in color but same in aromatic odor and pungent taste.

Table 1: The Formula of Lavangadi vati.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Content</th>
<th>Qty (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Syzygium aromaticum</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>Piper nigrum</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>Terminalia belerica</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Acacia catechu</td>
<td>30</td>
</tr>
<tr>
<td>5</td>
<td>Aqueous extract of Acacia arabica</td>
<td>q. s.</td>
</tr>
</tbody>
</table>

Procedure

Prepared Tulasi granules compressed by using 8mm punch and ten stations rotator tablet punching machine.

Evaluation of Tablet

2.3. Organoleptic evaluation [7]

The organoleptic evaluation of both Tablet was performed for the color, odor, and taste.

2.4 Physicochemical evaluation [7]

Physicochemical evaluation of laboratory prepared and marketed formulation of Tulasi tablets was performed according to the standardization parameters for the ash values, extractive values, foaming index, swelling index, loss on drying, microbial test, determination of arsenic [7]. And according to Pharmacopoeia of India for weight variation, hardness, friability and disintegration [8].

2.5 Extraction and Identification of Marker Constituents from Tulasi Tablet [9]

Preparation of extract of Lavangadi Vati

Taken approximately 5 gm of Lavangadi Vati powder were dissolved in 25 ml of methanol and stirred for 1 hour by a magnetic stirrer. Five samples were subjected to magnetic stirring for 1 hour and left for maceration for 24 hours. Each extract was filtered using Whatman filter paper and this filtrate was used for further analysis.

Sample preparation

Preparation of working standard solution of Catechin:

A standard stock solution of Catechin was prepared by dissolving 10mg of Catechin up to 10 ml of Methanol, to get a stock solution containing 1000μg/ml of Catechin.

The water-soluble extractive of Lavangadi Vati of different batches MK-1, MK-2, MK-3 and LB was found to be 24%, 21.6%, 23.2% and 18.4% w/w respectively. The alcohol-soluble extractive of Lavangadi Vati of different batches MK-1, MK-2, MK-3, and LB was found to be 14.4%, 13.6%, 12.8% and 16% w/w respectively. The hexane soluble extractive of Lavangadi Vati of different batches MK-1, MK-2, MK-3 and LB was found to be 3.2%, 2.5%, 2.4%, 1.6% w/w respectively. Water-soluble extractive value, ethanol
soluble extractive value and Hexane soluble extractive value is in the following tables.

The total ash value of Lavangadi Vati of different batches MK-1, MK-2, MK-3 and LB were found to be 3.5%, 4%, 3% and 2.5% w/w respectively. The water-soluble ash value of Lavangadi Vati of different batches MK-1, MK-2, MK-3 and LB were found to be 9.5%, 9%, 9.5% and 8% w/w respectively. The acid insoluble ash value of Lavangadi Vati of different batches MK-1, MK-2, MK-3 and LB were found to be 2.5%, 4.5%, 5% and 6% w/w respectively. The moisture content of different batches of Lavangadi Vati MK-1, MK-2, MK-3 and LB were found to be 2.6%, 3%, 2.8% and 2.4% w/w respectively. The water soluble ash value of Lavangadi Vati of all the four Batches mainly contains Tannins, Carbohydrates, Alkaloid, and flavonoids. A phytochemical investigation revealed that Tulasi tablet of all the five manufacturers mainly contained Alkaloids, Glycosides, Flavonoids, Carbohydrate, and Tannins. The presence of Arsenic in Lavangadi Vati of different batches MK-1, MK-2, MK-3, and LB. All sample showed Absence of arsenic.

Extraction was done by Soxhlet method. The extract of MK-1, MK-2, MK-3, and LB was used for the preparation of the sample solution that is S1, S2, S3 and S4 respectively and the standard catechin was S5. From extract, catechin was identified and confirmed by comparing Rf value obtained by using Thin Layer Chromatography. TLC: Rf value of standard catechin (S5) was found 0.69. This was compared with four sample of extract, in S1, S2, S3, and S4 sample catechin spot was observed.

### Table 4: Physiochemical properties

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parameters</th>
<th>MK-1</th>
<th>MK-2</th>
<th>MK-3</th>
<th>LB-1</th>
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<tbody>
<tr>
<td>1</td>
<td>Friability</td>
<td>0.64</td>
<td>0.29</td>
<td>0.41</td>
<td>0.42</td>
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<tr>
<td>2</td>
<td>Hardness</td>
<td>3.15</td>
<td>3.10</td>
<td>3.20</td>
<td>4.0</td>
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<tr>
<td>3</td>
<td>Disintegration time</td>
<td>3.43</td>
<td>3.43</td>
<td>3.47</td>
<td>3.48</td>
</tr>
<tr>
<td>4</td>
<td>Weight variation</td>
<td>0.95</td>
<td>1.44</td>
<td>1.83</td>
<td>3.43</td>
</tr>
<tr>
<td>5</td>
<td>Water-soluble extractive value (% w/w)</td>
<td>24</td>
<td>21.6</td>
<td>23.2</td>
<td>18.4</td>
</tr>
<tr>
<td>6</td>
<td>Alcohol soluble extractive value (% w/w)</td>
<td>14.4</td>
<td>13.6</td>
<td>12.8</td>
<td>16</td>
</tr>
<tr>
<td>7</td>
<td>Hexane soluble extractive value (% w/w)</td>
<td>3.2</td>
<td>2.5</td>
<td>2.4</td>
<td>1.6</td>
</tr>
<tr>
<td>8</td>
<td>Total ash value (% w/w)</td>
<td>3.5</td>
<td>4</td>
<td>3</td>
<td>2.5</td>
</tr>
<tr>
<td>9</td>
<td>Water soluble ash value (% w/w)</td>
<td>9.5</td>
<td>9</td>
<td>9.5</td>
<td>8</td>
</tr>
<tr>
<td>10</td>
<td>Acid-insoluble ash value (% w/w)</td>
<td>2.5</td>
<td>4.5</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>11</td>
<td>Moisture content (% w/w)</td>
<td>2.6</td>
<td>3</td>
<td>2.8</td>
<td>2.4</td>
</tr>
</tbody>
</table>

Absent, + Present

### Table 5: Microbial limit test

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Micro-Organism</th>
<th>Sample</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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<tbody>
<tr>
<td>1</td>
<td>Escherichia coli</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Salmonella typhi</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Pseudomonas aeruginosa</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Staphylococcus aureus</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Absent.

### Table 6: Phytochemical investigation

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Chemical</th>
<th>Sample</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Alkaloids</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
<td>Glycosides</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>Carbohydrates</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>4</td>
<td>Tannin</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>Flavonoids</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

+ Present

### Fig 1: TLC study compared with the standard catechin.

### Fig 2: Photo documentation for comparison of Rf value of all samples.

### 4. Conclusion

The Lavangadi vati is an Ayurvedic preparation for cold and cough was formulated in the laboratory and standardized against the marketed formulation of Lavangadi vati. Standardization was performed for organoleptic properties, physicochemical properties as per standard parameters. The standard parameters were recognized and also the results showed that ingredients used for formulation were found to be of good quality. From the qualitative HPTLC results of marketed Lavangadi vati and laboratory prepared standard Lavangadi vati, it revealed that marker catechin was present in all samples.
5. Reference