PHARMACEUTICO-ANALYTICAL STUDY OF DADIMAVALEHA

Vd. Manish S. Bhoyar¹, Vd. Neethu Tharol², Vd. Sujata Laddha³ and Vd. Sudheesh K.P⁴

1. Assistant Professor, Department of Rasashastra and Bhaishajyakalpana, Government Ayurved College, Nagpur, 440009.
2. PG Scholar, Department Of Rasashastra and Bhaishajyakalpana, Government Ayurved College, Nagpur, 440009.
3. PG Scholar, Department Of Rasashastra and Bhaishajyakalpana, Government Ayurved College, Nagpur, 440009.
4. PG Scholar, Department Of Shalakyatantra, Government Ayurved College, Tripunithura, Kerala, 682301.

Abstract

Background: Bhaishajyakalpana being a deep rooted science contains many unrevealed treasure of formulations. The present era demands scientific method and standardized protocol for any preparation. Here is an opportunity to revise the science using newer technologies in cost effective manner. Dadimavaleha, one of the most commonly used formulation in practice is least explored. Attempt has been made to study the pharmaceutico analytical parameters of Dadimavaleha and thereby establishing a standard operating procedure.

Aim
1. To study the pharmaceutico-analytical aspects of Dadimavaleha
2. To set a standard manufacturing procedure of Dadimavaleha.

Material And Methods: The preparation of Dadimavaleha was done according to the reference of YogaratnakarJwaratisaradhyay. All the procedure was done systematically and observations were noted.

Discussion: The study is aimed at setting a standard manufacturing procedure for Dadimavaleha thorough examination of pharmaceutico analytical characteristics of the same. The various analytical parameters like ph, total ash, acid insoluble ash, water soluble extractive, acid soluble extractive, specific gravity, sugar content were assessed.

Conclusion: The detailed pharmaceutico-analytical study of Dadimavaleha a detailed stepwise description and documentation in scientific, logical, sequential manner helps in developing a Standard Manufacturing Procedure for Dadimavaleha. Since there is no standard protocol and comparable analytical parameters available at present, this study can prove to be a milestone towards setting a standard manufacturing procedure for Dadimavaleha.

Corresponding Author:- Vd. Neethu Tharol
Address:- PG Scholar, Department of Rasashastra and Bhaishajyakalpana, Government Ayurved College, Nagpur, 440009.
Introduction:
Bhaishajyakalpana is a well-developed sub discipline wherein various pharmaceutical procedures are explained. Since every drug which occurs in the natural state cannot be assimilated as such it needs specific pharmaceutical processing to acquire more acceptable and palatable form. Inspite of all lexicons from the Samhitas and commentaries, there is a high need to ensure the quality of the formulations. The identification, authentication and then concerned analytical tests are needed for quality assurance.

In Ayurvedic Pharmaceutics various primary formulation like Kwath, Swaras, Kalketc, wide variety of secondary preparations have been detailed which do have higher shelf life and palatability. Avaleha, among one of the most common secondary Kalpana, is a semisolid preparation processed in decoction or extracts of different herbs by adding sweetening agents like jaggery, sugar or sugarcandy. It is easy for administration due to high palatability. The high potency, palatability and increased shelf life made avalehakalpana drug of choice amongsvaidyas for various ailments.

There are numerous references of Dadimavaleha in the classics. The marketed sample available is prepared as per AyurvedsaraSangraha reference. In this study Dadimavaleha has been prepared according to reference from YogaratnakarJwaratisarPrakaran

The consistency of the marketed sample (AyurvedsaraSangraha) and experimental sample (YogaratnakarJwaratisarPrakaran) shows huge disparity as the marketed sample is semi liquid (syrup) while the experimental sample is semi solid in nature. The formulation Dadimavaleha is quoted in YogaratnakarJwaratisarPrakaran. The main ingredients of Dadimalaveha are Dadimsaal, Sharkara, Madhu and Ghrita. This study is aimed at establishing a standard manufacturing procedure of Dadimavaleha by analyzing various Ayurvedic and modern parameters.

Ancient texts are treasure of potential formulations. Some of the beneficial formulations are ignored by vaidyas and Pharmaceutical companies as there preparatory procedure, analytical standards are not explained. Moreover these formulations are not as palatable as presently established formulations which does not give commercial values. All these factors results into hindrance of using therapeutically competent formulations in clinical practice. As Rasshastra and Bhaishajyakalpana disciple it is our prime duty to explore such formulations from ancient texts and establish their standards on identity, purity, strength basis. Till date there is no standard protocol for the preparation of Dadimavaleha even in Ayurveda Formulary of India, thus this study can prove to be a bench mark for developing standard manufacturing procedure of Dadimavaleha.

Aims And Objectives:
1. To study the pharamaceutico-analytical aspects of Dadimavaleha
2. To set a standard manufacturing procedure of Dadimavaleha.

Material And Methods:
This study has been done in following two steps –
1) Pharmaceutical study
2) Analytical study

Pharmaceutical Study
The preparation of Dadimavaleha was done according to the reference of YogaratnakarJwaratisaradhyay. दाडिभाददपरप्रस्थंचतुप्रस्थजरेऩचेत | चतुबाागकषामेस्भन्शकायाप्रस्थभेवच || नागयंपऩप्ऩरीभूरंकणाधान्मकदीप्मकं | जातीपरंजाततऩत्रंभरयचंजीयकंतुगा || पवजमातनम्फऩत्रंचसभंगंकूटशाल्भरी | अयल्वततपवषाऩािारवंगचऩृथक्ऩरं || घृतस्मभधुनप्रस्थंसवारेहंपवऩाचमेत

Material And Methods:-
This study has been done in following two steps –
1) Pharmaceutical study
2) Analytical study

Pharmaceutical Study
The preparation of Dadimavaleha was done according to the reference of YogaratnakarJwaratisaradhyay.[3]
All the raw materials of pharmacopeial quality were procured from authentic source and examined by the experts to confirm the identity, purity and strength.

**Ingredients:**

**Table no 1:** Showing the main ingredients of Dadimavaleha.

<table>
<thead>
<tr>
<th>Sr. no</th>
<th>Ingredients</th>
<th>Latin name</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dadimsaal</td>
<td>Punicagranatum</td>
<td>768g</td>
</tr>
<tr>
<td>2</td>
<td>Sharkara</td>
<td>Sugarcandy</td>
<td>768g</td>
</tr>
<tr>
<td>3</td>
<td>Ghrita</td>
<td>Cow’s ghee</td>
<td>768g</td>
</tr>
<tr>
<td>4</td>
<td>Madhu</td>
<td>Honey</td>
<td>768g</td>
</tr>
</tbody>
</table>

**PrakshepDravyas**

**Table no 2:** Showing the ingredients of PrakshepDravyas.

<table>
<thead>
<tr>
<th>Sr. no</th>
<th>Ingredients</th>
<th>Latin name</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Shunti</td>
<td>Zingiberofficinale</td>
<td>40 g</td>
</tr>
<tr>
<td>2</td>
<td>Pippali</td>
<td>Piper longum</td>
<td>40 g</td>
</tr>
<tr>
<td>3</td>
<td>Pippalimool</td>
<td>Piper longum</td>
<td>40 g</td>
</tr>
<tr>
<td>4</td>
<td>Dhanyak</td>
<td>Coriandrum sativum</td>
<td>40 g</td>
</tr>
<tr>
<td>5</td>
<td>Ajamoda</td>
<td>Apiumgraveolens</td>
<td>40 g</td>
</tr>
<tr>
<td>6</td>
<td>Jatiphal</td>
<td>Myristicafragrans</td>
<td>40 g</td>
</tr>
<tr>
<td>7</td>
<td>Jatipatri</td>
<td>Myristicafragrans</td>
<td>40 g</td>
</tr>
<tr>
<td>8</td>
<td>Marich</td>
<td>Piper nigrum</td>
<td>40 g</td>
</tr>
<tr>
<td>9</td>
<td>Jeerak</td>
<td>Cuminumcyminum</td>
<td>40 g</td>
</tr>
<tr>
<td>10</td>
<td>Nimbatatra</td>
<td>Azhadarachta indica</td>
<td>40 g</td>
</tr>
<tr>
<td>11</td>
<td>Lajalu</td>
<td>Mimoso pudica</td>
<td>40 g</td>
</tr>
<tr>
<td>12</td>
<td>Shalmalitwak</td>
<td>Bombaxmalabaricum</td>
<td>40 g</td>
</tr>
<tr>
<td>13</td>
<td>Musta</td>
<td>Cypreus rotundus</td>
<td>40 g</td>
</tr>
<tr>
<td>14</td>
<td>Pata</td>
<td>Cycleapeltata</td>
<td>40 g</td>
</tr>
<tr>
<td>15</td>
<td>Lavang</td>
<td>Syzygium aromaticum</td>
<td>40 g</td>
</tr>
</tbody>
</table>

**Procedure**

**Preparatory procedure:** Preparation of Dadimtwakkwath

1. 4kg of Dadim was procured from local market.
2. It was washed and cleaned properly and wiped out the remaining water on the surface with a clean cloth.
3. Dadimtwak was separated from the pulp carefully and twak was collected in a beaker.
4. The collected Dadimtwak was weighed 768 g and was taken in a stainless steel vessel.
5. 3 litre of water was added to it and reduced to ¼ under mild fire.
6. Then the Kwath obtained was filtered through a clean cotton cloth.
7. After completely dissolving, it was filtered through a clean muslin cloth to remove the physical impurities.

**Method of preparation of Dadimavaleha**

1. Dadimtwak Kwath was taken in a clean stainless steel container.
2. 768g of Sitasharkara was dissolved in Dadimtwak Kwath.
3. After completely dissolving, it was filtered through a clean muslin cloth to remove the physical impurities.
4. Mild heat was given throughout the procedure and continuous stirring was maintained till it reached Dotaripak (2 thread consistency ).
5. Simultaneously all the finely powdered Prakshep Dravyas were fried mildly in 768g of Ghrita.
6. After attaining Dotaripak, the Ghritabharjita Prakshep Dravyas were added and mixed homogenously.
7. After complete self cooling, 768 g Madhu was added and homogenously mixed to Avaleha consistency.
Observations:-

**Table no 3:-** showing the Organoleptic characteristics of Dadimavaleha.

<table>
<thead>
<tr>
<th>Shabda</th>
<th>Nothing specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roopa</td>
<td>Semi solid consistency</td>
</tr>
<tr>
<td>Rasa</td>
<td>Kashaya, Madhur</td>
</tr>
<tr>
<td>Gandha</td>
<td>Sugandhi</td>
</tr>
<tr>
<td>Sparsha</td>
<td>Mrudu</td>
</tr>
</tbody>
</table>

**Table no 4:-** Showing Time Required For Important Pharmaceutical Milestones During The Procedure.

<table>
<thead>
<tr>
<th>Pharmaceutical Milestones</th>
<th>Time Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kwathnirman</td>
<td>3 hrs</td>
</tr>
<tr>
<td>Sharkarapaknirman</td>
<td>2 hrs</td>
</tr>
<tr>
<td>Ghritabharjitprakshepnirman</td>
<td>20 min</td>
</tr>
<tr>
<td>Mixing of Sharkarapakand Ghritabharjitprakshep</td>
<td>15 min</td>
</tr>
<tr>
<td>Mixing of Madhuafter self-cooling</td>
<td>10 min</td>
</tr>
<tr>
<td>Total time taken</td>
<td>5 hrs 45 min</td>
</tr>
</tbody>
</table>

The prepared Dadimaleha passed the following Siddhi lakshanas

**Siddhi lakshanas**[5]
1. **Tantumattwam**– thread like appearance when pressed between thumb and index finger.
2. **Apsumajjati** – when a drop of avaleha is put on water, it settles down without spreading.
3. **Peditemudra** – when a small amount of avaleha is pressed between two fingers then impression of finger appears on it.
4. **Gandhavarnarasotpatti** – appropriate smell, color and taste of the avaleha.

**Precautions**
1. Mandagni should be maintained throughout the procedure.
2. Continuous stirring should be maintained throughout the procedure.
3. Khadishakara should be crushed uniformly.

**Analytical Study**

**Analysis of Dadimavaleha**

**Table no 5:-** showing the analytical parameters of Dadimavaleha

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values obtained</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ash</td>
<td>1.72</td>
</tr>
<tr>
<td>Acid insoluble ash</td>
<td>0.25</td>
</tr>
<tr>
<td>Water soluble extractive</td>
<td>56.25</td>
</tr>
<tr>
<td>Alcohol soluble extractive</td>
<td>23.85</td>
</tr>
<tr>
<td>PH</td>
<td>4.94</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.2568</td>
</tr>
<tr>
<td>Reducing sugar</td>
<td>37.50</td>
</tr>
<tr>
<td>Non reducing sugar</td>
<td>3.22</td>
</tr>
</tbody>
</table>

**Results & Discussion:-**

Standard Operating Procedure is a set of step-by-step detailed, written instructions to achieve uniformity of the performance of a specific function. Here the focus is always set on repeated application of unchanged processes and procedures and its documentation, hence supporting the segregation of origins, causes and effects. SOPs aim to achieve efficiency, quality output and uniformity of performance.

The preparation of Dadimavaleha was strictly carried out according to reference YogaratnakarJwaratisaradhyaadg guidelines for other similar avaleh preparation mentioned in Ayurvedic Formulary of India. As mentioned in reference Kwath has been prepared by using 4 times water by maintaining moderate heat (temperature not more than 90°c) so that extraction of active ingredients is carried out in gradual manner without
causing any harm to plant material due to excessive heat. 1 prastha (768 gm) Sitasharkara i.e. equal to the Dadimtwak was poured in Kwath and subjected to continuous moderate heat (temperature not more than 90°C to 105°C) to achieve two thread consistency (Dotaripaka). It takes 2 hours to achieve two thread consistency.

The analytical parameters assessment of prepared drug is an integral part for confirming quality of prepared formulation. Parameters like ash value, extractive value, specific gravity etc are used to determine the standards for herbs and polyherbal preparations. They help in determining the identity, authenticity, strength and purity of the substance and their qualitative standards. These analytical parameters also postulate the stability of formulations prepared. The acceptable range of values of these analytical tests signifies their bioacceptability for human.

**Total ash** –
All the traces of organic matter is incinerated during the procedure. High ash value indicates contamination, substitution, adulteration or even incorrect processing. It helps in determining both physiological ash (plant tissue) and non-physiological ash (extraneous matter like sand and soil).

Here, the analytical parameters suggest that total ash value is 1.72 and Acid insoluble ash is 0.25 since the value is minimal, which may be due to exudates from excipients or ingredients of Dadimavleh.

**Water soluble extractive and alcohol soluble extractive** –
The less extractive value indicates addition of any exhausted material, adulteration or incorrect processing during drying or storage or while preparing. Here the water soluble extractive is 56.25 and alcohol soluble extractive is 23.85. It indicates more water soluble content than alcohol soluble content in Dadimavaleha as the main chemical constituents isolated from Dadim (Skin/Pericarp/Peel) are flavonoids and tannins, complex polysaccharides, alkaloids etc which are more water soluble in nature. The high water soluble extractive value also indicates its more potency of bioassimibility in human consumption.

**pH** –
Indicating acidity or alkalinity which can be assumed to be suitable for human use. Acidic and alkaline pH influence the rate of decomposition of most drugs. Many drugs are stable between pH 4 and 8. Ph of Dadimavaleha is 4.94 indicates that prepared Dadimavaleha is pharmaceutically stable.

**Specific gravity** -
Specific gravity is the ratio of the density of a substance to the density of a reference substance. It gives the information about the concentration of formulations to evaluate the physical changes, or determine the degree of uniformity between the molecules indicating characteristics of the substance at specific temperature.

Here the specific gravity of Dadimavaleha is 1.2568 which indicates that the formulation is denser than water. This indicates the Siddhi lakshan of Avaleha i.e. it sinks in the water.

**Sugar content**-
It includes total sugar, reducing sugar and non-reducing sugar. The term free sugar or total sugar is applied to simpler carbohydrates.

**Reducing sugar** –
It is the one that contains or can form an aldehyde or ketone that can act as a reducing agent. A reducing sugar, when chemically altered, can donate electrons to another molecule, which will change the color and taste of food.

The main content i.e., Dadimtwak contains resin 4.5, manitol 1.8, sugars - 27, inulin 1, mucilage 0.6, tannin 10.4, galic acid 4, calcium oxalate 4, pectin 2-4% etc. This reveals high percentage of sugar in Dadimtwak.

The percentage of reducing sugar and non-reducing sugar are 37.50 and 3.22 respectively.

**Conclusion:**
Dadimavaleha is one of the most commonly used formulation in clinical practice. The detailed pharmaceutico-analytical study of the formulation has not yet done till date. The above detailed stepwise description and documentation in scientific, logical, sequential manner helps in developing a Standard Manufacturing Procedure for Dadimavaleha. This Standard Manufacturing Procedure helps other disciples of ayurved to achieve exactly similar
output when they follow the Standard Manufacturing Procedure of Dadimavleha. This study is also helps in standardization of Dadimavaleha.
References:
2. Ayurveda Sarasangraha, Baidyanath Ayurveda Bhavan Private Limited, reprint 2017 pg. no 532
3. TripatiIndradev, TripatiDayshankar, Yogaratnakar, SarvatisarChikitsa, ChoukambhaKrishnadasAcadamey, Varanasi, Shlok 156-60, pg no 215
4. Dr. AngadiRavindra, Sharangdharsamhita, Snehalpanadhaya, ChoukambhaSurbharatiPrakashan, Varanasi Shlok 3-4, pg no 284
5. Dr. AngadiRavindra, Sharangdharsamhita, Avalehakalpanadhaya, ChoukambhaSurbharatiPrakashan, Varanasi Shlok 3, pg no 273