STANDARD MANUFACTURING PROCEDURE OF ASHWAKANCHUKI RASA

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Abstract: Rasashastra is a branch of Ayurveda which deals with the processing of minerals, metals and poisonous herbs having their therapeutic importance. During the medieval period so many Rasa Acharya extensively worked and developed a number of processing method for a single or compound drug. They all are standard manufacturing procedure (S.M.P.) which ensure the quality, safety, efficacy and reproducibility of the product. Ayurvedic physician were producing medicines by themselves according to their need. Now a days, due to commercialization of Ayurvedic medicine and ignorance of classical method quality of the drug has deteriorated. At present, the demand of Ayurvedic drugs in the global market is so much increasing day by day. Hence, it is the need of time to develop S.M.P. of Ayurvedic product on modern parameter for global acceptability. This paper aims at providing S.M.P. for the manufacturing of Ashwakanchuki Rasa. It is a Kharaleeya Rasa preparation having herbo-mineral ingredients. All the prepared batches of Ashwakanchuki Rasa is evaluated on modern parameter shows the positive evidence in safety and efficacy.

Keywords: Ashwakanchuki Rasa, Bhavana, Shodhana, Kharaleeya, herbo-mineral.

Introduction: Herbo-mineral compound are at great demand globally for primary health care due to their higher safety margin and their cost effectiveness. Quality control of herbo-mineral compound generates a lot of problem. So, first and foremost task is the selection of the right kind of metals, minerals and herbs which is therapeutically efficacious compound. Herbo-mineral are being manufactured on a large scale where manufacture face many problem such as low quality materials, lack of authentication of raw materials, non-availability of standards, lack of standardisation methodology of compound drug or formulation and lack of quality control parameter. Various processing techniques are involved in order to make them suitable for human body and use of their in treating various diseases. Eg. different Shodhana media like Lime powder (Sudha), (Nistusha)Lahsuna, saindhava Lavana, Godugdha, Goghrita, Kushmanda swarasa, Gomutra, bhringaraja Swarasa are used for purification of Parada, Gandhaka, Tankana, Hartala, Vatsnabha, Jaypala for Ashwakanchuki Rasa preparation. Ashwakanchuki Rasa described in Rasayogasagara [1] for the treatment of various diseases. Now a days there is need to standardise pharmaceutical method, so that we can obtain Ashwakanchuki Rasa of same quality in every batch. In this paper, attempts are made to develop S.M.P. of Ashwakanchuki Rasa.

Aims and Objectives

• To develop standard manufacturing process of Ashwakanchuki Rasa.
• To develop analytical profile of formulation of Ashwakanchuki Rasa
• Heavy metal analysis of both compound AKR-001 & AKR-002
• To access microbial overload of Ashwakanchuki Rasa

Materials and Methods

Collection of Raw Materials: All the raw material were collected from Sundar Ayurveda teaching pharmacy, J. S. Ayurveda College,
Nadiad after authentication. Metals, minerals and poisonous herbs were processed through Shodhana and trituration with some herbs to prepare Ashwakanchuki Rasa. Table -1 gives information of materials required for Shodhana process.

**Table -1 : Shodhana of ingredients of Ashwakanchuki Rasa**

|----------------|------------------------|-----------|-----------|--------------------------|--------------------------|--------------|

**Note :** Kajjali, Triphala churna, Trikatu churna and (Bhavna Dravya) Bhringraja swarasa prepared as per reference.

**Preparation of Ashwakanchuki Rasa According to Rasayogasagar**

**Table-2 : Ingredients**

<table>
<thead>
<tr>
<th>Sr No</th>
<th>Classical name</th>
<th>Botanical name/ English name</th>
<th>Parts used</th>
<th>Quantity (gm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kajjali</td>
<td>-</td>
<td>-</td>
<td>50</td>
</tr>
<tr>
<td>2</td>
<td>Shuddha Hartala</td>
<td>Orpiment</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>3</td>
<td>Shuddha Tankana</td>
<td>Borax</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>4</td>
<td>Shuddha Vatsnabha</td>
<td>Aconitum ferox Wall.</td>
<td>Root</td>
<td>25</td>
</tr>
<tr>
<td>5</td>
<td>Shuddha Jaypala</td>
<td>Croton tinglingum Linn.</td>
<td>Seed</td>
<td>25</td>
</tr>
<tr>
<td>6</td>
<td>Haritaki churana</td>
<td>Terminalia chebula Retz.</td>
<td>Fruit</td>
<td>25</td>
</tr>
<tr>
<td>7</td>
<td>Bibhitaki churana</td>
<td>Terminalia bellirica Roxb.</td>
<td>Fruit</td>
<td>25</td>
</tr>
<tr>
<td>8</td>
<td>Amalaki churana</td>
<td>Emblica officina Gaertn.</td>
<td>Fruit</td>
<td>25</td>
</tr>
<tr>
<td>9</td>
<td>Santhi churana</td>
<td>Zingiber officinale Rosc</td>
<td>Rhizome</td>
<td>25</td>
</tr>
<tr>
<td>10</td>
<td>Pippali churana</td>
<td>Piper longum Linn.</td>
<td>Fruit</td>
<td>25</td>
</tr>
<tr>
<td>11</td>
<td>Maricha churana</td>
<td>Piper nigrum Linn.</td>
<td>Fruit</td>
<td>25</td>
</tr>
<tr>
<td>12</td>
<td>Bhringraja swarasa</td>
<td>Eclipta alba Hassk.</td>
<td>Plant</td>
<td>20,420 L</td>
</tr>
</tbody>
</table>

**Procedure**

- All the above mentioned materials/ingredients were taken in specified amounts separately and mixed well in a steel plate.
- This mixture was taken in khalvayantra and triturated till it forms homogenous fine powder.
- Now, Bhringraja Swarasa is extracted.
- The mixture powder was subjected to Bhavana with Bhringraja Swarasa as required and then triturated well carefully.
- This Bhavana process was repeated 21 times and triturated.
- After completion of Bhavana process when the mixture become like Kalka, the binding agent (Acasia Arabica) was added and prepared granules from granule machine and tablets of 125 mg. was prepared in automatic Tablet making machine.
- Prepared tablet kept in air tight glass jar.

**Precaution**

- Trituration should be done after each Bhavana process.
- Fresh BhringajaSwarasa was used during each Bhavana.
- Binding agent completely mixed and then granules should be prepared.
- After granulation process tablet must be prepared of 125 mg.
- Tablet must be kept in air tight glass jar.

**Table 3 : Showing description of Bhavana process**

<table>
<thead>
<tr>
<th>No of Bhavana</th>
<th>Date of starting</th>
<th>Date of completion</th>
<th>Wt. of Bhringraja (gm)</th>
<th>Volume of Bhringraja Swarasa (ml)</th>
<th>Time taken(in days)</th>
<th>Wt. after bhavana</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2-5-16</td>
<td>3-5-16</td>
<td>900</td>
<td>300</td>
<td>2</td>
<td>313</td>
</tr>
<tr>
<td>2</td>
<td>3-5-16</td>
<td>5-5-16</td>
<td>950</td>
<td>300</td>
<td>2</td>
<td>269</td>
</tr>
<tr>
<td>3</td>
<td>5-5-16</td>
<td>7-5-16</td>
<td>930</td>
<td>300</td>
<td>2</td>
<td>275</td>
</tr>
</tbody>
</table>

50 gm sample has taken for analysis
In this era, there is a shifting of expectations in the society from efficacy to safety. Hence it is necessary to identify the nature of compound which we prescribe to our patients. For knowing whether it contains any harmful substances or not, analytical study of Ayurvedic especially of metallic and mineral preparations is mandatory.

Table 4: showing result of Ashwakanchuki Rasa prepared in three different batches

<table>
<thead>
<tr>
<th>Sr no.</th>
<th>Date of starting</th>
<th>Date of completion</th>
<th>Wt. of drug taken</th>
<th>Wt. of drug after Bhavna</th>
<th>Volume of BhringrajaSwarasa used</th>
<th>Wt. of tablet formed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2-5-16</td>
<td>26-6-16</td>
<td>300 gm</td>
<td>370 gm</td>
<td>1000 L</td>
<td>430 gm</td>
</tr>
<tr>
<td>2</td>
<td>1-7-16</td>
<td>28-8-16</td>
<td>300 gm</td>
<td>432 gm</td>
<td>1000 L</td>
<td>403 gm</td>
</tr>
<tr>
<td>3</td>
<td>1-9-16</td>
<td>26-10-16</td>
<td>300 gm</td>
<td>441 gm</td>
<td>300 L</td>
<td>418 gm</td>
</tr>
</tbody>
</table>

Table 5: Classical analytical evaluation methods for powder form of Ashwakanchuki Rasa

<table>
<thead>
<tr>
<th>Sr No.</th>
<th>Parameters</th>
<th>Kajjali</th>
<th>Before Bhavna</th>
<th>After Bhavna</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rekhapurnatva</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>2</td>
<td>Varitara</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>3</td>
<td>Slakshnatva</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>4</td>
<td>Nischandratva</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

Table 6: Result of Physical analysis of Ashwakanchuki Rasa tablet

<table>
<thead>
<tr>
<th>Parameters</th>
<th>AKR – 001</th>
<th>AKR - 002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>Round &amp; Flat</td>
<td>Round &amp; Flat</td>
</tr>
<tr>
<td>Hardness</td>
<td>1.5 kg/cm²</td>
<td>1.5 kg/cm²</td>
</tr>
<tr>
<td>Average weight</td>
<td>122 mg</td>
<td>122 mg</td>
</tr>
<tr>
<td>Disintegration time</td>
<td>22 min</td>
<td>23 min</td>
</tr>
</tbody>
</table>

Table 7: Modern parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Batch 1 After Bhavna</th>
<th>Batch 2 After Bhavna</th>
<th>Batch 3 After Bhavna</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.79</td>
<td>6.45</td>
<td>6.23</td>
</tr>
<tr>
<td>Loss on drying(%)</td>
<td>76.9%</td>
<td>73.4%</td>
<td>70.2%</td>
</tr>
<tr>
<td>Ash value(%)</td>
<td>13.1%</td>
<td>26.6%</td>
<td>29.8%</td>
</tr>
<tr>
<td>Acid insoluble ash(%)</td>
<td>2.0%</td>
<td>1.9%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Water soluble extract(%)</td>
<td>31.2%</td>
<td>10.9%</td>
<td>30.5%</td>
</tr>
<tr>
<td>Alcohol soluble extract(%)</td>
<td>12.1%</td>
<td>10.2%</td>
<td>8.7%</td>
</tr>
</tbody>
</table>

HPTLC profile of AKR 001 & AKR 002 tablet

Preparation of Reference Solution: Piperine and Gallic Acid: Reference standard – Piperine (S1): Exact 10.00 mg of Standard Piperine (Purity 99%) was taken in 10mL volumetric flask and volume was made up to 10mL with Methanol. Take the solution for HPTLC Profiling.

Reference Standard: Gallic Acid (S2): Exact 10.00 mg of Standard Gallic Acid (Purity 99%) was taken in 10mL volumetric flask and volume was made up to 10mL with Methanol. Take the solution for TLC/HPTLC Profiling.
**Preparation of Test Solution**: Extract 2.0 gm of Test material with 20 mL of Methanol & reflux it on water bath at 90-100°C for 20 min. Filter and evaporate up to 5mL in porcelain dish. Fill in 10mL volumetric flask and volume made up to 10mL with Methanol. Take the solution for HPTLC profiling.

<table>
<thead>
<tr>
<th>Application mode</th>
<th>CAMAG Linomat 5 - Applicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stationary Phase</td>
<td>MERCK - HPTLC Silica gel 60 F254 on Aluminum sheets</td>
</tr>
<tr>
<td>Application (Y axis) Start Position</td>
<td>10 mm</td>
</tr>
<tr>
<td>Development (Y axis) End Position</td>
<td>80 mm from plate phase</td>
</tr>
<tr>
<td>Band width</td>
<td>6 mm</td>
</tr>
<tr>
<td>Sample Application Volume</td>
<td>5µL and 10µL</td>
</tr>
<tr>
<td>Development Mode</td>
<td>CAMAG TLC Twin Trough Chamber</td>
</tr>
<tr>
<td>Chamber Saturation Time</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Mobile Phase (MP)</td>
<td>Toluene: Ethyl acetate: Methanol: Formic Acid (6:6:1.8:0.25)</td>
</tr>
<tr>
<td>Visualization</td>
<td>@254nm, @366nm, @ Visible (after spray of Anisaldehyde Sulphuric acid reagent)</td>
</tr>
<tr>
<td>Derivatization mode</td>
<td>CAMAG – Dip tank for about 1 minute</td>
</tr>
<tr>
<td>Drying Mode, Temp. &amp; Time</td>
<td>TLC Plate Heater Preheated at 100± 5°C for 3 minutes</td>
</tr>
</tbody>
</table>

**Quantification of Piperine & Gallic acid was carried out at 254 nm.**

<table>
<thead>
<tr>
<th>Table – 9 : Quantification of Piperine</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Piperine</td>
<td>AKR 001 Tablet</td>
</tr>
<tr>
<td>Inj. Vol</td>
<td>5 µL</td>
</tr>
<tr>
<td>Area @ 254nm</td>
<td>15572.8</td>
</tr>
<tr>
<td>Max Rf</td>
<td>0.79</td>
</tr>
<tr>
<td>Result(%)</td>
<td>---</td>
</tr>
<tr>
<td>Mean result(%)</td>
<td>---</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table – 10 : Quantification of Gallic Acid</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gallic Acid</td>
<td>AKR 001 Tablet</td>
</tr>
<tr>
<td>Spots</td>
<td>7</td>
</tr>
<tr>
<td>Inj. Vol</td>
<td>5 µL</td>
</tr>
<tr>
<td>Area @ 254nm</td>
<td>19371.8</td>
</tr>
<tr>
<td>Max Rf</td>
<td>0.52</td>
</tr>
<tr>
<td>Result(%)</td>
<td>---</td>
</tr>
<tr>
<td>Mean result(%)</td>
<td>---</td>
</tr>
</tbody>
</table>

**HPTLC Chromatogram at three different wavelengths:**

![HPTLC Chromatogram at three different wavelengths](image-url)
Table – 11 : Heavy metal analysis

<table>
<thead>
<tr>
<th>Sr No.</th>
<th>Parameters</th>
<th>Permissible limit</th>
<th>Result</th>
<th>Test Method Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AKR 001 Tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Lead (Pb)</td>
<td>10 ppm</td>
<td>0.364 ppm</td>
<td>API, Part- II, Vol. III</td>
</tr>
<tr>
<td>2</td>
<td>Cadmium (Cd)</td>
<td>0.3 ppm</td>
<td>72.365 ppm</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Arsenic (As)</td>
<td>3 ppm</td>
<td>12540 ppm</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Mercury (Hg)</td>
<td>1 ppm</td>
<td>41062 ppm</td>
<td></td>
</tr>
<tr>
<td>AKR 002 Tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Lead (Pb)</td>
<td>10 ppm</td>
<td>0.432 ppm</td>
<td>API, Part- II, Vol. III</td>
</tr>
<tr>
<td>2</td>
<td>Cadmium (Cd)</td>
<td>0.3 ppm</td>
<td>89.617 ppm</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Arsenic (As)</td>
<td>3 ppm</td>
<td>15394 ppm</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Mercury (Hg)</td>
<td>1 ppm</td>
<td>47861 ppm</td>
<td></td>
</tr>
</tbody>
</table>

Data of heavy metal analysis of AKR-001 & AKR-002 reveal that tablets contain very high level of Mercury, Arsenic and Cadmium as that of permissible limit of API. This is probably due to cross contamination because of simultaneously ongoing formulation containing these elements.

Table – 12: Microbial overload of Ashwakanchuki Rasa

<table>
<thead>
<tr>
<th>Sr No.</th>
<th>Parameters</th>
<th>Permissible limit</th>
<th>Result</th>
<th>Test Method Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AKR 001 Tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Total Plate Count</td>
<td>10^5 cfu/g</td>
<td>326 cfu/g</td>
<td>API, Part-1, Vol.VI</td>
</tr>
<tr>
<td>2</td>
<td>Total Yeast &amp; Mould Count</td>
<td>10^3 cfu/g</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Escherichia coli</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Salmonella sp.</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Staphylococcus aureus</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Pseudomonas aeruginosa</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>AKR 002 Tablet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Total Plate Count</td>
<td>10^5 cfu/g</td>
<td>397 cfu/g</td>
<td>API, Part-1, Vol.VI</td>
</tr>
<tr>
<td>2</td>
<td>Total Yeast &amp; Mould Count</td>
<td>10^3 cfu/g</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Escherichia coli</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Salmonella sp.</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Staphylococcus aureus</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Pseudomonas aeruginosa</td>
<td>Absent</td>
<td>Absent</td>
<td></td>
</tr>
</tbody>
</table>

Observation & Results

Ashwakanchuki Rasa is a Kharaleeya Rasayana and very potent drug for the treatment of Tamaka Shwasa (Bronchial Asthma). In Rasatantrasara and Siddhaprayoga sangraha, therapeutic usage of Ashwakanchuki Rasa is elaborated with different Anupana. The potency of Ashwakanchuki Rasa will be increases due to repeated Bhavna of Bhringraja Swarasa. The manufacturing process of different batches and analytical profile of Ashwakanchuki Rasa shows the efficacy and safety of particular drug compound. In microbial evaluation there is no unwanted yeast and particular bacilli Eg. Escherichia coli, Salmonella Sp., Staphylococcus aureus and Pseudomonas aeruginosa not seen in both samples of Ashwakanchuki Rasa (AKR-001 & AKR-002). It shows that, both samples are very safe and efficacious in therapy.

Note

- AKR- 001 is Ashwakanchuki Rasa prepared with Bhringraja Swarasa Bhavna
- AKR-002 is Ashwakanchuki Rasa prepared with additional bhavna of Ardraka Swarasa.

Conclusion

- Ashwakanchuki Rasa is a herbo-mineral compound widely used in Tamaka Shwasa (Bronchial Asthma).
- Very potent Kharaleeya Rasayana prepared in three batches in regard to S.M.P. purpose.
- All the prepared batches of Ashwakanchuki Rasa is evaluated on modern parameter shows the positive evidence in safety and efficacy.

References


