A COMPARATIVE PHARMACEUTICALLY-ANALYTICAL EVALUATION OF RASAMANIKA PREPARED WITH THREE DIFFERENT METHODS

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ABSTRACT

Ayurveda has interacted with various medical systems from time to time and this interaction along with updated research has facilitated quality assurance. Physico-chemical analysis of the drugs was carried out by using current analytical methodologies for better understanding and interpretation of changes occurring during and after pharmaceutical processing. It was found that there were minimal differences found in the three samples of Rasamanika but when the three samples were compared together it was assessed that Rasamanika-I prepared out of abhrraka patra method showed better results from the standardization point of view and quality assurance of Rasamanika.

KEY WORDS: Rasamanika, Physico-Chemical parameters, X-RD, ICP-AES

INTRODUCTION

Ayurveda has interacted with various medical systems from time to time and this interaction along with updated research has facilitated its growth. The single drug treatment was the base which was being fulfilled by the plant origin drug. The curiosity and advancement of mankind, single drug treatment was over ruled by multiple combinations containing numerous ingredients containing minerals too. Rasashastra holds supremacy among all other branches of Ayurveda. It states the importance of herbo-mineral preparations emphasizing towards the chikitsa on which all principle is laid down in acute condition leading in better and quicker results.

Rasamanika is one type of preparation made out of only shuddha haratala. It is a very famous drug frequently used by different Ayurvedic physicians effectively in various respiratory conditions, skin diseases, allergic and obstructive urinary disorders, autoimmune disorders etc and which has a high demand in current pharmaceutical industry.

Rasamanika possesses many different pharmaceutical methods but to produce standardized, reproducible clinically effective medicine a standard operation procedure (SOP) in the preparation of Rasamanika along with certain Analytical methods helps to reveal out the chemical composition of a formulation with their concentration and also ensure safety limits and accuracy of the drug. In the present era in order to establish the safety concern the prepared drug should be understood well and interpreted with the help of modern technology backed by proper scientific validation. The use of genuine ingredients ensures the potency and efficacy of the formulation. Hence in the present study a comparative pharmaceutical-analytical study of Rasamanika prepared with three different methods was attempted following classical and adopted method along with current analytical methodologies including organoleptic characters, physicochemical analysis, x-ray diffraction and elemental analysis.

AIMS AND OBJECTIVES

1. To prepare Rasamanikya by three different pharmaceutical procedures.
2. Physico-chemical analysis of Rasamanikya along with qualitative and quantitative properties by following Particle Size Analysis, X-ray diffraction and ICPAES.

MATERIALS AND METHODS

Selection and Collection of Raw material

The crude patra haratala was selected and collected as per grahya lakshanas from SDMCA, Pharmacy, Udupi. Haratala shodhana was carried out by doing swedana kriya in kushmanada swarasa and churnodaka for 1 yama (3hrs) each time as mentioned in the Rasa tarangini.

Method of preparation of the Rasamanika by classical abhrraka patra method (R.M-I)

Masha of shudha patra haratala churna is put in between two shweta abhrraka patras and placed over gas stove/charcoal fire and mild heat is given by blowing the coal with the help of vankanala. When the colour of haratala inside abhrraka patra turns to manikya varna, patras are then taken out of the fire. After swarga shita Rasamanika is collected from the abhrraka patras.

Method of preparation of the Rasamanika by classical (modified) sharava samputa method (R.M-II)

Shudha patra haratala churna is taken and is kept in lower sharava. One sharava is kept over it having a hole of 1 angula in its centre. The gap between the 2 sharavas was enclosed which is sealed with the help of multani mitti. This sharava samputa is kept on fire and heated till the lower sharava turns aruna varna. After swarga shita Rasamanika is collected from the lower sharava.

Method of preparation of the Rasamanika by adopted fused electric bulb method (R.M-III)

In this method shudha patra haratala churna is taken in an electric bulb, which is heated on the mild fire until the colour of haratala changes to manikya varna. Once varna achieved it is immediately wrapped in a wet cloth and rolled over, thereby Rasamanika is separated carefully from the glass pieces.
Pharmaceutical study
The shodhana of haratala was done by sewdana kriya (dola yantra method) as mentioned in Rasa tarangini & preparation of Rasamanikya as per classical guidelines and adopted method was carried out in Rasashastra-Bhaishajya Kalpana practical hall, S.D.M. College of Ayurveda, Udupi, Karnataka.

Analytical study
The Analysis of the drug Rasamanikya prepared with three methods was carried out on the basis of their organoleptic characters, physico-chemical properties, qualitative & quantitative analysis methods in Sophisticated Analytical Instrumentation Facility (IIT) Powai, Mumbai and Bangalore Drug Test House, (BTH), Bangalore, Karnataka.

RESULTS & DISCUSSION

1. Pharmaceutical Study
A. Output
Maximum yield of Rasamanikya was observed in the abhraka patra method.

B. Time duration
Minimum time for the preparation of Rasamanikya was observed in the abhraka patra method.

C. Colour (manikya varna lakshana) and after grinding-sieving
Depending upon the use of materials for the preparation of Rasamanikya, the manikya varna was appreciated in both abhraka patra and fuse electric bulb method but different coloured powders were obtained after grinding and sieving.

Final results of Rasamanikya prepared with three different methods w.r.t time duration, paka lakshana- colour, colour after grinding- sieving & output % is tabulated in table 1.

D. Advantages & Disadvantages of Rasamanikya prepared with classical abhraka patra method
I. Advantages
1. It takes very short time to prepare
2. Characteristic manikya varna can be appreciated.

II. Disadvantages
1. Only little quantity of Rasamanikya can be prepared, not in a big scale.
2. Shweta abhraka patras are not easily available.
3. Repeated process is required to achieve large quantity and moreover same patras can’t be used as they leave their layers and becomes blackish on repeated heating.

E. Advantages & Disadvantages of Rasamanikya prepared with classical modified sharava samputa method
I. Advantages
1. Large quantity of Rasamanikya can be prepared in a single sharava.
2. A shallaka can be inserted in the sharava through the hole in order to observe the Tantu-paka which was taken as assessment criteria for the completion of the preparation.

II. Disadvantages
1. After opening of sharava it was observed that most of the haratala remained as it is in sides of lower sharava without any color change.
2. Less yield of Rasamanikya and no appreciation of manikya varna.

F. Advantages & Disadvantages of Rasamanikya prepared with adopted fuse electric bulb method
I. Advantages
1. Small quantity of Rasamanikya can be prepared very easily in the bulb.
2. The appearance was exactly like ruby colored with the shape of bottom of electric bulb.

Disadvantages
1. This method is little tedious while taking out the coil of the fuse bulb.
2. Less yield of Rasamanikya.
3. Holding the bulb on fire is difficult.

2. Analytical Study
A. Organoleptic characters
The characters of the sample are tabulated in table 2.

B. Qualitative Analysis (physico-chemical parameters)
The samples of Rasamanikya were evaluated for physico-chemical parameters like total ash value, total acid insoluble ash, total water soluble ash, moisture content, pH values. The parameters followed were taken from Ayurvedic Pharmacopoeia of India. Presence of more moisture content may create problems in preservation of the sample. Hence it was also selected as one of parameters. The results are placed at table 3.

C. Quantitative Analysis
1. Particle size assessment
The particle size of the three samples was 50.23% in R.M-I, 76.19% in R.M-II & 90.26% in R.M-III respectively with the help of mechanical shaker. The assessment as per API protocol was found to be as moderately fine powder (the particles of powders passes through a sieve with a nominal mesh aperture of 355 μm and not more than 40.0 per cent through a sieve with a nominal mesh aperture of 180 μm). In the assessed samples the size of the particle was increased consecutively in the order of the samples. Lesser the particle size-better absorption in the body. The size of the particle is influenced by the kind of heat given, pressure applied for powdering & the filter medium used during the pharmaceutical process. the results are placed at table 4.

2. Chemical test
Inductive Coupled Plasma Atomic Emission Spectroscopy (ICP-AES)
Elemental analytical reports of all 5 samples crude haratala, shuddha haratala, R.M-I, R.M-II, R.M-III respectively were obtained by using Inductive coupled plasma atomic emission spectroscopy. Fe, Mg, Si, As & S were detected in sample crude haratala-sample-A, shuddha haratala-sample-B, R.M-I-sample-C, R.M-II-sample-D, R.M-III-sample-E. In this analysis it was found that the proportion of the entire elements ratio varied in a minimal state in all the samples. But from the quantitative analysis of all the 5 samples Arsenic and Sulphur were found to be main contents of the drug. The results are placed at table 5.

3. Instrumental test
X-Ray Diffraction (XRD)
For the present study the X-ray analysis of four samples were carried out using Bruker’s D-8 Advance X-ray diffractometer. The machine is equipped with CuKa1: 1.54060 radiations and graphite monochromator operated at 40 kV / 30 mA). All samples were very well grounded to 200 meshes and air-dried. The X-ray diffractometer scans was made on randomly oriented samples from 3-65° 2-theta (d=29.42 to 1.43 angstrom) with a step size of 0.02° and 1 second time per step. About 1 gram of fine powder of sample was put in the groove of sample holder of the X-Ray diffractometer. Surface of the sample was made flat to avoid any error coming out of rough surface specimen. The X- ray diffractograms were taken in an X- Ray diffractometer with target at 25 KV and 10 MA. Observations were obtained as follows:
In the ashudha haratala X-RD analysis it was observed that it was highly crystalline (~100%) and Monoclinic system pattern, by using powder diffraction file database-JCPDS it showed that it is purely AsS2 with graph showing prominent peaks of Arsenic trisulphide with many impurities present in it.
Rasamanikya Sample-I powder showed that it is relatively amorphous in nature remaining particles may have been converted to low crystalline shape or amorphous shape as few peaks of AsS2 and AsS were seen giving pattern corresponds with arsenic sulphide.

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Rasmanikya Sample-II powder showed that it is relatively amorphous in nature showing 20% crystallinity remained few prominent peaks of As₂S₃ was observed along with small peaks indicating little quantity of AsS. The graph of this sample was zigzag in shape and was not having many peaks. This indicated that the Rasamanikya had lost the crystallinity and attained the amorphous form.

Rasmanikya Sample-III powder showed that whole particles converted into amorphous form-shape with very low peaks. The graph of this sample was zigzag in shape and was not having any long peaks at all. This indicated that the Rasamanikya had lost the crystallinity and fully attained the amorphous form. The results are placed at table 6.

CONCLUSION
Patra haratala variety of haratala is considered as shrestha in maximum number of Rasa literatures. Shodhana is necessary because of proven toxicity effects and was conducted by subjecting it to the swedana following dola yantra method in kushananda swarasa and churnodaka which has majority of opinions. Rasamanikya is such yoga which is derived out from only one single drug i.e. haratala, rather it can be said as a modified form of haratala obtained from the shudha patra haratala.

Rasamanikya prepared by classical abhraka patra method is very easy but only a little quantity of the product can be prepared on a small scale. The other classical sharava samputa method with suitable modifications is laborious but appreciable for large scale pharmaceutical preparation. The adopted method of I.P.G.T&T.R.A, Jamnagar prepared by fused glass bulb varies from the basic idea of preparation where in direct air contact will be there.

A hypothesis can be given by above pharmaceutical discussion that considering quality wise proper paka lakshana, time duration, heat factor and the output gain%, the 1st procedure that is abhraka patra method holds good for proper and genuine preparation of Rasamanikya at a small scale but as the quantity used for this procedure is very less giving less yield, from commercial point of view it depends upon the demand and supply.

Analytically there were minimal differences found in all the three samples of Rasamanikya but considering from standardisation point of view and also to establish standards for quality control of Rasamanikya 1st procedure that is abhraka patra method holds good for proper and genuine preparation of Rasamanikya.

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REFERENCES

Table 1: Final results of Rasamanikya prepared with three different methods w.r.t time duration, paka lakshana- colour, after grinding -sieving & output % & content

<table>
<thead>
<tr>
<th>Method</th>
<th>Output %</th>
<th>Time duration</th>
<th>Colour manikya varna lakshana-</th>
<th>Colour after grinding sieving</th>
</tr>
</thead>
<tbody>
<tr>
<td>R.M-I Abhraka patra</td>
<td>90%</td>
<td>5 mins</td>
<td>Manikya varna appreciated</td>
<td>Reddish brown</td>
</tr>
<tr>
<td>R.M-II Sharava samputa (modified)</td>
<td>70%</td>
<td>1 hr 15 min</td>
<td>Manikya varna not appreciated</td>
<td>Brick red</td>
</tr>
<tr>
<td>R.M-III Fuse Electric bulb</td>
<td>85%</td>
<td>15 mins</td>
<td>Manikya varna appreciated</td>
<td>Reddish black</td>
</tr>
</tbody>
</table>

Table 2: Organoleptic characters of Rasamanikya prepared with three methods

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Organoleptic Characters</th>
<th>R.M-I</th>
<th>R.M-II</th>
<th>R.M-III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Colour</td>
<td>Reddish brown</td>
<td>Brick red</td>
<td>Reddish black</td>
</tr>
<tr>
<td>2.</td>
<td>Odour</td>
<td>Odourless</td>
<td>Fanti</td>
<td>Odourless</td>
</tr>
<tr>
<td>3.</td>
<td>Taste</td>
<td>Tasteless</td>
<td>Tasteless</td>
<td>Tasteless</td>
</tr>
<tr>
<td>4.</td>
<td>Touch</td>
<td>Soft</td>
<td>Soft</td>
<td>Soft</td>
</tr>
<tr>
<td>5.</td>
<td>Appearance</td>
<td>Powder form</td>
<td>Powder form</td>
<td>Powder form</td>
</tr>
</tbody>
</table>

Table 3: Physico-chemical parameters of Rasamanikya prepared with three methods

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Parameters</th>
<th>R.M-I</th>
<th>R.M-II</th>
<th>R.M-III</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>% Of Total ash</td>
<td>0.50%</td>
<td>1.09%</td>
<td>0.28%</td>
</tr>
<tr>
<td>2.</td>
<td>% Of Acid insoluble ash</td>
<td>0.34%</td>
<td>0.27%</td>
<td>0.07%</td>
</tr>
<tr>
<td>3.</td>
<td>% Of Water soluble ash</td>
<td>0.29%</td>
<td>0.19%</td>
<td>0.21%</td>
</tr>
<tr>
<td>4.</td>
<td>P&lt;sub&gt;T&lt;/sub&gt;</td>
<td>6.91</td>
<td>6.63</td>
<td>7.32</td>
</tr>
<tr>
<td>5.</td>
<td>Moisture content</td>
<td>0.02%</td>
<td>0.01%</td>
<td>0.02%</td>
</tr>
</tbody>
</table>
Table 4: Particle size assessment of Rasamaniya prepared with three methods

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Particle size (Sieve method)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R.M-I</td>
<td>50.23%</td>
</tr>
<tr>
<td>2</td>
<td>R.M-II</td>
<td>76.19%</td>
</tr>
<tr>
<td>3</td>
<td>R.M-III</td>
<td>90.26%</td>
</tr>
</tbody>
</table>

Table 5: Elemental analysis of all samples using ICP-AES

<table>
<thead>
<tr>
<th>Elements</th>
<th>Raw Haratala Sample A (ppm)</th>
<th>Shuddha Haratala Sample B (ppm)</th>
<th>R.M-I Sample C (ppm)</th>
<th>R.M-II Sample D (ppm)</th>
<th>R.M-III Sample E (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fe</td>
<td>363.8187</td>
<td>283.1833</td>
<td>362.4671</td>
<td>351.7045</td>
<td>535.2871</td>
</tr>
<tr>
<td>Mg</td>
<td>95.99535</td>
<td>95.36257</td>
<td>108.1555</td>
<td>106.592</td>
<td>114.1348</td>
</tr>
<tr>
<td>Si</td>
<td>5964.8</td>
<td>5891.7</td>
<td>6760.1</td>
<td>10787.5</td>
<td>7161.2</td>
</tr>
<tr>
<td>As</td>
<td>422665.1</td>
<td>418895.3</td>
<td>421724.2</td>
<td>404026.9</td>
<td>431120.4</td>
</tr>
<tr>
<td>S</td>
<td>309613.6</td>
<td>302699.2</td>
<td>312356.5</td>
<td>297732.6</td>
<td>3037554.5</td>
</tr>
</tbody>
</table>

Table 6: X-Ray Diffraction of all samples using XRD powder technique

<table>
<thead>
<tr>
<th>Sys:</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Space group:</td>
<td>P₂₁/n (14)</td>
<td>PM₂₁</td>
</tr>
<tr>
<td>a:</td>
<td>11.464</td>
<td>9.168</td>
</tr>
<tr>
<td>b:</td>
<td>9.572</td>
<td>9.503</td>
</tr>
<tr>
<td>c:</td>
<td>4.225</td>
<td>11.466</td>
</tr>
<tr>
<td>α:</td>
<td>90.123</td>
<td>90</td>
</tr>
<tr>
<td>β:</td>
<td>90.500</td>
<td>90.12</td>
</tr>
<tr>
<td>γ:</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Cell Volume:</td>
<td>3.490Å³</td>
<td>999Å³</td>
</tr>
</tbody>
</table>

Figure 1: XRD graph- raw haratala
Figure 2: XRD graph- R.M-I
Figure 3: XRD graph- R.M-II
Figure 4: XRD graph- R.M-III

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