Pharmaceutical Standardization

Standardization of Shirishavaleha with reference to physico-chemical characteristics

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Abstract

Ten batches of Shirishavaleha were prepared by using Twak (Bark) and Sara (Heartwood) of Shirisha [Albizia lebbeck Benth]. The adopted formulation was based on Shirisharishta of Bhaishajya Ratnavali. Though Shirisharishta has significant therapeutic effect in cases of Tamaka swasa, etc.; it has few difficulties during the pharmaceutical procedure like consuming long time, climatic influences etc. Considering these inconveniences, the formulation composition has been converted in to Shirishavaleha. Avaleha has been prepared by using Twak and Sara of Shirisha. No significant differences were found in pharmaceutical aspects of both the samples of Shirishavaleha and the current method of preparation can be considered as standard. Attempts were also made to develop analytical profile of avaleha, which were almost similar in both the samples, except showing more Rf values in High Performance Thin Layer Chromatography profile of Sara group.

Key words: Albizia lebbeck, Avaleha, Bark, Heartwood, Shirisha, Shirishavaleha

Introduction

Shirisha [Albizia lebbeck Benth] is a drug with multi-dimensional activities mentioned in Ayurvedic classics for different disease conditions like Swasa, Visha etc.¹,² Studies conducted in recent past reveals anti-asthmatic,³ anti-tussive,⁴ anti allergic,⁵ mast cell stabilizing⁶ and immuno modulatory activities⁷ of the drug. Ayurvedic classics holds a number of formulations where Shirisha is one of the active components. Shirisharista⁸ is one amongst them. Though Arista form of the drug is effective, it has certain disadvantages such as:

• Prolonged duration of pharmaceutical procedure,
• To be prepared only in specific seasons,
• Temperature regulation is needed during the manufacturing,
• Liquid dosage forms are difficult to transport,
• Some part of the community may not accept alcoholic preparations to consume.

Considering these disadvantages, it has been planned to convert the formulation composition of Shirisharishta into Shirishavaleha.

Further, the part of Shirisha advocated to use in sandhana (fermentation process) is Sara.⁹ Collecting Sara is difficult and it involves destruction of a plant, while Twak can be easily collected. Looking in to this, it has been planned to prepare shirishavaleha by using Twak and Sara of Shirisha.

Aims and objectives

• To formulate Shirishavaleha with Twak and Sara of Shirisha and evaluate their physico chemical characteristics.

Materials and Methods

Test drugs

Shirishavaleha is a pure herbal formulation holding 11 ingredients [Table 1] in its composition. Shirisha was collected from botanical garden of Gujarat Ayurved University after proper authentication. Prakshsha dravyas were obtained from the Pharmacy, Gujarat Ayurved University except Haridra, Nilini and Nagakesara. Nilini was collected from surrounding areas of Jamnagar, Haridra was purchased from local markets of Jamnagar and Nagakesara was procured from markets of Udupi, Karnataka. All the components were separated from physical impurities like small stones, sand particles etc. Guda of satisfactory quality was purchased from local market of Jamnagar. The herbal material was authenticated by the Pharmacognosy laboratory of IPGT and RA, Gujarat Ayurved
Table 1: Formulation composition of Shirishavaleha

| Ingredient | Botanical name       | Part used   | Quantity     | Conversion* | Amount taken in the current study |
|------------|----------------------|-------------|--------------|-------------|----------------------------------|
| Kwatha dravya            |                       |             |              |             |                                  |
| Shirisha | Albizia lebbeck Benth. | Bk./Ht. Wd. | 1/2 Tula    | 2400 g      | 1250 g                           |
| Jala (w/w) | Potable water | - | 2 Drona      | 2456 ml     | 12500 ml                         |
| Praksepa dravas          |                       |             |              |             |                                  |
| Pippali   | Piper longum Linn.    | Fr.         | 1 Pala       | 48 g        | 24 g                             |
| Priyangu  | Callicarpa macrophylla Vahl. | Fl.        | 1 Pala       | 48 g        | 24 g                             |
| Kushtha   | Saussurea lappa C. B. Clarke | Rt.      | 1 Pala       | 48 g        | 24 g                             |
| Ela       | Elettaria cardemomum Maton. | Sd.      | 1 Pala       | 48 g        | 24 g                             |
| Nilini    | Indigofera tinctoria Linn. | Rt.      | 1 Pala       | 48 g        | 24 g                             |
| Haridra   | Curcuma longa Linn.   | Rz.         | 1 Pala       | 48 g        | 24 g                             |
| Daruheridra | Berberis aristata DC. | St.         | 1 Pala       | 48 g        | 24 g                             |
| Shunthi   | Zingiber officinale Roscoe. | Rz.      | 1 Pala       | 48 g        | 24 g                             |
| Nagakesara | Mesua ferrea Linn.  | Stmn.       | 1 Pala       | 48 g        | 24 g                             |
| Madhura dravya          |                       |             |              |             |                                  |
| Guda       | Jaggery              | -           | 2 Tula       | 9600 g      | 5000 g                           |

(*Reference for metric equivalents: Ayurvedic Formulary of India: Part – I, Second Revised English Edition: Appendix 5, Page No. 483, Govt. of India, Ministry of Health and Family Welfare, New Delhi)

University, Jamnagar, followed by size reduction in a mixer and sieving through #72.

**Equipment specification**

1. **Size of stainless steel vessel**:
   - Depth: 8.25 inch
   - Diameter: 14.5 inches
   - Circumference: 39.4 inches
   - Capacity: 15 l

2. **Length of stainless steel ladle**: 21.5 inches
3. **Cotton cloth**: 1 x 1 meter
4. **Measuring cylinder**: 2 l
5. **Heating Device**: LPG with Gas burner

**Pharmaceutical procedure**

It involves manufacturing of Kwatha and Avaleha.

**Process validation of Kwatha preparation**

*Kwatha* of *Twak* and *Sara* were prepared individually. In both the cases, 1250 g of *Shirisha yavakuta* was transferred into a stainless steel container of 15 l capacity. 12.5 l of potable water was added[10] and allowed to soak overnight. Next day morning, the contents were subjected to heat and the contents were stirred continuously throughout the process till the volume reduced to 1/4th, i.e., 3.12 l. Throughout the procedure of *kwathana* (boiling), the temperature was maintained in between 85-95°C and approximately it took 6.40 h to complete the process of *kwatha*. Total 10 batches of *kwatha*, 5 each with *Twak* and *Sara* were prepared; the average details of which are shown in Tables 3 and 4. *Shirishavaleha* prepared with *Twak* has been labeled as *Shirishavaleha* - A and the later one as *Shirishavaleha* - B.

**Process validation of Avaleha preparation**

*Shirisha Kwatha* (3.12 l) was shifted into a stainless steel vessel and was added with 5 kg of *Guda*. The contents were subjected to mild heat over LPG stove till complete of *Guda*. The mixture was filtered through clean cotton cloth to separate undissolvable material, if any, in *Guda*. The filtrate was collected into another sterile vessel and subjected to heat till *Avaleha* Siddha *Lakshanas* appear. After observing the classical characters of *Avaleha*, heating was stopped and *praksepa dravas* in the specified quantities were added. The temperature was maintained in between 95-110°C during the procedure of *Avaleha paka* and average it took 6.45 h to complete the process in both cases. Total 10 batches of *Avaleha*, 5 each with *Twak* and *Sara* were prepared; the average details of which are shown in Tables 3 and 4. *Shirishavaleha* prepared with *Twak* has been labeled as *Shirishavaleha* - A and the later one as *Shirishavaleha* - B.

**Analytical study**

Both the samples of *Shirishavaleha* were subjected to organoleptic [Table 5] and physico chemical studies in order to develop analytical profile. The following parameters were carried out in this phase:

- **Organoleptic characteristics**: Colour, odour, touch and taste.
- **Physico-chemical analysis**: Loss on drying at 110°C[11] pH value,[12] water soluble extractive,[13] methanol soluble extractive,[14] determination of sugar contents,[15]
- **Qualitative test for various functional groups**, and
- **HPTLC profile**.[16] Toluene: Ethyl acetate (8: 1.5 v/v) was selected as solvent system through trial and error method. The developed plate was visualized under visible day light, short UV (254 nm), long UV (366 nm) and after spraying

Table 2: Average practical details of Shirisha (Twak) (Sara) Kwatha

| Parameter         | Twak | Sara |
|-------------------|------|------|
| Quantity in (g)   | 1250 | 1250 |
| Water (l)         | 12.50| 12.50|
| Reduced to        | 1/4th| 1/4th|
| Temperature (°C)  | 85-95| 85-95|
| Total yield (l)   | 3.12 | 3.13 |
| Total duration (h)| 6.43 | 6.40 |
| Total solid contents in % | 3.46 | 6.04 |
Table 3: Details of Shirishavaleha - A

| Parameter          | Batch I | Batch II | Batch III | Batch IV | Batch V | Avg. ± SD |
|--------------------|---------|----------|-----------|----------|---------|-----------|
| Twak Kwatha (l)    | 3.10    | 3.10     | 3.15      | 3.10     | 3.15    | 3.12 ± 0.012 |
| Guda (kg)          | 5.00    | 5.00     | 5.00      | 5.00     | 5.00    | 5.00 ± 0.00  |
| Total duration (h) | 6.40    | 6.50     | 6.45      | 6.40     | 6.50    | 6.45 ± 0.002 |
| Temp. at Asanna paka °C | 95-110 | 95-110  | 95-110   | 95-110  | 95-110 | 95-110   |
| Temp. when Prakshpea added °C | 60 | 60 | 60 | 60 | 60 | 60 |
| Total yield (kg)   | 5.290   | 5.390    | 5.267     | 5.312    | 5.350   | 5.32 ± 0.022 |

Table 4: Details of Shirishavaleha - B

| Parameter          | Batch I | Batch II | Batch III | Batch IV | Batch V | Avg. ± SD |
|--------------------|---------|----------|-----------|----------|---------|-----------|
| Sara Kwatha (l)    | 3.10    | 3.15     | 3.15      | 3.10     | 3.15    | 3.13 ± 0.012 |
| Guda (kg)          | 5.00    | 5.00     | 5.00      | 5.00     | 5.00    | 5.00 ± 0.00  |
| Total duration (h) | 6.45    | 6.50     | 6.45      | 6.35     | 6.50    | 6.45 ± 0.027 |
| Temp. at Asanna paka °C | 95-110 | 95-110  | 95-110   | 95-110  | 95-110 | 95-110   |
| Temp. when Prakshpea added °C | 60 | 60 | 60 | 60 | 60 | 60 |
| Total yield (kg)   | 5.30    | 5.40     | 5.39      | 5.34     | 5.35   | 5.35 ± 0.018 |

Table 5: Comparative organoleptic characters of Shirishavaleha

| Parameters               | Shirishavaleha - A | Shirishavaleha – B |
|-------------------------|---------------------|---------------------|
| Rupa (Colour)           | Dark reddish brown  | Darker reddish brown|
| Rasa (Taste)            | Madhura, Katu, Kashaya | Madhura, Katu, Kashaya |
| Gandha (Odour)          | Typical smell of Jaggery | Typical smell of Jaggery |
| Sparsa (Consistency)    | Semi solid         | Semi solid         |

Discussion

In preparation of Shirisha Kwatha, stable extensive froth with honeycomb like structure appeared over the surface of reddish brown menstrum. It appeared to be light reddish brown in color, which may be due to the presence of saponins and tannins present in the raw material. Initially some of the raw material was floating over the surface, which gradually settled down to the bottom. During the boiling the temperature was maintained in between 85-95°C. During the process, the froth started to limit to the edges of the container. Continuous stirring was done for proper extraction and to lessen the possible chances of degradation of some active constituents which may be decomposed due to hydrolysis. Continuous stirring is also needed to facilitate the natural circulation evaporation.

In Avaleha, after dissolving jaggery in Kwatha, color of solution becomes darker and typical smell of jaggery was observed during Baka. Excessive frothing was observed at final stages which need continuous stirring of Avaleha.

Purana Guda was used in the procedure of Avaleha, as it is Kapha Vata Shamaka and Anabhisyandri, the qualities of which are most essential in breaking the pathological manifestation of Tamaka Swasa. Temperature was maintained at low flame, recorded carefully and was observed that at an average temperature of 95°C (Darvi pralepa), at 98°C (Apsu Majjanam) and at 105°C (Pattiststu na shiryete) appear. Throughout the process care was taken not to cross 110°C temperature. After observing the Siddhi Lakshanas, the container was removed from the heat source and allowed to become cool. When the temperature of the contents reached to 60°C, the fine powders of praksepa dravyas were added and stirred thoroughly to form a homogenous blend. The average time took for completion of the practical was 6.45 h.

Constant observation and continuous stirring are essential in obtaining a good quality of Kwatha and Avaleha. Particularly, during the initial stages of the procedure; otherwise Guda in the central part will get caramelized. Katu, Madhura and Kashaya rasas were found in both the samples of Shirishavaleha with little predominance in Sara group.

Variations in analytical profile of both the samples were insignificant. Total sugar content in both the samples of Shirishavaleha were found to be more than 65% [Table 6], which may help in preserving the medicament for longer duration and make it palatable. Almost all the functional groups were found to be available in both the samples of Shirishavaleha except cardiotonic glycosides, which were absent in Shirishavaleha - A [Table 7]. The samples were analyzed for the presence of heavy metals, which were found to be below detection limit [Table 8]. No Bacterial or Fungal growth was observed in both the samples, which indicates the safety of the product [Table 9]. HPTLC profile of Shirishavaleha - B showed more Rf values (13) in comparison to Shirishavaleha - A (9) indicating the presence of more active components in the Sara group [Table 10 and Figure 1].
Yadav, et al.: Physico chemical characterization of Shirishavaleha

**Table 6: Average data on physico-chemical analysis**

| Physico-chemical parameters | Shirishavaleha – A* | Shirishavaleha – B* |
|-----------------------------|----------------------|----------------------|
| pH of 5% aqueous sol.       | 4.75 ± 0.06          | 4.55 ± 0.11          |
| LOD at 110°C (% w/w)        | 6.79 ± 0.044         | 6.60 ± 0.27          |
| Water soluble extractive (% w/w) | 85.58 ± 0.60     | 87.37 ± 0.53         |
| Methanol soluble extractive (% w/w) | 83.31 ± 0.57      | 84.26 ± 0.94         |
| Sugar content                 |                      |                      |
| Total                        | 75.41 ± 0.04         | 77.64 ± 0.031        |
| Reducing                     | 35.45 ± 0.02         | 35.61 ± 0.05         |
| Non-reducing                 | 39.96 ± 0.023        | 42.03 ± 0.011        |

*Average of 5 readings±SEM

**Table 7: Presence of functional groups**

| Functional group             | Shirishavaleha - A | Shirishavaleha - B |
|------------------------------|---------------------|---------------------|
| Alkaloid                     | +ve                 | +ve                 |
| Glycosides                   | +ve                 | +ve                 |
| Cynogenic                    | −ve                 | +ve                 |
| Cardiotonic                  | −ve                 | +ve                 |
| Flavonoids                   | +ve                 | +ve                 |
| Tannins                      | +ve                 | +ve                 |
| Saponins                     | +ve                 | +ve                 |
| Triterpenoids and steroids   | +ve                 | +ve                 |
| Carbohydrates                | +ve                 | +ve                 |

**Conclusion**

No significant difference was found in pharmaceutical aspects of both the samples of Shirishavaleha. The method preparation mentioned in the current study for Shirishavaleha can be considered as standard. HPTLC profile of Sara showed more no. of spots (13) in comparison to Twak (9) indicating presence of more therapeutically active ingredients. Total solid contents were also found to be more (6.04%) in Sara than Twak Kwatha (3.46%) indicating possibilities of more water soluble extraction from Sara. No bacterial or fungal growth could be isolated in both the samples after storing in identical conditions for 6 months, which proves the safety and stability of the product. As the Sara of Shirisha observed to
Table 8: Heavy metal analysis of *Shirishavaleha*

| Element       | Wave length | Instrument detection limit (ppm) | Results in ppm |
|---------------|-------------|----------------------------------|----------------|
| Group - A     |             |                                  |                |
| Cadmium (Cd)  | 228.802     | 0.0027                           | Not detected   |
| Lead (Pb)     | 220.353     | 0.0420                           | Not detected   |
| Mercury (Hg)  | 253.652     | 0.0610                           | Not detected   |
| Arsenic (As)  | 193.696     | 0.0530                           | Not detected   |
| Group - B     |             |                                  |                |
| Cadmium (Cd)  | 228.802     | 0.0027                           | Not detected   |
| Lead (Pb)     | 220.353     | 0.0420                           | Not detected   |
| Mercury (Hg)  | 253.652     | 0.0610                           | Not detected   |
| Arsenic (As)  | 193.696     | 0.0530                           | Not detected   |

Table 9: Microbial count in samples of *Shirishavaleha*

| Sample       | Bacterial growth | Fungal growth          |
|--------------|------------------|------------------------|
| *Shirishavaleha* - A | No bacterial growth isolated | No fungal growth isolated |
| *Shirishavaleha* - B | No bacterial growth isolated | No fungal growth isolated |

Table 10: HPTLC profile of *Shirishavaleha* – A and B

| Conditions            | No. of spots | Max. Rf |
|-----------------------|--------------|---------|
| A B                   |              |         |
| Short UV (254 nm)     | 09            | 0.17    |
|                       | 13            | 0.24, 0.3, 0.3, 0.34, 0.44, 0.55, 0.53, 0.55, 0.55, 0.60, 0.64, 0.7, 0.72, 0.77 |
| Long UV (366 nm)      | 06            | 0.16    |
|                       | 06            | 0.3, 0.35, 0.35, 0.35, 0.49, 0.7, 0.72 |
| After spraying        | 03            | 0.36    |
| Anisaldehyde in HSO4  | 04            | 0.48, 0.48, 0.71 |
|                       | 0.21, 0.36, 0.45, 0.53 |

contain higher percentages of active ingredients in analytical studies, it is needed to be validated their exact nature and their respective therapeutic utilities through well stratified analytical, experimental and clinical studies.

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यदव, आर्थिक, फिब्रिलेशन का मानकीकरण
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बढ़ते औद्योगिकरण और वस्त्र तमक शास क्रम में उत्पन्न होने वाले उद्देश्य एवं उद्देश्य कर के सहायक हैं। आंशिक चिकित्साओं में अत्यधिक तत्व लाभ पहुँचाया है। अन्य जनसमुदाय का ध्यान ऐसी चिकित्सा पद्धति की ओर आकर्षित हो रहा है जो विनाशी कालम बढ़ाये। यदानू ऐसी व्यवस्था है जो विभिन्न रोगाओं में अपने अनेकों ओपियंट कर्मों से आयुर्वेद में उपयोग है। जिसमें एनिक-एलर्जिक, मार्ग सेल टेक्विलाइजिंग और इम्युनोमोडिलेशन कर्म दर्शाये गये हैं। जो एलर्जिक विकारों में इस ओपियंट की उपयोगिता का स्पष्ट करते हैं। प्रस्तुत अध्ययन का उद्देश्य तंत्र एवं सार के क्रांति द्वारा निर्मित शिरीषावलेह के चिकित्सकीय प्रभाव का तुलनात्मक अध्ययन करना है। परिणामों के मूल्यांकन चिकित्सकीय स्वास्थ्य लाभ, लक्षणिक लाभ, फुफ़ा प्रत करम लाभ के संदर्भ में किया गया है। हीमोलोगियन, एसोसियेट इयोनिकाफिल काउन्ट, इसुटुएट सेडिमेन्टेशन रेट आदि में सार्थक लाभ पाया गया। चिकित्सा के पश्चात 21. 65% चोटियों में उद्देश्य, 40% चोटियों में मध्यम सुधार तथा 99.23% चोटियों में अत्य सुधार पाया गया। यह अध्ययन दर्शाता है कि शिरीषावलेह तमक शास की चिकित्सा में लाभकारी है।

Announcement

iPhone App

A free application to browse and search the journal’s content is now available for iPhone/iPad. The application provides “Table of Contents” of the latest issues, which are stored on the device for future offline browsing. Internet connection is required to access the back issues and search facility. The application is compatible with iPhone, iPod touch, and iPad and requires iOS 3.1 or later. The application can be downloaded from http://itunes.apple.com/us/app/medknow-journals/id458064375?ls=1&mt=8. For suggestions and comments do write back to us.