



Proportional Studies Of Babularista With Various Herbal Formulations From Marketed Brands.

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Article History	Abstract
Received: Revised: Accepted	Plants/herbs are the primary source of organic chemicals utilised in contemporary medicine to treat various ailments in the most ancient system of therapy known as Ayurveda. Acharya Sharangdhar was the first to describe a scientific method for preparing Asavas/Arista, a fermented food containing various plant-derived medications as well as jaggary. The worked out parameters for the quality control and stability of Asavas/Arishtas were addressed in this study report for the two Arishtas. The pH, % alcohol, percentage sugar, and other formulation parameters are observed. The observed values indicate that there is no unique change in the data that support the scriptural reference that Asavas and Arishtas did not lose their efficacy over a longer length of time. The pH of Asavas and Arishtas employed in this investigation was determined to be between 3.60 to 4.30, indicating that the preparation is acidic. Whereas the alcohol range of 5% to 8% revealed that the organic components associated with the ingredients contained in the formulation are well preserved in their self-generated alcohol created during the fermentation process. The calculated parameters for transmittance also result in its prolonged stability.
CC License CC-BY-NC-SA 4.0	Key words: Asthma, polyherbal, Ayurvedic, Standardization

1. INTRODUCTION

Ayurvedic medicine emphasises the use of natural items derived from plants, minerals, and animals for both medicinal and preventative purposes ^[1]. Making these medicines into medicaments in various dose forms to satisfy therapeutic needs is a magnificent contribution to humanity ^[2]. Sandhana kalpana is a unique dosage form in which medications are put into acidic and alcoholic formulations. These Asavaristas (fermented items) include self-generated alcohol, which functions as a natural preservative; they are also distinguished by their superior stability, palatability, and clinical result ^[3]. This specific pharmaceutical preparation entails several procedures, with various medications being added at various phases of manufacture.

The whole approach is built upon traditional wisdom. Sandhana is a process of fermentation, when the drava-dravya (Kwatha, Swarasa or any other liquid preparation), Madhuradravya (Jauggary, honey or sugar), Prakshepaka dravyas (fine powder of aromatic/spicy drugs and Sandhana dravya (Dhatakpushpa and Madhukapushpa as initiators of fermentation) are put together in an inert vessel (mud pot), sealed for a specific period of time to facilitate the process of fermentation^[4]. Asava and Arista are the two major products of this process. Role of Sandhana dravya (fermentation agents) of natural origin (Dhataki and Madhuka flowers) is a beautiful scientific concept involved in this process as natural fermentation initiators^[5]. Researchers suggest the micro flora of these flowers having a great role in this process. Madhukapushpa (flowers of Madhuka indica Gmel) commonly known as Mahua flowers are edible fragrant cream coloured flowers collected out of Madhuka indica found in Western Ghats^[6]. These flowers are said to be rich source of sugars along with other essential nutrients and vitamins^[7]. Since ancient times Madhuka flowers were used as natural fermentative agents in different asava and aristas. But exactly the role of these flowers in Sandhana Kalpana is not yet explored.^[10]

2. APPROACHES TO STANDARDIZATION

Standardization of Ayurvedic products is an area of scientific and industrial interest. Large scale production need changes in preparations of classical Ayurvedic products^[11]. Satisfying needs of large scale production while adhering to principles of Ayurveda require careful considerations before adapting to new methods. Different parameters have been applied to standardize this self-generated alcohol based liquid classical dosage forms^[13]. Over a period of several year different approaches to standardize Babul -arishta have been undertaken.^[14] These quality control approaches can be broadly divided into three categories –

2.1. Approach related to raw material and equipment

The quality of raw material, herbs and other ingredients used for these preparations have a strong bearing on the process and the finished product.^[15] Raw material for these preparations must be authenticated and examined for required quality. Testing of limits of heavy metals, microbial load and residual pesticides are envisaged as these will have impact on the main fermentation process and certain impurities may get retained through the process. It is desirable that the right storage conditions are followed for these raw material before being taken up for main production process.^[16] The type of equipment used, material used for fermentation and storage vessels, treatment mooted to the vessels, temperature and storage conditions factors that will impact the process.^[17]

3. Materials and methods

Method of Preparations of Babul- arishta

In preparation of Babul- arishta, Each 50ml contain, Babul (10.16gm), Water (114.27ml), Guda (22.32gm), Dhataki (1.785gm), Shweta Jira (0.112gm), Musta (0.112gm).5 The basic were first cleaned and rinsed in water to get rid of dirt. For preparation of arishta a decoction was obtained by boiling the drugs in the specified volume of water used should be cleaned, cleared and potable. When the extracts are obtained the sugar (cane sugar), jaggery and or honey are added and completely dissolved. Sometimes any one or more of these sugary substances are omitted if so directed in the recipe. The sugar jaggery and Honey should be pure the jaggery to be added should be very old (prapurana) because fresh jaggery aggravates kapha and suppresses the power of digestion.^[18] The flavoring agents are coarsely powdered and added to sweetened extract. The earthen pot or jar intended for fermenting the medicine is tested for weak spot and cracks and similarly lid is chosen. 6 Collection of Babul arishta Three different brands Babul arishta were purchased from local market and in-house formulation prepared in laboratory scale.^[19]

S. No	Brand Name	Main Ingredients	Uses
1	Amar babbularista	Babbula , Guda, Dhataki, , Bibhitaka, Haritaki, Shunthi, Amrasthi. Vasa, Shveta chandana, Daruharidra, Musta, Utpala, Shveta jiraka and Water.	Relieves backache and abdominal pain, reduces irritation, improves strength and stamina, ensure active and energetic life throughout the month
2	Baidhyanath babbularista	Babbula , Guda, Dhataki, Ajaji, Musta, Sunthi, Daruharidra, Utpala, Haritaki, Bibhitaka,	Excellent tonic for women, relieves backache,

		Amalaki, Amla, Sveta jiraka, Vasa, Condana.	stomachache, headache, debility etc
3	In-house formulation	Babbula , Dhataki, Daruharidra, Jiraka, Sunthi, Condana, Amla, Guda	diseases of skin, urinary disorder)

4. Evaluation of different marketed brands and in-house formulation of Babul- arishta

Organoleptic properties All the different brands and in-house formulation of Babul- arishta were evaluated organoleptically for their colour, odour and taste^[20]. The results are shown in table-2.

S. No	Brand Name	Appearance	Colour	Taste	Odour
1	Amar babbularista	Liquid	Brown	Sour	Pleasant
2	Baidhyanath babbularista	Liquid	Brown	Sour	Pleasant
3	In-house formulation	Liquid	Dark Brown	Sour	Pleasant

5. Physicochemical properties

All the three different marketed formulations and in-house formulation of Babul- arishta were evaluated by determining its physicochemical parameters. Physicochemical parameters include alcohol content, water and alcohol soluble extractive, pH, total solid content, density, surface tension and viscosity.^[21]

5.1 Determination of alcohol content, water and alcohol soluble extractive Values of Alcohol content, water soluble extractive and alcohol soluble extractive were determined as per the method described in Indian Pharmacopoeia⁷ and the results are shown in table-3.

5.2 Determination of pH

The digital pH meter was used for the pH measurement after calibration with buffer solution. pH was noted for all brands of Babul- arishta after opening the bottle and 7 days and 14 days after opening the bottle.^[25] The results have been shown in the table-3

5.3 Determination of total solid content

The total solid content was calculated for each brand of Babul- arishta. 10ml of each brand of Babul- arishta were taken in pre-weighed petri dish and dried under oven.^[26] The total solid content was calculated in % w/v basis. The results are shown in table-3.

5.4 Determination of density

Density of all the samples was determined by using pycnometer¹⁰ and the results for different formulations are shown in table-3. Determination of surface tension Surface tension provides the information regarding the structure of molecule.^[28] Surface tensions of all the samples were determined by using Stalagnometer¹⁰ and the results have been shown in table-3.

Observation and Result

Results of microbiological study are displayed in table different formulation of babul arishta were found contaminated with colonies of yeast. Fresh flowers have shown less colonies of yeast, whereas dried flowers have shown indefinite colonies of yeast.^[30] Three samples of Babul arishta a polyherbal compound was prepared as per classical references, and proper fermentation features observed on 45th day of its initiation (among M1, M2 and M3).^[31] However these three samples were filtered, and taken for further study. Organoleptic characters observed have been displayed in Table 2. Comparative analytical test reports on these three samples displayed in Table 3.

Physicochemical Parameters	Formulations		
	Amar babbularista B1	Baidhyanath babbularista B2	In-house formulation B3
PH	4.5	4.2	4.4
Alcohol content (%v/v)	2.63	2.22	2.9

Water-soluble extractive (% w/w)	7.1	8.1	8.4
Refractive Index	1.351	1.521	1.66
Specific Gravity	1.026	1.126	1.056
Total Sugar	4.692	5.522	8.519
Total Acidity	0.354	0.454	0.854
Total solid content	10.55	10.15	12.575

6. Phytochemical screening

Active phytoconstituents like carbohydrates, alkaloids, glycosides, tannins and flavonoids were identified in all three marketed formulations and in-house formulation of Babul- arishta 12 as shown in table-4.

Table 4: Phytochemical screening

Phytochemical Screening	Formulations		
	Amar babbularista	Baidhyanath babbularista	In-house formulation
Carbohydrates	+	+	+
Proteins	+	+	+
Alkaloids	+	+	—
Glycosides	+	+	+
Tannins	+	+	+
Flavonoids	+	+	+

Microbiological study

Total aerobic microbial count of test drug was carried out by plate count method [9]. The place of work was cleaned in laminar air flow using 70% ethanol and switched on the UV for 20 minutes.^[32] One gram of Babul arishta were mixed with 10 ml of sterile BSCPS to make dilution 10^{-1} .

After cooling Sabouraud dextrose agar medium, added one ml of diluted sample into petridish containing the media. Plates were gently rotated in a circular motion to achieve uniform distribution of the sample and allow the media to solidify. Incubated all petri dishes for 5 days at 25° C in BOD incubator.^[33] Experiment was carried out in duplicate for fresh and dry samples. Number of colonies counted using digital colony counter:

S No	Sample name	Dilution	Number of Colonies (NOC)		CFU/g
1	Amar babbularista	1/10 (10^{-1})	4	9	6.5×10^1
2	Baidhyanath babbularista	1/10 (10^{-1})	3	8	6.5×10^1
3	In-house formulation	1/10 (10^{-1})	4	6	6.5×10^1



Discussion

In traditional systems of medicine, the drugs are primarily dispensed as water decoction or ethanolic extracts, fresh plant parts, juices and crude powder.^[35] Therefore, medicinal plant parts should be authentic and free from microbial contamination. This is the reason why the World Health Organization has set specific guidelines for the assessment of safety, efficacy and quality of the herbal medicines as a prerequisite for global harmonization.¹⁴ Still, very few Ayurvedic industries follow Good Manufacturing practices (GMPs) and are ISO-certified.

CONCLUSION

Medicinal wines or Babul- arishta is a formulation wherein microbial transformation helps in initiating the process of generating alcohol which helps in extracting the attributes and enhancing the bioavailability of the ingredients. Changes in fermentation techniques and adaption to modern technologies are followed for better standardization and quality control. A range of galvanometric, spectroscopic and chromatographic techniques as with TLC, HPTLC or Gas chromatography methods have been applied to evolve standards for asava-arishta. The outcome of these different methods have been variable. Some of these techniques have further potential to contribute to evolve better standardization methods for this liquid dosage form in its totality. There are not many comparative analytical studies between traditional and modern methods of preparations. Confirmation of therapeutic and clinical assessment between the traditional and modern methods of preparations will definitely provide better insights to develop more reliable methods of preparations and better parameters of standardization. Critical evaluation of Ayurvedic principles will help examine innovative applications of present day technologies to develop better standardized, more safe and more clinically effective asava and arishta.

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