A Comparative Study of Alcohol Estimation in Different Samples of Draksharishta

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

Background: Among all Arishta, Draksharishta is manufactured and sold on large amount by various pharmaceutical companies and widely prescribed by the physicians. Due to its effective properties and pleasant test resembling to that of Alcohol, Draksharishta is used by the patients in over dose for longer duration irrespective of the physician's prescription. Hence, to estimate and compare the level of alcohol and to detect the absence/presence of Methanol content in self-prepared and market samples of Draksharishta, this study was undertaken by comparing the permissible limits of alcohol in all the samples so as to inhibit alcohol intoxication due to Draksharishta. Draksharishta was prepared by two methods.

Methodology: In method 1, Dhataki (Woodfordia floribunda) flowers and in method 2, Yeast was used for inducing fermentation. Analytical study of two self prepared and five market samples of Draksharishta was conducted to estimate the level of alcohol, reducing sugar, non reducing sugar and to detect the absence/presence of Methanol content. The detected values of the parameters were compared among all the samples.

Results: The data reveal that there is difference in the physicochemical values of the Draksharishta samples. The alcohol content in samples M-E (2.8 %), S-A (3.40 %) and S-B (3.80 %) is low as compared to other sample of Draksharishta. Alcohol content in self prepared and market samples of Draksharishta is within permissible limits. Methanol is absent in all the sample of Draksharishta.
1. INTRODUCTION

Ayurvedic herbal dosage forms are formulated through the transference of active ingredients by different manufacturing processes. Among these dosage forms, *Sandhana kalpana* is a unique form in which acidic and alcoholic fermented formulations are prepared. In order to manufacture these medicines, liquid basic drugs (juices or decoctions) are kept for fermentation as indicated in the classics [1]. In this process, ethyl alcohol is self-generated by source material used in pharmaceutical procedure, and is not added from outside. These formulations have longer shelf life, quick absorption and action and excellent therapeutic efficacy as compared to other Ayurvedic herbal medicines [2]. Therefore, the Ayurvedic fraternity relies on this unique dosage form, i.e., *Sandhana kalpana* (*Asava, Arishta, kanji*, etc) to treat diseases in routine practice.

*Asava* and *Arishta* are medicinal preparations made by biomedical fermentation. They are hydro-alcoholic medicaments prepared by soaking of raw herbs either in coarse powder form or in the form of decoction. This undergoes into fermentation with addition of sugars or sweetening agents mainly jaggery, sugar or fresh fruit then it is kept for a specified period of time [3].

*Arishta* are made with decoction of herbs in boiling water [4]. Fermentation of *Arishta* is brought by addition of a source of sugar. Many of them contain additional spices for improving their assimilation. They contain moderate alcohol (up to 10% by volume) and are mostly sweetish with slight acidity and agreeable aroma. This alcohol acts as the medium for active ingredient of the herbs to dissolve in it. These medicinal forms have several advantages, like better keeping quality, enhanced therapeutic properties, improvement in the efficiency of extraction of drug molecules from the herbs and improvement in drug delivery into the human body sites [3]. Due to their medicinal value, sweet taste and easy availability people are prone to consume higher doses of these drugs for longer period.

According to Ayurvedic Pharmacopoea of India, all *Arishtas* should have 5 to 10% of self-generated alcohol. Some manufacturing companies add alcohol in the *Kwatha* directly leading to high alcohol level in the *Arishta* without letting natural fermentation of the ingredients. If the level is more than 10% then it may cause alcoholism by forming addiction, there by leading to hazardous effects on the body [5]. Moreover, alcohol is banned in most of the places in India. Hence, now a day, people are finding another solution for Alcohol such as fruit wine, spirit and wine made from herbs, grain etc. Due to unavailability of alcohol in future, the demand of drug testing like alcohol may be increased and such drug may be misused against Alcohol. *Asava* and *Arishta* are such formulation of Ayurveda which can be misused against alcohol affecting the status of Ayurveda.

*Draksharishta* is a liquid Ayurvedic medicine. It contains 5-10% self-generated alcohol. *Draksharishta* have *Balakaraka* (tonic), *Dipana* (appetizer), *Pachana* (digestive), *Malashodhana* (laxative), *Rasayana* (rejuvenation) and *Hridya* (cardiac tonic) properties. It is used in *Uraaksha* (chest disorder), *Kshaya* (debility), *Kasa* (cough), *Swasa* (asthma), *Galaroga* (Disease of Throat) and *Malavibhandha* (constipation). Its dose is one *Pala* (48 ml) usually advised after food with equal quantity of boiled and cooled water as *Anupana* (Vehicle) [6].

*Draksharishta* is a formulation that is widely prescribed by the physicians. Among all *Arishtas*, *Draksharishta* is manufactured and sold on large amount by various pharmaceutical companies. Due to its effective properties and pleasant test resembling to that of Alcohol, *Draksharishta* is used by the patients in over dose for longer duration irrespective of the physician’s prescription.

Hence, to estimate and compare the level of alcohol and to detect the absence/presence of...
Methanol content in self-prepared and market samples of Draksharishta of Five different reputed Pharmaceutical Companies this study was undertaken by comparing the permissible limits of alcohol in all the samples so as to inhibit alcohol intoxication due to Draksharishta.

2. MATERIALS AND METHODS

The ingredients of Draksharishta were procured from market and it was prepared by two methods. Method of preparation was same for both samples of Draksharishta. In method 1, Dhataki (Woodfordia floribunda) flowers and in method 2, Yeast was used for inducing fermentation.

2.1 Procedure

Dried fruits of Draksha (Vitis vinifera) after proper crushing were placed in polished vessel of brass along with prescribed quantity of water (12 liter). The vessel was kept on medium flame until the water for decoction reduced to one fourth of the prescribed quantity (3 liter), and then the heating was stopped and filtered with muslin cloth.

Four kg Jaggery (Guda) was added to it and stirred well to dissolve completely and again the liquid was filtered. The decoction was allowed to cool up to room temperature. A china clay vessel was washed with hot water and kept for drying. Properly cleaned and dried vessel was fumigated for 10 minute with the fumes of ignited drugs like Guggula (Commiphera mukul), Jatamansi (Nordostachis jatamansi), Haridra (Curcuma longum), Vacha (Acorus calamus), Chandana (Santalum album).

The decoction was poured into dry, clean and fumigated china clay jar, leaving one third parts empty. Prakshep Dravya (ingredients numbering from 5 to 12) were made into fine powder and were added in the vessel along with fine powder of Dhatki Pushpa and the solution was stirred carefully. The container was closed and sealed with strip of cloth smeared by hot water soaked mud (Mulattani Mitti). The vessel was air tightly sealed by mud smeared cloth. Hot boiling water was used to prevent contamination during mud smearing. The vessel was placed in clean and dry place, so that the vessel was not directly exposed to sunlight, air and to prevent temperature variations. Container was reopened, for the observation of stages of fermentation. After the completion of fermentation, the liquid (prepared arishta) was carefully filtered into another jar and kept closed and sealed. The fermented preparation was filtered with unstarched muslin cloth and kept in cleaned covered vessel for further next seven days. Then, it was poured in clean amber colored glass bottles. The same procedure was used for sample 2 in which Dhataki Pushpa were replaced by Yeast for fermentation.

The two samples of Draksharishta were labeled as S-A (Draksharishta with Dhataki flower) and S-B (Draksharishta with Yeast). Market preparations of Draksharishta from five different pharmacies were procured and coded as M-A, M-B, M-C, M-D and M-E. Chemical analysis of all the seven samples was carried out by employing parameters like estimation of Alcohol (by Distilled method), test for absence of Methanol (by U.V.spectrophotometric method), reducing sugar and non reducing sugar (by Titrimetic method).

3. RESULTS AND DISCUSSION

The main aim of analysis of pharmaceutical preparations is to check their quality for obtaining desired therapeutic efficacy. To get uniform therapeutic efficacy, it is necessary to control batch-to-batch variation, which is possible through standardization of protocols. For standardizing a formulation it is necessary to standardize (i) raw material (ii) processes involved and (iii) finished product. Regarding manufacturing, sale and distribution of Asava–Arishta dosage forms of Ayurvedic medicines, Department of AYUSH, Government of India, has laid down certain provisions under Schedule T (GMP norms for preparation), measures for quality and standard production of Asava–Arishta and under rule 161 of drugs and cosmetics rule, 1945, for packing and maximum permissible limit of self-generated ethyl alcohol in medicine is directed [7].

Madya kalpana, a type of sandhana kalpana which generates alcohol, has good preservative value, vyavayi and ashukari properties. These properties of madya contribute to its quick action and target cited delivery of the active principle. Amongst the madya kalpana, Arista are extensively used. The complexes of carbohydrates, nitrogenous substances, vitamins and other additives are essential for the process of fermentation.

Draksharishta is a good example of Sandhana Kalpana (alcoholic fermentation). Considering the popularity of Arishta Kalpana in the clinical
field of Ayurveda among the patients, it was selected for the present study with special reference to the Alcohol intoxication due to Draksharishta. Standardization of Draksharishta as per pharmacopoeia was carried out based on the physicochemical parameters. The market sample of Draksharishta was found to pass all the pharmacopoeial tests.

Before the onset of fermentation liquid was dark brown. Temperature was same as that of room. Consistency was thicker than water. After the onset of fermentation the colour of the fermenting media became slightly lighter. Mild alcoholic odour could be appreciated. Effervescence was visible and a typical sound could be heard, close to the sandhanpatra (vessel). Burning match stick got extinguished when it was taken near the surface of fermenting liquid (due to the generation of CO2). After the completion of fermentation colour of decoction before the fermentation was dark brown, which became lighter after fermentation. Consistency became thinner. Sweet Guda (jaggery) smell got converted into sweet alcoholic odour. Arishta was cold to touch in comparison with decoction. Taste became strong with a production of warm feeling.

The data reveal that there is difference in the physicochemical values of the Draksharishta samples. The alcohol content in samples M-E (2.8 %), S-A (3.40 %) and S-B (3.80 %) is low as compared to other sample of Draksharishta. If the level is more than 10 %, then it will cause of alcoholism by forming addiction, there by leading to hazardous effects on the body.

The formulation having less alcohol percentage can be used easily from children up to adults. Moreover, it can be understood that the percentage of alcohol in Asava-arishta should be sufficient to enhance digestion and absorption of food and should not be upto the level which may causes any adverse drug reactions. In the present study obtained percentage of alcohol in studied samples are satisfactory. Both prepared samples of Draksharishta have alcohol percentage (3.40%) and (3.80%), and it can be interpreted that these percentage includes specific Vyavayi and Vikasi properties needed for effective uses.

Draksharishta contains Draksha (Vitis vinifera Linn.) Its rasa (taste) and vipaka is madhura (sweet) and amla rasa is absent. Hence it contains less acidic value resulting into less alcohol percentage. There is no problem in the formulation which contains less alcohol percentage but, addiction can occur when the alcohol percentage is more. Hence the alcohol percentage should not be more than 10 percents. Every formulation contains alcohol as preservative. Hence it should be used in prescribed limits. Methanol is absent in all samples. Its presence is fatal for life.

The Reducing sugar of sample S-A (63.66) and S-B (53.12) are higher than market samples. During preparation, jaggery was added in little bit excess quantity. Alcohol contents hydroxy (OH) group. Hence the formulations which have less alcohol percentage will have more reducing sugar. The formulation having more reducing sugar will have better nutritional value as well as better therapeutic efficacy. The formulation having more reducing sugar will be absorbed better in the body and produces energy rapidly in the body.

The non-reducing sugars of sample M-D (16.46 w/v) is higher as compared to all other sample values of Draksharishta. Non reducing sugar value is better in self-prepared sample (S-A, S-B) as compared to market preparation. Hence this formulation (S-A, S-B) can be used better for mrudu kostha person.

In this study, four parameters (Alcohol content, Absence of methanol, Reducing sugar and Non reducing sugar) were studied in two self-prepared samples and five market samples. The values of parameters are different for all the samples. However they depend upon the ingredients, their quantity as well as methods of preparation of the formulation. Every pharmaceutical company has used different method of preparation according to the different references.

Moreover the utensils used for the preparations may be different. In ancient times, Arishta were prepared and stored in earthen pots. Now a day, earthen pots are replaced by big plastic containers. Fermentation occurs more in plastic container in comparison with earthen pots, hence alcohol percentage may be high in the Arishta prepared in plastic containers.

Shingadiya et al reported that classically prepared Asava Arishta are more efficacious than prepared with modified methods. Effect of Asava Arishta is more prone towards the diseases in which Mandagni is involved [8].
Table 1. Ingredients and quantity for preparation of Draksharishta

| Sr. no | Ingredients                                         | Quantity      |
|--------|-----------------------------------------------------|---------------|
| 1      | Draksha (Vitis vinifera)                            | 2.50 kg       |
| 2      | Water quantity                                      | 24 liter.     |
| 3      | Reduced water                                       | 6 liter.      |
| 4      | Guda (Jaggery)                                      | 08 kg         |
| 5      | Dhakati Pushpa (Woodfordia floribunda)              | 125gm         |
| 6      | Ela (Elettaria cardamomum)                          | 50gm          |
| 7      | Twak [Dalchini] (Cinnamom zeylanicum)               | 50 gm         |
| 8      | Tejapatra (Cinnamom tamala)                         | 50 gm         |
| 9      | Nagakesara (Mesua ferrea Linn)                      | 50 gm         |
| 10     | Maricha (Piper nigrum)                              | 50 gm         |
| 11     | Priyangu (Callicarpa macrophyllia)                   | 50 gm         |
| 12     | Pippali (Piper longum)                              | 50 gm         |
| 13     | Vidang (Embelia ribes)                              | 50 gm         |
|        | Yeast                                               | 4 gm          |

Table 2. Comparative physico-chemical values of Draksharishta

| Parameters                  | S-A    | S-B    | M-A   | M-B   | M-C   | M-D   | M-E   | API Standard values [5] |
|-----------------------------|--------|--------|-------|-------|-------|-------|-------|------------------------|
| Alcohol content             | 3.40%  | 3.80%  | 10.4% | 10.8% | 5.80% | 5.80% | 2.80% | 5 to 10 % v/v          |
| Absence of methanol         | AB     | AB     | AB    | AB    | AB    | AB    | AB    | Absent (AB)             |
| Reducing sugar              | 63.66  | 53.12  | 21.97 | 19.33 | 19.86 | 36.89 | 35.74 | Not less than 14.0 % w/v|
| w/v                         | w/v    | w/v    | w/v   | w/v   | w/v   | w/v   | w/v   | -                      |
| Non-Reducing sugar          | 9.48   | 10.62  | 15.44 | 6.46  | 7.86  | 16.46 | 3.25  |                        |
| w/v                         | w/v    | w/v    | w/v   | w/v   | w/v   | w/v   | w/v   |                        |
 Images

Ingredients of Draksharishta

Draksha  Guda  Twaka (Dalchini)  Ela
Tejapatra  Nagkeshara  Vidanga  Maricha
Pippali  Dhataki Flower  Yeast

Fig. 1. Ingredients of Draksharishta

Fig 2 Preparation of Draksha Kwatha  Fig 3 Draksha Kwatha SA  Fig 4 Draksha Kwatha SB
Fig 5 Mud plastering (Mat hapad)  Fig 6 Prepared Draksharishta kept For Fermentation
Tekeshwar Kumar et al reported that the self-fermented products can undergo continuous chemical transformation which goes on beyond hydro-alcoholic extraction of the suspended material. This may result in novel natural molecules with enhanced therapeutic activity [9].

Kadam et al. reported that the arishta prepared by using traditional techniques showed superiority over the modern techniques of preparation, minor modification in the procedure will lead to the change in the qualitative and quantitative parameters of the formulation, which cannot be approved for Arishta [10-13].

4. CONCLUSION

Alcohol content in self prepared and market samples of Draksharishta is within permissible limits. Draksharishta prepared according to reference (S-A and S-B), satisfy the standard parameters of Arishta kalpana. According to the values of parameters, samples have nutritional value and thus may have better therapeutic absorption and efficacy. Draksharishta sample S-A and S-B can be easily used in all age groups even in higher dose. As alcohol contents is less and methanol is absent in self-prepared samples, they are safe to use.

The veracity was found in all the parameters of marketed samples. This may be due to unauthentic ingredients, or their inappropriate proportion. This can also occur due to different method of preparation of formulation as every pharma company has used different method of preparation according to different references. The expected results can be achieved with traditional methods. Moreover, analytical value of Ayurvedic formulation changes according to season, place of collection, place of drug preparation, temperature variation and quality of utilized ingredients. However, various phyto constituents and parameters like pesticide residue, heavy metal contaminants and microbial load should be checked to assess its safety and batch to batch consistency.

CONSENT

It's not applicable.

ETHICAL APPROVAL

Ethical approval from IEC ref. no. DMIMS (DU)/IEC/2014-15/1255 dated: 31/03/2015 was received

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Fig 7: Self Prepared Samples of Draksharishta
Fig 8: Market Samples of Draksharishta
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