Research Article

Formulation and Evaluation of Sugar Free Ashwagandharishta for Diabetic Population through Biomedical Fermentation – A Holistic Approach

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ABSTRACT
Research is the prime need of contemporary Ayurveda, but modern research on Ayurveda has not been very rewarding for Ayurveda itself. Much of it uses Ayurveda to extend the modern bioscience. In contrast, Ayurveda needs research designed to test and validate its fundamental concepts as well as its dosage forms. Considering Arishta; a unique dosage form under Ayurveda in which alcohol is self-generated within itself with the breakdown of carbohydrates present in the jaggery, which after fermentation leaves out 30-40% of the sugar content in the product. Arishta thus produced using jaggery as the fermentation media, would not be tolerable in case of diabetics and therefore they would prefer an alternate source of medication. In order to prevent this issue here is a formulation where the base used as a fermentation media is changed using wheat flour in the place jaggery, thus resulting in a sugar free product where the basic Ayurvedic principles are not altered and also the therapeutic efficiency is maintained.

Keywords: Arishta, jaggery, fermentation media, wheat flour, sugar free.

1.0 INTRODUCTION

Natural products have been an important resource for maintaining life for ages. Even today, natural products are becoming increasingly important as alternative medicines and source of pharmacotherapeutics either directly or as raw materials from which more or less complex chemical structures with proven biological activity are isolated. The last few decades have seen a resurgence of interest in the use of herbal products.

Today the medical world is posed with complex challenges. Thus time demands an integrated and pluralistic approach towards healthcare to cope effectively with this situation. There has been a growing interest in Ayurveda in the past few years. To initiate fruitful dialogues between Ayurveda and modern science, an in-depth understanding of both the systems becomes an essential prerequisite. Such an exercise should emerge from a standpoint accepting that there are different worldviews existing in the world, Ayurveda being one among them. This may sound quite contrary to the common belief that the science is only one as expressed in modern scientific paradigm. Both modern science and Ayurveda have universal attributes and share the common objective of well-being of mankind. But they are quite different in their philosophical and epistemological foundations, conceptual framework and practical outlook. So, let us examine what are the fundamental differences between *Sastra* (Ayurveda) and the modern science.

1.1 Various Stable dosage forms in Ayurveda

1.1.1 Arka is a liquid preparation obtained by distillation of certain liquids or drugs soaked in water using the Arkayantra (a type of steam distillation apparatus) or any convenient modern distillation apparatus. It is a suspension of the distillate in water having slight turbidity and colour according to the nature of the drugs used and smell of the predominant drug.

1.1.2 Asava or Arishtas

These are fermented preparations of medicinal plants. The fermentation procedure adopted to prepare these preparations is termed as ‘Sandhaana kalpanaa’ and the ferment used to

stimulate fermentation is termed as 'Sandhaana dravya'. Asavas are usually prepared by fermenting expressed juice ('swarasa'), whereas 'Asavas' are prepared from fermentation of decoction (Kwaatha). Sugar or jaggery and powders (choorna) of other medicinal plants as required along with a natural ferment are added to these two liquids and they are left in a closed container till the fermentation is completed. Asava and Aristas can be prepared from 'swarasa' or 'kwaatha' (as the case may be) of single plant or from a mixture of 'swarasa' or 'kwaatha' from multiple plants. This facilitates the extraction of the active principles contained in the drugs. The alcohol generated in this process serves as a self preservative. Both function as weak wines but rich and fortified with active principles.

1.1.3 Avaleha

It is a semi-solid preparation of the drugs meant for licking. It acquires the consistency of a thick paste. After strained decoctions (Kwaatha) are boiled down, sugar or jiggery is added to it. The other similar forms are known as Modaka, Guda, Khanda, Lehya, Praasa etc.

1.1.4 Choorna

Is a fine powder of drug or drugs. Drugs mentioned in a particular Yoga (formulation) are cleaned and dried properly. They are finely powdered and sieved. Where there are a number of drugs in yoga, the drugs are separately powdered and sieved. Powder of each drug is weighed separately and mixed thoroughly. This will ensure proper mixing in comparison to mixing the drugs and preparing the powder of the drug-mix. In industry, however, all the drugs are cleaned, dried and powdered together by disintegrators. Mechanical sifters are also used. Salt, sugar, camphor- the material with water content, when mentioned are separately powdered and mixed with the rest at the end. Asafoetida and salt may also be roasted, powdered and then added. Sometimes it is necessary to use plant ingredients in fresh form in such a case drug paste is prepared, dried, and then added. The powder should be fine at least of 80 mesh sieves. It should not adhere together or become moist. The finer the powder, the better is its therapeutic value. They retain potency for two months as per the classical.

1.1.5 Ghana

Is a dried aqueous extract. It is the solidified mass prepared by evaporating the entire aqueous portion from 'kwaaha'. The water content of the 'kwaatha' is evaporated by subjecting it to slow heating. The 'kwaatha' passes through various stages as it solidifies from clear liquid to semi-solid and then solid form through the process of heating. These dosage forms are grouped as 'Rasakriyaa' and are broadly classified as Avlaleha and Ghana. Avaleha is the one which is semi-solid and can be licked whereas 'Ghana' is the one which is a solid.

1.2 Imperative issues for accurate initiation of Sandhana kalpana (Arishta)

Looking at the significance of *Sandhana kalpana* from the perspectives of pharmaceutical progress, therapeutic trends, and commercial issues, many researchers are exploring every possibility for the advancement and acceptability of these products to physicians and patients. Some of these are presented here for a better understanding of thrust areas of *Sandhana kalpana*.

1.2.1 Proportion of carbohydrates (Madhura Dravya)

Microorganisms involved in the preparation of *Asava–Arista* for fermentation require water, specific nutritive material as growth promoter and source of energy for their fermenting activity. Carbohydrate acts as the main source of nutrition in the products of *Sandhana kalpana*. Nature and concentration of carbohydrates affect the rate of fermentation and final product produced, i.e., biomass and primary and secondary metabolite. Increased concentration of carbohydrate in liquid upsurges the viscosity of solution. Only a certain group of microorganisms can survive in a higher concentration up to 65-70%. While at above 40% concentration, only few osmophilic type of yeast can grow.

1.2.2 Container

All classical texts recommended the use of earthen and wooden containers for the fermentation process, but these have certain limitations as earthen pots may break, while wooden containers require pre-treatment. Even after all these tedious processes, there may be chances of contamination. Hence, with the development of technology in the field of pharmaceutics, these pots were replaced by plastic and steel containers. To address the question of equal efficacy with the specific variety of containers, studies were carried out to analyze the final product, organoleptically and physicochemically. It is concluded that plastic and steel containers are suitable for carrying out the *Sandhana* process.

1.2.3 Temperature

Sandhana kalpana is placed for the process with minimum temperature variation at the site. In the ancient time, to serve this object, containers for preparation of *Asava–Arista* were placed in *Dhanya Rashi*(*Kanakbindu Arista - Charaka Chikitsa Sthana* 7/76-79), *Bhugarbha, Chaulyagara* (*Kharjurasava –Gada Nigraha* 7/266-274), *Koshthasara* (*Kumaryasava - Gada Nigraha* 6/1-14), etc. This practice ensured that optimum temperature, direct avoidance of light and air, etc was maintained. Specific microorganisms require specific temperature for optimum growth and product formation. In general, optimum temperature needed for initiation of fermentation is in the range of 20-35°C.

1.2.4 Duration

Jatarasam is the word, which denotes completion of fermentation and formation of appropriate product as per indication quoted in *Sushruta Sutra Sthana* 45/203 and for *Loharista - Sushruta Chikitsa Sthana* 12/12-17. Duration of fermentation varies with formulation, which ranges from 7 days (*Ashtashatarista- Charaka Chikitsa Sthana* 12/32- 33) to 180 days (*Guggulu Asava -Gada Nigraha* 6/213-221). *Kinva* and slurry are separated through collation process carried out by double-layered cotton cloth for further processing of next batches. Nowadays, electrical filtration press, bacteria filters like advanced techniques are used for large-scale production of these products.

1.2.5 Sandhana Dravya (Fermenter)

Fermenter acts as a supply depot of microorganism, which initiates the process of fermentation. The *Asava—Arista* quoted in *Charak -Samhita* are devoid of use of the *Dhataki Pushpa* as an initiator of fermentation. *Acharya Vagbhata* was pioneer, who made the use of *Dhataki Pushpa* extensively in the manufacturing of *Asava–Arista*.

A thorough study of ancient literature reveals that following drugs plays the role of *Sandhana dravya* (Fermentor) in *Sandhana kalpana*.

- *Dhataki Pushpa*, eg, *Ashwagandharista* (*Ashtanga Hridaya Chikitsa Sthana* 08/66)
- *Madhuka Pushpa*, eg, *Kutajarista* (*Sharangadhara Samhita Madhyam Khanda* 10/44-46)
- *Surabeeja/Kinva*, eg, *Sura* (*Sushruta Samhita Chikitsa Sthana* 10/8)

1.3 Ashwagandharista

Ashwagandharishta is an Ayurvedic polyherbal hydro-alcoholic preparation and is used as rasayana; Rasayanas are used to promote health and longevity by increasing defence against disease, arresting the ageing process and revitalizing the body in debilitated conditions. The chief ingredient of Ashwagandharishta is roots of Ashwagandha, Withania somnifera, is known for its varied therapeutic uses in Ayurvedic and Unani practices in India. Roots of Withania somnifera, commonly known for its usefulness in the treatment of hypercholesterolemia, arthritis in combination with other drugs, is also credited to be hypoglycemic and diuretic. The pharmacological effect of the roots of Withania somnifera is attributed to withanolides, a group of steroidal lactones. Earlier studies have reported the absence of any side effects of Withania somnifera in animals.

2.0 METHOD

2.1 Selection of traditional product (Arishta) for the study

Task seemed to be hard on which product to be chosen out of 45 traditional formulations. Since the fact that the study is based on the beneficiary of diabetic population, and statistically the people suffering from hyperglycaemia are mostly geriatrics or the elderly, where the elderly often are struck with age related problems such as General debility, arthritis, epilepsy, muscle cramps etc. The formulation was needed to be chosen such that, the respective product was confirmed to be consumed majorly by the geriatrics. As a result of above discussion the product reaching the above requirements was Ashwagandharista, which was clinically proven to be effective in treating ailments which are mentioned above.

2.2 Collection of Pre standardised raw crude drugs

Raw crude drugs were collected as per the reference formula from the Raw Material Store (RMS). Before collection the drugs were ensured to be pre standardised for following parameters Foreign Matter, Microbial Load, Limit of detection, pH, Water soluble extract, Total Ash Acid, Insoluble ash.

2.3 Review of Standard values

Values of standardisation for above parameters of crude drugs were reviewed and therefore reported the drugs to be eligible for the work.

2.4 Proposed formula of the new product

The formula was calculated on basis of the classical formula with little modifications.

Table 01: Formula

Ingredients	Working formula (2 ltrs)
Decoction liquid	02 Litres
Raw wheat powder	400 gm (20%)
Yeast	200gm (10%)
Dhataki Flower	200gm (10%)
Prakshepa Dravya	200gm (10%)

2.5 Method of preparation

- ✓ Collection of ingredients
- ✓ Pulverization of crude drugs
- ✓ Soaking of pulverized powder with sufficient water.
- ✓ Boiling (decoction) for 4 hours.
- ✓ Filtration (Using Muslin cloth)
- ✓ Addition of plain powdered raw wheat flour
- ✓ Stirred using a stirrer.
- ✓ Addition of yeast, powdered Dhataki flower, Prakshepa dravya.
- ✓ Stirred & transferred to a pot.
- ✓ Placing the pot in a dry and warm place for fermentation
- ✓ Mouth of the container sealed and kept undisturbed
- ✓ Sampling after 15/30/45 days for organoleptic observations.
- ✓ Testing for total alcohol content
- ✓ Filtration, Analysis.

3.0 RESULTS & DISCUSSION

3.1 RESULTS

3.1.1Sample Analysis for active principles by Thin Layer Chromatography

Retardation Factor (Rf) of sample solution= a/b = 7.2/9 = 0.80.

Retardation factor (Rf) of reference solution= c/b = 7.4/9= 0.82.

3.1.2 OBSERVATIONS

Table 02: Observation table

Description	Day 15	Day 30	Day 45
Colour	Slight cream to brownish	Slight cream to brownish	Slight brownish
Taste	Bitter/ Tasteless	Bitter/ Sour	Bitter/ Sour
Odour	Mild Alcoholic odour	Alcoholic odour	Alcoholic odour
Effervescence	Slightly present	Present	Absent
Hissing sound	Slightly heard	Heard	Heard
Stage	Onset of fermentation	Onset of fermentation	Onset of fermentation

3.2 DISCUSSION

3.2.1 Comparison of results between traditional product and the formulated product

Table 03: Comparison of results

TEST	Values of formulated product	Values of traditional product	Prescribed value	REF
Microbial load count	Nil	Nil	NMT 10^4CFU/ml	PSAF
pH	5.16	3.653	3.5-5	
Sp gravity	0.99	1.10	1-1.15	
Wt/ml	1.00804g/ml	1.10g/ml	-	
Total solids	0.94%	27.26%	NMT 40%	
Sugar content	3.6%	30%	NMT 30%	
Alcohol content	6.44% v/v	7.05% v/v	4-10% v/v	
Kinetic viscosity	80.28mm2/sec	112.72mm2/sec	NLT 75mm2/sec	

3.2.2 Discussion on comparison of results

3.2.2.1 Description

3.2.2.2 Differences in colour i.e. brown and cream to brownish colour would be because of the colour influenced by jaggery in the traditional product. Wheat used in the formulated product whose colour is visibly creamish, brown appearance would be because of the reactions caused during its fermentation.

3.2.2.3 Microbial Load Count

The value co-ordinates in both to be Nil.

3.2.2.4 pH

Acidity levels in the formulated product is observed to be quite low compared to the traditional product. This difference could be because of the influence of jaggery in the traditional product, However acidity recorded in the formulated product is advantageous to be less as it would be calm without causing much of irritation in GIT and much preferred for patients suffering from gastritis and stomach ulcers.

3.2.2.4 Specific Gravity

The value recorded nearly co-ordinates in both the products.

3.2.2.5 Total Solids

High reduction of total solid content in formulated product is assumed to be because of absence of monosaccharide and disaccharide sugar in the formulated product which influences total solid content.

Advantage of carrying less solid content in the product, leads to its faster absorption as there is no necessity of dissolution.

3.2.2.6Sugar Content

This is a major parameter for which the new product is formulated. The monosaccharide/ disaccharide sugar content differs as much as 1000% between the traditional and formulated product. This is because of the main reason that the jaggery which is been used in the traditional formulation contains 46g/100g of sugars where as wheat only contains 0.3g/100g of sugar. This is useful in cutting down the disadvantages of sugar caused from its intake.

3.2.2.6 Alcohol Content

Alcohol content generated in the formulated product implies within the prescribed limit of 4-7% v/v which is assumed to be because of addition of yeast powder which sometimes may be a little disadvantageous resulting in bloating.

3.2.2.7 Viscosity

Less viscosity levels in the formulated product may once again result in the quicker absorption through GIT where the absence of jaggery is assumed to influence the reduction in the viscosity of the formulated product.

4.0 CONCLUSION

The conventional method of preparations of Ashwagandharista by measuring its fermentation capacity, leading to *in situ* alcohol generation maximum of 10% v/v where jaggery is being used as fermentation media. The presence of jaggery in such formulations perhaps also increases the taste. Such formulation is being used for general well-being of human population resulting in a good health. The administration of such preparation to the diabetic population might be a risk by aggravating the blood sugar level as because of the presence of the jaggery, great source of monosaccharide sugar.

An alternative approach in place of jaggery, wheat flour is used to maintain the same percentage of alcohol by *in situ* fermentation without keeping the risk of enhancement of sugar levels in diabetic patients, almost 6.44% v/v alcohol generation was observed by this alternative formulation by keeping all the ingredients as such and unaltered Ayurvedic principles made the formulation ideal even for the diabetic patients.

Though the *in vitro* results indicated its positive effects for diabetic patients, with 3.6% of sugar in the formulated product, compared to that of traditional product with 30% of sugar concentration, still *in vivo* experimentation will be reflecting the actual claim and thereby it is expected to conclude its beneficial effects in diabetic cases with clinical situation.

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