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Review Article

A progressive review of *Sandhana kalpana* (Biomedical fermentation): An advanced innovative dosage form of Ayurveda

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Abstract

Sandhana kalpana (biomedical fermented formulations) are one of the best dosage forms of Ayurveda in practice since thousands of years. In order to prepare these medicaments, certain sets of conditions are prearranged, which lead to fermentation. Thus, products bequeath with self-generated ethyl alcohol, which potentiate these preparations (*Asava–Arishta*), pharmaceutically and therapeutically. Commonly, medicinal and commercial components of these formulations are prompting many researchers to contribute in manufacturing, quality control, safety, and efficacy of these formulations. To cope up with this, literature related to *Asava–Arishta* has been surveyed from the *Vedic* period to recent publications of Government of India, ie, Ayurvedic Formulary of India, and presented briefly here. In this review paper, we have discussed pioneering facts such as nature and amount of carbohydrate, type of containers, optimum temperature, variety and relevance of initiator of fermentation, manufacturing, regulatory rules, and business aspects of *Asava-Arishta*. After going through this basic information, any academician or researcher may show a way to further strengthen this dosage form.

Key words: *Asava, Arishta,* ethyl alcohol, fermentation, quality control, *Sandhana kalpana*

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.[1]

Ayurvedic herbal dosage forms are formulated through the transference of active ingredients by different manufacturing processes.[2] Among these dosage forms, '*Sandhana kalpana*' is a unique form in which acidic and alcoholic fermented formulations are prepared.[3] In order to manufacture these medicines, liquid basic drugs (juices or decoctions) are kept for fermentation as indicated in the classics.[4] In this process, self-generated (in these dosage forms) ethyl alcohol is produced by in-source material used in pharmaceutical procedure, and is not added from outside. Here, ethyl alcohol is not the only product yielded but is a part of many other organic compounds; further, alcohol/acetic acid (as per desired indications) is formulated and extraction of active principles of the herbal drugs is done. Thus, these formulations have longer shelf life, quick absorption and action and excellent therapeutic efficacy as compared to other Ayurvedic herbal medicines.[5] Therefore, the Ayurvedic fraternity relies on this unique dosage form, ie, *Sandhana kalpana* (*Asava*, *Arishta*, *kanji*, etc) to treat diseases in routine practice.

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Significance of *Sandhana kalpana*

Progressive history

Chronologically, the fermentation technique may be revealed in each period of Indian civilization, ie, from *Vedic* period to till date. Even this is true on record that alcoholic drinks are well known to men from the Paleolithic age. Maple fruits, bark of tree, cereals, etc were used to formulate these drinks. In *Vedic* rituals, the knowledge of fermentation was advanced. *Sura* was used as food and in divine, evening offerings. In the Neolithic period, cereal eating civilization was well known to prepare fermented drink by using cooked cereals. In the Egyptian civilization, it was an important drink in their routine life.[5]

In Ayurvedic science, these drugs are formulated in such a way that the alcohol-soluble extractives of herbal drugs are

preserved in self-generated alcohol and used as medicines. On the other side, in European countries, different healthy drinks such as wine and beer are formulated as stimulants, used for the pleasure and enjoyment.[6]

Literature review reveals that the basic principles to prepare fermented products are fundamentally similar from those prevalent in the ancient time to modern era. The difference observed is in the use of equipment, type of raw drugs, sterilization techniques, and preparation methods. Evolution is noted in testing parameters and also quality standards of the finished products. In the ancient period, subjective parameters were used in the process and finished drug testing, while in the modern era, various analytical and advanced biotechnological techniques are utilized to test the quality of the finished drug.[7]

A) Vedic period: Literary evidence from *Vedic* literature gives a clear idea about the confirmation of the existence of fermentation process. *Vedas* such as *Rigveda*, *Yajurveda*, and *Atharvaveda* have focused on various fermented formulations prepared in wooden containers. The sweet liquid *Somarasa* is a unique formulation, which is supposed to be a product obtained with the help of the fermentation technique. In *Rigveda*, along with *Somarasa* (*Rigveda* -2/14/01), another alcoholic drink *Sura* was prepared by fermentation process. *Somarasa* was used as an offering to God and *Sura* (*Rigveda* -6/66/10) was for human consumption. The people in this period were well known for the production of an acidic fermented product curd, which was routinely used in the daily diet.[8]

In *Kautilya Arthashastra (Suraadhayay 1, 2, and 3)*, two types of *Sandhana kalpana* preparations derived from fruit juice and molasses are mentioned when these are kept for a certain period; some of these preparations converted into specific liquid and addressed with terminologies viz *Medaka*, *Prasanna*, *Asava* and *Arishta*. It gives an indication of the fermentation technique that was in use for preparing these products.[9]

B) Post Vedic period: In this period, addition of new techniques and development in the preparation of fermented products took place such as grape and sugarcane, juice of *Kharjura*, bark of herbal trees, etc were added, along with rice, barley and cereals, fruits as these formulations were advocated as medicines. The use of honey, flower of *Madhuka* (*Madhuca longifolia Koen.*), *Dhataki* (*Woodfordia fruticosa L. Kurz.*) were also quoted in different preparations of alcoholic fermented drugs.[10] Authors are placing here some important facts of *Sandhana kalpana* for ready reference.

Vrihat trayee (Three great classics of Ayurveda)

The good properties and adverse effects of *Sandhana* (fermented) formulations are nicely elaborated here. They were tested biologically and documented in *Vrihat trayee*. These three major classics—*Charaka Samhita*, *Sushruta Samhita*, and *Ashtanga Hridaya*—are explored to compile information regarding ancient methods of preparation of fermented drugs and other related information. It is revealed that '*Madya*' term was used for alcoholic drink. Referred authors found many innovations in this period, which were introduced by Ayurvedic scholars for preparation of *Sandhana kalpana*.[11]

a) *Charaka Samhita*

In this period, several original revelations were made about preparation of different herbal formulations as medicines. Literary review says that several *AsavaArishta* were well known to physicians during that period. *Charaka Samhita* explains that especially the nine herbal sources—*Phala* (fruits), *Dhanya* (cereals), *Mula* (roots), *Pushpa* (flowers), *Twak* (bark), *Sara* (exudate), *Kanda* (branches), *Patra* (leaves), and *Sharkara* (sugar) for the preparation of fermented medicines, definition of fermentation, specification in the container, place to keep the basic drug, the time period for fermentation, subjective parameters to test elaborately the end point of the procedure and finished product. The application of the prepared medicines (*Asava–Arishta*) is recommended in different disease conditions.[12]

The basic concepts of these specific arrangements are responsible for better yield and quality production of *Asava–Arishta* even today. This indicates that the fermentation technology was well known in that period.

b) *Sushruta Samhita*

Among Ayurvedic basic literature, *Sushruta Samhita* is considered as the treaty of surgical treatment. A number of *Sandhana kalpana* (fermented products) were prescribed for surgical procedures as anesthetic drug as well as a medicine to treat different disease conditions. A total of 21 fermented drugs such as *Asava–Arishta* and 46 *Madya* products named as *Madya*, *Sura*, *Prasanna*, *Jagala*, *Surasava*, *Madhvasava*, *Shukta*, *Dhanyamla* are well documented in this classical text. *Sushruta Samhita* may be credited for addition of botanical ash (*Apamarga*, *Palasha* ash) as ingredients of *Asava–Arishta*. These formulations are prescribed for certain therapeutic purposes. Other essential elements for the preparation of *Asava–Arishta* are also discussed in this text in detail.[13]

c) *Ashtanga Hridaya* and *Sangraha*

Herbal medicine stream was fully developed in this period; this is reflected in the formulation of different *Sandhana kalpana*. Along with other ingredients, the use of *Dhataki Pushpa* (*Woodfordia fruticosa*) as a fermentation initiator is documented for the first time in *Ashtanga Hridaya*.[10] This could be considered as one of the innovatory steps in pharmaceutical practice to formulate *Sandhana kalpana*. Physicians were well aware of the fermentation techniques, as the container, the place, duration and criteria for testing the product are clearly mentioned in various formulations usually in accordance with previous classics. '*Draksha* (grapes), *Ikshu* (sugar cane), *Makshika* (honey), *Shali* (rice), *Vrihi* (grains) are the five source materials found to be used to prepare *Madya* and *Sandhana kalpana*.[14] *Draksha* is the most acclaimed source material. A total of 17 *Asava–Arishta* are quoted in *Ashtanga Sangraha* and 8 in *Ashtanga Hridaya*.[11]

This may also be an inference after going through *Vrihat trayee* that in this period, sharp difference in preparations of *Asava – Arishta* on the basis of *Kwatha* and *Swarasa* used as source was not clearly established. Table 1 gives a quick review of input of *Vrihat trayee* regarding *Sandhana kalpana*. About the contribution of *Vrihat trayee*, Joshi and Jha[11] concluded that according to *Sushruta*, *Asava* has a predominance of *drava* (liquid) while *Arishta* has a predominance of *dravya* (drugs) *(Dalhana on Sushruta Sutra Sthana* 45/197). *Asava–Arishta* preparation consists of liquids, medicinal material

Table 1: *Asava-Arishta* of *Vrihat trayee* prepared by boiling and without boiling

Categories of *Asava-Arishta*	*Charaka Samhita*	*Sushruta Samhita*	*Ashtanga Sangraha*	*Ashtanga Hridaya*	Total
Asava prepared by boiling	09	01	03	03	16
Asava prepared without boiling	01	06	01	00	08
Arishta prepared by boiling	13	04	10	04	31
Arishta prepared without boiling	07	10	03	01	21
Total	30	21	17	08	76

(Source: Reference no 11)

(as main ingredient of formulation), sweet substances and *prakshepa dravya* (additional medicinal/palatable substances) as their important constituent. No definite proportion of these constituents could be worked out on the basis of the present study of the text of *Vrihat trayee*. The fermenting pots are made of the either soil or metal and should be smeared and fumigated first with the recommended drugs and is then used for fermentation. Further, these texts mention that the fermentation process is faster in summer and slow in winter. It needs a minimum of seven days and may be extended up to six months.

d) *Kashyapa Samhita*

In this classic, the term *Abhishava* is included in seven basic *kalpanas* (dosage forms) to indicate a fermented product. But we did not find a specific process of fermentation mentioned in preparation method. Different formulations are advocated in this time period, which denotes the existence of *Sandhana kalpana* and preparation techniques related to fermented drugs.[15]

e) Chakradatta

Ayamakanjika for the treatment of *grahani* and *siddhamla kalpana* for the treatment of *amavata* and many more products of the *Asava- Arishta* category are quoted in *Chakradatta*. This may be considered as a prominent contribution of *Acharya Chakrapani*.[16]

f) *Gada Nigraha*

In this classical text, few ideas were put to formulate various herbal compound medicines. The wide use of these formulations was seen in the treatment of diseases. A total of 60 *Asava-Arishtas* (fermented drugs) are mentioned in the chapter *Asavadhikar*. Different pharmacodynamic actions of drugs are elaborated, wherein the therapeutic potential of *Sandhana kalpana* is also mentioned.[17]

g) *Sharangadhara Samhita*

In the medieval period, due to the varied needs, pioneer dimensions and proper understanding of different Ayurvedic medicines related knowledge was compiled and written properly in this text. *Sandhana kalpana* is elaborately described in this text. One chapter explains acidic and alcoholic fermentation, its various formulations prepared from barley, rice, sugar cane juice, grape juice, etc. This book also properly discusses pharmaceutical aspects as well as therapeutic efficacy of fermented formulations. The most significant contribution of this treatise is establishing a rule to prepare *Asava-Arishta* where definite proportions of ingredients are not quoted.[18]

h) *Yogaratnakara*

In *Yogaratnakar*, a detailed description of *Asaava–Arishtas* in *madya kalpana* is given.[19] All these descriptions are similar to the narrations given about *Asava-Arishta* in the previous classical treatise. However, it is interesting to note that the total number of formulations of *Sandhana kalpana* in this book is larger as compared to the earlier classics. It may be interpreted as a greater acceptability of these formulations among physicians and patients in this period.

i) *Bhaishajya Ratnavali*

The information regarding *Sandhana* formulations is found here as a handbook, which can be simpler in routine use for the physicians. In the preparation of these drugs, the ingredients, the specific duration to keep the container—for 15 days or 1 month—is mentioned. In this book, a total of 50 *Sandhana kalpanas* are quoted, of which 15 are *Asava*, 29 *Arishta*, 2 *Chukra*, 2 *Sura*, 1 *Shukta*, and 1 *Kanji kalpana*[20]

j) Ayurvedic Formulary of India

Parts I and II of Ayurvedic Formulary of India describes 40 *Asava–Arishta*, with complete detail of their pharmaceutics and therapeutics. In this publication by Department of AYUSH, Government of India, the manufacturing process of *Asava–Arishta* are described in the beginning of the chapter and the ingredients (with their part used) and proportion of every formulae are described systematically.[21]

Imperative issues for accurate initiation of *Sandhana kalpana*

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*.

a) Proportion of carbohydrates (Madhura Dravya)

Microorganisms involved in the preparation of *Asava–Arishta* 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, ie, 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. Table 2 presents different (concentration) proportions of sweet substances mentioned in the Ayurvedic *magnum opus*.

Acharya Charaka and *Sharangadhara* have mentioned using 39.06% of sweet substances (generally carbohydrate) for the process of fermentation in *Sandhana kalpana*. But to initiate the easy and early fermentation, only 40% of sweet substances are advised to be added and the remaining quantity of sweet substances is supplemented after fermentation process begins.[22]

b) 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.[23,24]

c) 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–Arishta* were placed in *Dhanya Rashi* (*Kanakbindu Arishta - 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 were 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.[25,26]

d) 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 *Loharishta - Sushruta Chikitsa Sthana 12/12-17*. Duration of fermentation varies with formulation, which ranges from 7 days (*Ashtashatarishta - 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.[11,27]

e) Significance of Sandhana Dravya (Fermentor)

Fermentor acts as a supply depot of microorganism, which initiates the process of fermentation. The *Asava–Arishtas* quoted in *Charaka 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–Arishta*.

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

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

The use of *kinva* or *surabeeja* as an accelerator of fermentation process is evident from *Rigveda* and *Kautilya Arthashastra* as well (42nd *Prakarana - Suradhyakshaha*, 2:25:17, *Kautilya Arthashastram*). Few contemporary researches are showing the effect of different ingredients as initiator of fermentation (in supposition) in *Asava–Arishta* of Ayurveda, which are mentioned here.

The effect of addition of yeast (*Saccharomyces cerevisiae*) and *Dhataki pushpa* to fermenting media was studied. The study reveals that the onset and completion of fermentation process in the samples containing yeast were quick, as in these samples, fermentation started on the second day and was completed within one month. However, in the group where yeast was not used, fermentation started on the fifth day and was completed in second month. Fermentation may be delayed because of natural growth and multiplication of yeast cells as well.[23]

Another report says that the flowers of *Dhataki pushpa* are used as inoculum in the preparation of *Asava-Arishta*. Here, attempts have been made to decode its role in alcoholic fermentation. The flowers were screened for micro flora and yeast strain of *S. cerevisiae*, which was isolated from the flowers and its morphology reported. The flowers of *Dhataki* were found capable to initiate alcoholic fermentation as normally achieved by the use of pure yeast culture.[28]

Further, Das *et al.* showed that the flowers of *Dhataki* contain substantially high concentration of tannins, to the extent of 22%, and such polyphenolic compounds are susceptible to enzymatic conversion to simple phenols and alcohol during anaerobic fermentation of *Arishta* preparations. Perhaps, this justifies the extensive use of *W. fruticosa* in *Arishta* preparation, the main purpose of which is to produce alcohol.[29]

Contrary to this belief of Ayurveda specialists that inoculum

Table 2: Minimum and maximum proportion of the sweet substance as mentioned in the Ayurvedic classics

Name of text	Proportion of sweet substances as mentioned in classics	
	Minimum %	Maximum %
Charaka Samhita	15.18 (*Madhukasava, Chikitsa Sthana* 15/146)	156.25 (*Dantyarishta, Chikitsa Sthana* 14/147)
Sushruta Samhita	25 (*Vrishchiradyarishta, Uttar Tantra* 42/47)	178.57 (*Putikadyarishta, Chikitsa Sthana* 10/06)
Ashtanga Hridaya	20.23 (*Madhukasava Chikitsa Sthana* 10/47)	156.25 (*Dantyarishta, Chikitsa Sthana* 08/64)
Sharangadhar Samhita	32.03 (*Lohasava, Madhyam Khanda* 10/34)	156.25 (*Draksharishta, Madhyam Khanda* 10/73)

(Source: Lakhani Rupa, Chaudhary A, Ravishankar B, Dey S, Pandy D, A Comparative Pharmaceutico-clinical study on Arka Kalpana and Arishta Kalpana w.s.r. to Jirakadyarka and Jirakadyarishta on Grahani, PG theses, IPGTRA, G AY U, Jamnagar, 2002)

of yeasts comes from *Dhataki* flower; Das *et al.* have different opinion and findings. They argued that an endogenous invertase (fructofuranosidase) found in *Dhataki* flowers helps in sucrose hydrolysis to alcohol. The alcohol production helps in promoting the extraction of biologically active components including gallic acid from plant materials, and absorbs active principles in the gastrointestinal tract. This alcohol, in turn, resists the growth of any microorganism in *Arishta* preparations for years together. Increased content of gallic acid, which is otherwise present in traces, if at all, as well as the Ayurvedic process of 'self-generating alcohol' insinuates a conjecture. Here, the researchers referred earlier have tried to establish that *Dhataki* flower is an essential component of *Asava–Arishta*, not only for initiation of fermentation, but for enhancing clinical efficacy as well.[28] This concept was supported by the fact that, in some of these formulations, *Dhataki* is not a compulsory ingredient, so it may be perceived that role of *Dhataki* is not a carrier of the inoculums only.[30]

Satyanarayan *et al.* opined on the use of *Dhataki Pushpa Phanta* or *Hima* for checking contamination instead of the whole flower. The *Kinva* act as a ready source of microbial flora. They grow and initiate the fermentation process early, when favorable media and condition are formed. The dangers inherent in this practice are the introduction of contaminants and a change in the degree of flocculence and attenuating abilities of the yeast due to degeneration in the yeast cell.

f) Metal/Minerals in *Asava–Arishta*

Fine powders of metals (*Ayaskriti*) have been used as essential ingredients in some *Asava-Arishtas* [Table 3]. Indication of *Loha churna* and *Suvarna patra* are predominant examples. Table 4 depicts how some microorganisms consume metals under optimum growth conditions. Assessment of Tables 3 and 4 reveals the wisdom of ancient scholars in how they suggested addition of fine powders of metals and minerals as ingredient or use of containers made of metals for preparation of *Sandhana kalpana* to have some vital therapeutic effects. Saxena *et al.* inform that *Loha churna* gets converted into minute particles by the action of alcohol in finely prepared *Lohasava* and shows high iron content, ie, 0.0612 g%.[31]

In a nutshell, some of the benefits of fermented herbal products, ie, *Sandhana kalpana* (biomedical fermentation) are reproduced as mentioned below.[32,33]

- Fermentation removes most of the undesirable sugars from plant material, making the product more bio-available and eliminating side effects such as gas and bloating.
- Fermentation extracts a wider range of active ingredients from the herb than any other extraction method since the menstruum undergoes a gradient of rising alcohol levels.
- Yeast cell walls naturally bind heavy metals and pesticide residues and, therefore act as a natural cleansing system.
- Not only does fermentation remove contaminants, it also lowers the toxicity of some of the toxic components in plants.
- Fermentation actively ruptures the cells of the herb, exposing it openly to the menstruum, and bacteria have enzymes that break down cell walls to further assist in the leaching process. Fermentation also creates an active transport system that moves the dissolved constituents from the herbal material to the menstruum.

Manufacturing and completion tests of *Asava-Arishta*

Naturally, the method of preparation of *Asava–Arishta* is now comprehensible. Authors would like to submit here that classical indications of manufacturing norms must be followed with compliance of Good Manufacturing Practices (GMP) guidelines. Authors would not restrain adoption of any new technique for preparations of *Asava–Arishta*, which does not violate fundamental manufacturing principles of *Sandhana kalpana* with uncompromised therapeutic efficacy and safety.

Completion and in-process testing of *Asava–Arishta* are indicated in classics such as *Sharagadhar Samhita*, which must be professionally endorsed by operation supervisors. Authors are not detailing these narrations of classics here due to the concerns of the length of this paper, but because we realize that for these two titles included with parameters of analytical consideration for standardization and quality control and experimental models generating data of its pharmacological action of *Asava–Arishta*; for this, an exclusive review cum research paper is required. These all are not a mandate of this paper.

Discussion

The superiority of *Sandhana kalpana* in the practice of Ayurveda obliged us to deliver this review paper before every stakeholder of Ayurveda. Authors have argued about basic essentials for the preparation of *Sandhana kalpana* under the title of imperative issues in this field. Here, authors are inclined to carry forward some vital aspects, which may be adopted for additional advancement of this dosage form.

Khan *et al.* are responsive to the fact that medicinal plants are the most important source of life-saving drugs for the majority of the world's population. Plant secondary metabolite is economically important as drugs, fragrances, pigments, food additives and pesticides.[34] Hence, documentation and utilization of traditional knowledge in the field of medicine, healing and biodiversity conservation has attained greater dimensions. Although rural folk of our country unknowingly used microorganisms for varied purposes, there is no major effort to document and protect them. The art of preservation and enrichment of vegetables by microbial systems, preserving microbial culture starter for beverage production and production of diverse traditional beverages from plant material is essential now.[35]

Astonishingly, they prepare microbial culture starter for use as inoculums in beverage production. The art of making culture starter is based on the principles of microbiology and much is based on the preservation of desired microorganisms in encapsulated form. Therefore, the concerned people preserve these specific microorganisms in an inactive phase by applying specific methods. These microorganisms initiate the desired process when they received optimum and favorable condition for the same. In the Indian context, the states of North-East India have the richest reserve of traditional knowledge due to their hilly nature where harsh condition generally prevails. The major contributors to this knowledge are tribal people living in such hills and their use of different kinds of fermented beverages and foods.[36]

In recent time, the knowledge of Ayurveda is validated by a

Table 3: Metals and minerals as constituent of *Asava-Arishta*

Name of treatise	No. of total *Asava-Arishta*	No. of metal containing *Asava-Arishta*	Name of *Asava-Arishta*
Charaka Samhita	28	02	*Punarnavarishta, Phaltrikarishta*
Sushruta Samhita	11	02	*Loharishta, Pindarishta*
Ashtanga Sangraha	14	01	*Lohasava*
Ashtanga Hridaya	09	01	*Lohasava*
Gada Nigraha	67	09	*Abhayarishta, Kusmanadasava, Lohasava, Mandoorarishta, Gandirasava, Triphalarishta, Kharjurasava, Rasayanarishta, Rohitkasava*
Sharangadhar Samhita	13	02	*Kumariasava, Lohasava*
Bhaishajya Ratnavali	44	03	*Lohasava, Patrangasava, Sarswatarishta*

(Source: Gandhi P, Chaudhary A K, Ravishankar B, Dey S, Prajapati P K, A comparative study of different formulations of Vasa (Avaleha, Sneha, Sandhan) wsr to its Swasahar effect, PG Theses, IPGTRA, Gujarat Ayurveda University, Jamnagar, 2005)

Table 4: Bioadsorption and bioaccumulation capacity of different microorganisms

Metal ion	Microorganism	Metal uptake capacity		
		Mmol/g	g/g	Reference
Fe	Rhizopus arrhizus	10.96	0.612	Aksu Zand Calik A , Sep Sci Technol, 34 (1999) 817
Au	Ixalotriton niger	0.893	0.176	Kuyucak N, Proc Int Sympo Biohydroetall (UK) 1988
	Rhizopus arrhizus	0.832	0.164	Volesky B, Proc Int Sympo Biohydroetall (UK) 1988
Ag	Fungal biomass	0.606	0.065	Brierly J L and Goyak C M, cited in Fundamental and applied Biohydrometallurgy
	Yeast species	0.004	0.0004	Pumpel T and Schinner F, Biotechnol Lett, 10 (1988), 137
	Saccharomyces cerevisiae	0.044	0.0047	Pighi P L, Pumpel T, Biotechnol Lett, 11 (1989), 275

(Source: Murlidhar *et al*, A Comparative Pharmaceutico-pharmaco-clinical study of different samples of *Shirisharishta* and its Shwasahara Effect, PG Theses, IPGT&RA, Gujarat Ayurveda University, 2004)

contemporary research work in which five different mutant strains were developed from the wild strain of *S. cerevisiae* using UV irradiation technique and by varying the exposure timings. All the mutant cultures were used for ethanol production by using banana peel as a substrate in a batch fermentor. The effect of temperature, pH, and initial substrate concentration on ethanol production were studied and optimized. One mutant strain yielded a maximum ethanol production of 9 g/L under identical conditions. The conditions were optimized for this mutant strain at a temperature of 33°C, pH 4.5, and initial substrate concentration of 10% (w/v).[37]

Heller *et al.* supplemented the techniques of ancient India to prepare *Sandhana kalpana* as a result of current findings of probiotic bacteria. These bacteria are mainly found in fermented foods, and dairy products, which play a predominant role as carriers of various other health benefits. These foods are well suited to promoting the positive health image of probiotics for several reasons.[38] The vital role of probiotics in manufacturing of *Sandhana kalpana* may be an area of great interest.

Products of *Sandhana kalpana* have now demonstrated its ascendancy on other dosage forms of Ayurveda, as *Arjunarishta* (*Parthadyarishta*) is used for cardiovascular disorders and prepared by fermenting a decoction of specified plant materials using flowers of *W. fruticosa*. The developed method was validated with respect to linearity, precision, accuracy, and robustness. The High-Performance Liquid Chromatography (HPLC) analysis showed an increase in the amount of ellagic acid and gallic acid during preparation, ie, decoction versus formulation. A similar increase in free radical scavenging activity of formulation versus decoction was also observed. Arjunolic acid and arjunic acid were not detected in the formulation.[39]

Among new progresses of drug delivery system is pharmacogenomics, which is the study of genetic factors that mediate an individual's drug response. The pharmacogenomic analysis promises to identify disease susceptibility genes, thus discovering new drug targets.[40] This individualized approach of drug dispensing was ubiquitous in practice of Ayurveda. Perhaps, this is one reason why in compilations of different classical formulae of Ayurveda with a single name, and minor differences in ingredients and their proportion are frequently observed. Four types of *Abhayarishta* is quoted in *Bharat Bhaishajya Ratnakar*; therefore, the concept of pharmacogenomics may be applied here in selection of medicine for a particular patient.[41]

In general lifestyle, an aware citizen always accentuates the implication of a diet regimen for diseased as well as healthy individuals.[42] It pays rich dividend in eliminating ailments.[43] In Ayurvedic *Sandhana kalpana*, products such as *Kanji, Takra, Sidhu rasa,* and *Varuni* are used in routine diet as nutritive products and to prevent and cure diseases. Therefore, an attempt may be advocated in the lines of recent inventions in the field of nutrigenomics. The ultimate aim of this emerging field of science is prevention rather than cure.[44] An auxiliary approach of combinatorial biosynthesis is another move towards generation of novel natural products and for production of rare and expensive natural products and this may be in the field of *Sandhana kalpana* as well.[45]

In a nutshell, pharmacogenomics, nutrigenomics, and

combinatorial biosynthesis with its novel doctrines may be interrelated with Ayurvedic principles of drug delivery system. Concepts of *Asava–Arishta* manufacturing may attract these new concepts, as its constituents are proficient in completion of therapeutic and nutritional responsibilities to the patient.

Contemporary relevance of the concept

Ayurveda practitioners invented *Sandhana kalpana* to obtain all active principles of plants under duress of aqueous as well as alcohol solubility. These medicaments have higher hand in therapeutics due to this supplementation of alcohol soluble matters. Contemporary pharmaceutics have also developed various new chemical entities on the basis of alcohol solubility of plants. From the pharmaceutical point of view, hydroxylations and glycosylations (occur in alcoholic extractions) are considered to be particularly useful bioconversions. These processes can yield new drugs and help improve existing drugs in terms of increased activity and decreased toxicity.[46,47]

One study was planned to explore the hepatoprotective activity of the ethanol extract of leaves of *Gymnosporia montana* against paracetamol-induced hepatotoxicity. This ethanol extract of *G. montana* at a dose of 100 mg/kg reduced the same hepatoprotective effect comparable to silymarin.[48] Another study evaluated the ant diarrheal property of the alcohol extract of *Butea frondosa* leaf on mice and rats. This study revealed that at a dose of 25 and 75 mg/kg, a considerable reduction was observed in the extent of diarrhea, but at a dose of 100 mg/kg, the animals appeared completely constipated when subjected to castor oil-induced diarrhea and intestinal motility model.[49] Products of *Sandhana kalpana*, especially *Asava–Arishta* are alcohol based so this may be one reason why these are showing better therapeutic efficacy.

Authors appreciate this approach of new researchers where they are exploring new Active Pharmaceutical Ingredients (API) from botanical sources, taking lead from the concept of Ayurveda.

Regulatory references

a) Existing national rules

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, which is depicted in Tables 5-7.[50]

Table 5: Preparation *(Asavas)* with high content of alcohol as base {Rule 161 (3) (ix) (a)}

Name of the drug	Maximum size of packing
Karpurasava	15 ml
Ahiphenasava	15 ml
Mrgamadasava	15 ml

(Source: Malik Vijaya, Law relating to Drugs and Cosmetics, Eastern Book Company, Lucknow, 20th edition, 2010)

Table 6: Preparations containing self-generated alcohol {Rule 161 (3) (ix) (b)}

Name of the drug	Maximum content of alcohol (ethyl alcohol v/v)	Maximum size of packing
Mritasanjeevani sura	16%	30 ml
Mahadrakshasava	16%	120 ml

(Source: Malik Vijaya, Law relating to Drugs and Cosmetics, Eastern Book Company, Lucknow, 20th edition, 2010)

Table 7: Standards to be complied with during manufacturing for sale or distribution of Ayurvedic, *Siddha* and Unani Drugs (Rule 168)

Class of drugs	Standards to be complied with
Drugs included in Ayurvedic Pharmacopoeia	The standards for the identity, purity, and strength as given in the editions of Ayurvedic Pharmacopoeia of India for the time being in force
Asava and Arishta	The upper limit of alcohol as a self-generated alcohol should not exceed 12% v/v, expecting those that are otherwise to be notified by the Central Government from time to time

(Source: Malik Vijaya, Law relating to Drugs and Cosmetics, Eastern Book Company, Lucknow, 20th edition, 2010)

b) State wise

It has been observed that in certain states, namely, Andhra Pradesh and Maharashtra, rule of taxation of Ayurvedic medicine under these categories are under scrutiny of the Excise Department of the concerned states. As this matter is judicial, we are not making any comment herewith.

c) Misuse of Asava–Arishta

In the ninth decade of the last century, at Ghaziabad (Utter Pradesh), several people had died and/or lost their vision after consumption of adulterated, misbranded, and spurious *Mrita sanjeevani sura*, which they are consuming on the pretext of wine, and certainly not as medicine to attain the therapeutic range of *Mrita sanjeevani sura*. Such abuses of *Asava–Arishta* are still in practice in some places, especially in the proximity of slum dwellers. The authors suggest for stern action against this malpractice by regulatory authorities.

d) View of stake holders

By and large, all stakeholders of Ayurveda (physicians, patients, manufacturers, and regulators) moderately desire better management of manufacturing, sale, and distribution of *Asava–Arishta* with its extensive therapeutic uses from pediatrics to geriatrics. Some questions regarding application of these products for patients of Diabetes considering its higher percentage of sugar, which must be addressed properly.

Commercial compliance

i) Famous brand

While moving across India, one is bound to see some kind of advertisement on roadside regarding the type of *Asava–Arishta*, namely, *Dashmoolarishta* and *Ashokarishta*. This is enough indication about the extent of consumption of the two brands as per rules of market. The reason is obvious; therapeutic utility of these two brands in obstetrics and gynecological disorders, eg, *Abhayarishta*, *Amritarishta*, *Arjunarishta*, *Draksharishta*, *Kanakasava*, *Shirisharishta*, etc are some other famous examples established in the market. Among manufacturers at the national level, companies like Baidyanath, Dabur, Sandu and Dhootpapeswar are leaders in market. Arya Vaidya Sala and KAPL,

Kerala, are other emerging players in the field internationally.

ii) Value of turnover

Facts analyzed from the balance sheet of various leading companies of Ayurveda endorsed magnitude of business of *Asava–Arishta*. Overall, approximately 20% business of Ayurvedic drugs is in the periphery of products of *Asava–Arishta* (result drawn from annual report of several companies, this is not quoted at one place).

iii) Prospects of international marketing

With the growing acceptability of Ayurveda globally, it is possible that the demand of *Asava–Arishta* will rise in the market of medicines. New rules are being framed by governments across continents such as Health Australia, US Food and Drug Administration (USFDA), UK Medicines and Healthcare Products Regulatory Agency (UKMHRA) for manufacturing, sales, and distribution of Ayurvedic medicine contemporary to their standard of pharmaceutical products and requirement of their citizens. *Asava–Arishta* may qualify on these parameters.

iv) Quality control

Taking view of researchers for quality control of *Asava–Arishta*, this refereed paper may be a milestone. The present investigations evaluated five different brands of *Dashmoolarishtam* available in the market as per World Health Organization (WHO) and specifications of the Pharmacopoeial Laboratory for Indian Medicine. Various physicochemical parameters were determined, such as alcohol-soluble extractives, water-soluble extractives, total ash, acid-soluble ash, total solid, and alcohol content. The present investigations reveal that all preparations contain acceptable levels of alcohol (less than 12% v/v). However, the preparations were found to contain unacceptable limits of microbial load, although all showed the absence of *Escherichia coli*, *Salmonella* species and *Staphylococcus aureus*.[51]

The Central Council for Research in Ayurveda and Siddha (CCRAS) and Pharmacopoeial Laboratory for Indian Medicine have notified standard protocol for quality control of *Asava–Arishta*.[52] Authors request all manufacturing units of *Asava–Arishta* to follow the same with a holistic approach.

v) Business abuses

Asava-Arishta is preparations containing 3-10% alcohol. They are mild in their action, mostly pleasant in taste, and are sold across the country without any prescription. Such properties render these ideal for the drug faker as a cover for spurious preparations containing alcohol, chloral hydrate, morphine, and other drug of addiction as well as sedatives like potassium bromide. It can very well be inferred from the nature and composition of the ingredients used in the preparation of *Asava-Arishta* that substances foreign to it, such as morphine and chloral hydrate, cannot be present in such preparations unless deliberately added.[53] More percentage of alcohol than recommended, adulteration of intoxicating material are the most concerned abuses of *Asava–Arishta*.

Conclusion

Asava-Arishta is considered as the best formulation in Ayurveda because they possess better keeping quality, which is likely due to the contribution of fermentation to preservation. Microbes mediate this process, and enhance therapeutic properties, which may be due to microbial biotransformation of the initial ingredients of *Asava-Arishta* into more effective therapeutics as end-products, alcohol-aqueous milieu, which is also produced by microbes. Moreover, improvement in drug delivery in the body increases due to alcohol–aqueous milieu. These products in general possess preservative properties and potentization of drug due to biotransformation mediated by native microbes.[54] This advanced dosage form probably results into transformation of several phytochemical compounds present in the herbs used to prepare it, and thereby rendering them either less toxic or more potent, besides helping in their rapid absorption.[55]

There is an urgent need for close and continuous interaction between the medical and biotechnology communities in India, to bring the full benefit of biotechnology for healthcare. A particular challenge and opportunity for Indian biotechnology is to build a golden triangle between ancient, experiential Indian medical wisdom, modern medicine and modern science, and validate the effectiveness of Ayurvedic drugs and practices in terms of current understanding of molecular biology and molecular pharmacology.[56,57] This becomes visible in case of *Asava–Arishta* at the National Institute of Pharmaceutical Education and Research (NIPER), SAS Nagar.[58] Also, the authors of this paper believe that new pharmaceutical and therapeutics domain will prove to be authentic in the near future.

Clearly, there is an urgent need for scientific searching of Ayurvedic *Asava–Arishta* for providing better services to human civilization.

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हिन्दी सारांश

सन्धान कल्पना–एक प्रगतिशील वैज्ञानिक आख्या

आनंद चौधरी, नीतु सिंह, माधुरी दलवी, अस्मिता वेले

सन्धान कल्पना आयुर्वेद की एक अत्यन्त महत्वपूर्ण कल्पना है। आसव–अरिष्ट के रुप में यह कल्पना अनेकों उद्देश्यों को पूरित करती है। एतदर्थ आसव–अरिष्ट कल्पना के युगानुरुप आधुनिकीकरण के लिए अनेकों अनुसन्धान हो रहे हैं। प्रस्तुत संक्षिप्त निबन्ध में भविष्य की सम्भावनाओं को बल प्रदान करने के लिए उपयुक्त तथ्यों को समावेशित किया गया है।