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Shelf life of fermented Ayurvedic products: An overview

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Abstract:

The analysis of regulations regarding shelf life of fermented Ayurvedic products Asava *and Arista* is presented on the basis of classical references, official compendium and notifications. The overview is based on classical preparations, production of fermented of Ayurvedic drugs, various guidelines and shelf life regulations and current industrial practices. After 13th century Ayurvedic classical texts including *Sharangdhar Samhita, Vanga Sen and Yogaratnakar,* well described the Shelf life, quality of packaging material and storage conditions of various Ayurvedic products including *Sandhan kalpana*. Due to recent developments in packaging and storage technology by Ayurvedic industries, a need arises to validate and re-establish the new criteria for evaluation of shelf life. Recently, Ministry of AYUSH has also amended guidelines regarding the shelf life of Ayurvedic products through Gazette notification and proposed the new shelf life of the Ayurvedic fermented products, in which the shelf life rules of *asava and arista* is restricted up to 10 years. Present paper highlights the development of shelf life regulations of *Asava* and *Arista* since ancient time to modern era

Key Words- *Asava and Arista*, *Shelf life*, Fermentation, Classical Ayurvedic text, guidelines, sandhan

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Introduction

Shelf life (*saviryta avadhi*) of the fermented Ayurvedic products is explained in various classical texts of Ayurveda. According to classical texts, *Asava and Arista* have properties of long-term stability and they get more potent as they get older. *Asava and Aristas* are self-generated alcohol which helps to keep product stable. These formulations are absorbed faster and show quick action on the body. Presence of *prakshepa dravyas* and sugar increase the palatability of product. In Ayurveda various types of fermented product are classified under the category of *Sandhan kalpana*. Fermentation is a unique method of preparing herbal drugs as mentioned in classical literatures of Ayurveda. *Asava* (infusion) and *Arista* (decoction) is mainly prepared by extraction of medicinal plant Woodfordia fruticosa. [2] After 13th century *Sharangdhar Samhita* and Ayurvedic scholars clearly mentioned the shelf life of various Ayurvedic dosage form. Currently shelf life of *Asava and Arista* is amended by recent AYUSH guidelines based on the factors such as drug, dosage forms, humidity, temperature, light, microbial limits and storage condition. [3,4] *Asava and Arista* are used in the treatment of various diseases of nervous system, respiratory system, digestive and urinary system, skin disorders and many more. [5] Ayurvedic texts like *Sharangdhar Samhita, Vanga Sen and Yogaratnakar* well described the indication, quality of packaging and storage conditions. Nowadays, due to development and adaptation of packaging and storage technology system, a need arises to validate and re-establish the new criteria for evaluation of shelf life. [6]

Historical background

Vedic period-Rigveda, Yajurveda, and Atharva veda mentioned various fermented formulations prepared in wooden and earthen pot container. The sweet test liquid *Somarasa* is Prepared with the fermentation technique. In Rigveda, (Rigveda -2/14/01), sura is different alcoholic beverage was synthesized by fermentation process.[6]

Kautilya Arthashastra- Two types of *Sandhana kalpana* preparations derived from fruit juice and molasses are mentioned in this text. when these are kept for a certain period some of these preparations converted into specific liquid and addressed with terminologies like *Medaka, Prasanna, Asava and Arista*. [6]

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Post Vedic period: Development of new techniques' in the preparation of fermented products such as Honey, flower of *Madhuka* (*Madhuka longifilia*), flower of Dhatki (*Woodfordia fruticosa*) grape and sugarcane [7]

Vrihat trayee

a) Charaka Samhita- Explains the nine botanical sources viz. *Phala* (fruits), *Dhanya* (cereals), *Mula* (roots), *Pushpa* (flowers), *Twak* (bark), *Sara*(exudate), *Kanda* (branches), *Patra* (leaves), and *Sarkara* (sugar) for the preparation of *sandhan kalpana*, definition of the fermentation, specifications of the container, temperature and time period also included in the literature.[9]

b)Sushruta Samhita- *Sandhana Kalpana* were prescribed for surgical treatment drug as well as anesthetic medicine. 21 fermented drugs such as *Asava–Arista* along with 46 *Madya* products named as *Madya, Sura, Prasanna, Jagala, Surasava, Madhvasava, Shukta, Dhanyamla* are mentioned in the text. [10]

c)Ashtanga Hridaya and Sangraha- Stream of Fermented medicine was fully developed in this period of time. Use of *Dhatkipushpa* (*Woodfordia fruticosa*) as fermentation initiator is the first time documented in this text11]

Kashyapa Samhita

In this period, *Abhishava* is included in seven basic *kalpanas* (dosage forms) to indicate a fermented product.[12]

Chakradatta- In this text *Ayamakanjika* for the treatment of *grahani* and *siddhamla kalpana* for the treatment of *amavata* is mentioned.[13]

Gada Nigraha-In this classical text, A total of 60 *Asava–Arista* maintained in the chapter Asavadhikar. Explain the different pharmacodynamic drug action and therapeutic potential of sandhan. [14]

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Sharangadhara Samhita- Explained about the acidic and alcoholic fermentation which gives the clear idea about difference between acidic and alcoholic fermentation the text also indicates numerous preparations prepared from barley, rice, sugarcane juice, grape juice, etc. The most significant contribution of this text is establishing a rule to prepare *Asava-Arista* where definite proportions of ingredients are not mentioned [15]

***Yogaratnakara*-**In this classical text *Asaava–Aristas* in *madya kalpana* are given. All these descriptions are similar to the narrations given about *Asava-Arista* in the previous classical texts. [6]

Bhaishajya Ratnavali- In this classical text, 50 *Sandhana kalpanas* are mentioned. Out of them 15 are *Asava, 29 Arista, 2 Chukra, 2 Sura, 1 Shukta,* and 1 *Kanji Kalpana*. [17]

Ayurvedic Formulary of India- Ayurvedic Formulary of India describes 40 *Asava–Arista*, with complete details [18]

Method of preparations fermented Ayurvedic products-

Madhur Dravyas (sweetening agent)-major sweetening agent used in preparation of sandhan Kalpana mainly guda (Jaggery), Sarkara (sugar), Phanita (molasses), sitopala (candy sugar) and honey. Guda (Jaggery) is the best sweetening substance contain 40% of sugar used in the preparation of fermented product. According to Acharya sharangdhar, Jaggery and honey should be one tula and half tula. In modified methods yeast are used in preparation of fermented products. Yeast is high concentration sugar it contains the solution 30-40% of sugar [19,20]

Sandhan Dravyas (fermentive agent)- Natural fermentation organism such as Dhatkipuspa, *Madhuca pushpa, surabeej/kinwa*, are used in preparation of *Asava and Arista* .Now a days, dried active yeast granules can also be used for the purpose of fermentation[19,20]

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Prakshepa Dravyas (Additive) –Prakshepa dravyas are mainly used in formulation e.g. *Lavang, Ela, Tejpatra Nagkeshar, Trikatu* etc. These drug highly enriched with various therapeutic activities and contribute to the aroma, color & taste of the formulation. [19,20]

Container All traditional writings utilized of earthen and wooden compartments for the maturation procedure, yet these have more confinements as earthen pots may break, but wooden compartments need pre-treatment. With the innovation of field plastic and stainless-steel containers are also utilized for the preparation of *Asava and Arista* [19,20]

Temperature–

In the ancient time, the fermented product was used to kept in the container of the *Asava Arista*. Usually ideal temperature required for inception of fermentation is in the array(limit) of 25-30 ºC [19,20] **Table No. 1** showing the *Asavas'* and *'Aristhas' of Brhattrayee* prepared by boiling and without boiling. **Table 2** showing the *Asava* and *Arists* prepared by different methods.

Table 1 :Asavas' and 'Aristhas' of Brhattrayee prepared by boiling and without boiling

S.No	Method of preparations	Total Number	*Charaka*	*Susruta*	*Astanga sanghra*	*Astanga Hrdaya*
1	Asavas' prepared by boiling	16	9	1	3	3
2	Asavas' prepared without boiling	08	1	6	1	-
3	'Aristhas' prepared by boiling	31	13	04	10	04
4	Aristhas' prepared without boiling	21	07	10	03	01
Total		76	30	21	17	08

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Table -2 (*Asava-Arista* prepared with different methods)

Factor	Classical method	Modified method
1. Sweating agent	By using jaggery, sitopala, sharkara, phanita	By using sugar, candy sugar, molasses
2. Containers	earthen and wooden container	plastic and steel
3. Temperatures	Asava –*Arista* placed in DhanyaRashi, Koshthasara, Bhugarbha, Chaulyagara	Temperature Range of 20-35°C.
4. Filtrations	Double-layered cotton cloth	Electrical filtration Press
5. Duration	Duration of fermentation varies with formulation, loh*Arista*-which ranges from 7 days Ashtashat*Arista* to 180 days.Normal 15 to 30 day duration of fermentation.	Fermentation happen with the duration of time
6 Prakshepa dravyas(Additives)	Lavang, Ela,Tejpatra Nagkeshar, Trikatu etc.	Acacia, Caraway Oil, Vanillail, Mannitol etc.

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7. Sandhan Dravyas (fermentive agent)	Dhatkipuspa, Madhuca pushpa, surabeej/kinwa.	Yeast

Source Ambika *et.al* Sandhan Kalpana A Progressive review, IJGP

Regulatory Aspects and shelf life:

The Drug and Cosmetic Act 1940 and Rules 1945 and ministry of AYUSH has given various rules regarding standards and expiry date of Ayurvedic products the details are mentioned in Table 3, Table 4, Table 5 and Table 6 [21]

Table-3{Preparation (Asava*)* with high content of alcohol as base "{Rule 161 (3) (ix) (a)"

S.No	**Drug's name**	**Packaging size**	**{Rule 161 (3) (ix) (a)}**	**Acc. to Rule 161-B vide G.S.R. 764 (E*)*** [a]	**Acc. to Rule 161-B; vide G.S.R. No. 789 (E)** [b]
1.	*Karpurasava*	15ml	No expiry date	No expiry date	10years
2.	*Ahiphenasava*	15ml	No expiry date	No expiry date	10years
3.	*Mrgamadasava*	15ml	No expiry date	No expiry date	10years

Source*: Choudhary et,al Progressive review of Sandhan Kalpana AYU &* Lamare et.al JPR A survey on labeling challenges related to Ayurvedic and proprietary medicines

Table-4 Formulations containing shelf generated alcohol, Rule 161 (3) (ix) (b)

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S.No	Drug's name	Alcohol quantity (ethyl alcohol v/v)	Packaging size
1.	Mritasanjeevanisura	16%	30ml
2.	Mahadrakshasav	16%	120ml

Source:

Choudhary et,al Progressive review of Sandhan Kalpana AYU

Table -5 Some standard to be shown in table as per rule 168 for the distribution, manufacturing as well as sale of Ayurvedic, Siddha and Unani Drugs

Class of drugs	**Standards to be complied with**
Drugs included in Ayurvedic Pharmacopoeia	The guidelines for the character, purity, and quality as given in the versions of Ayurvedic Pharmacopeia of India for the present in power
Asava and *Arista*	The maximum range of the alcohol must not go 12% v/v, but as per the policy of central government it is change time to time

Table-6 Comparison of shelf life according to classical texts and various regulatory guidelines

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Name of scholar	**Description of expiry**	**GSR No. 691 (E) Dated 24 th November, 2005**	**GSR No. 789(E) dated 12th August, 2016**
Charak Samhita	No expiry date	No expiry date	10 years
Sushruta Samhita	No expiry date	No expiry date	10 years
Ashtanga Hridaya	No expiry date	No expiry date	10 years
Ashtanga Sangraha	No expiry date	No expiry date	10 years
Sharangadhara Samhita	No expiry date	No expiry date	10 years
Gada Nigraha	No expiry date	No expiry date	10 years
Yogaratnakara	No expiry date	No expiry date	10 years
Bhaishajya Ratnavali	No expiry date	No expiry date	10 years

Conclusion:

By this study we concluded that the shelf life of *Asava and Arista* is 10 years as per current guidelines of ministry of AYUSH is acceptable till further validation of the stability studies of *Asava and Arista.* As it might be differing from product to product for *Asava and Arista* category. Asava and *Arista* have considerably very high shelf life –older is better quoted in various literatures. The potency increased with duration.

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