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Review Article

A CRITICAL REVIEW ON *AVALEHA KALPANA*

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ABSTRACT

Avaleha is the most common secondary *Kalpana* (dosage form) which has been employed in various disorders and this product is gaining popularity due to its easy administration, palatability and longer shelf life. It is a semisolid preparation of herbal drugs prepared in decoction or extracts of different herbs by adding sweetening agents like jaggery, sugar or sugar candy. The component drugs which are used in the preparation of *Avaleha* are aqueous medium, substrate, *Oushada dravyas*, lipid medium, additives etc. By analyzing consistency of various *Avaleha* varies from freely-flowing, paste-like, semisolid and granular, which depends upon the substrate and *Oushada churna* ratio. *Avaleha* can be compared to confections because both contains essential ingredients as sugar and water and optional ingredients as edible oils, honey, flours, starches, edible salts etc. *Avaleha* are intend to provide better drug absorption through the oral cavity along with absorption through villi. The literature related to *Avaleha* has been surveyed from various Ayurvedic literatures, journals, Ayurvedic Formulary of India etc. and presented briefly here. Here we have discussed the information regarding *Avaleha* like ingredients, method of preparation, *Avaleha paka lakshana,* non-conformances related to *Avaleha* production, comparison between *Avaleha* and confections and absorption.

KEYWORDS: *Avaleha*, confection, non-conformances, *Avaleha paka lakshana.*

INTRODUCTION

Avaleha is a semisolid preparation of herbal drugs prepared in decoction or extracts of different herbs by adding sweetening agents like jaggery, sugar or sugar candy.[1] *Avaleha Kalpana*is considered as an *Upakalpana* of *Kwathakalpana*. Different varieties of *Avaleha* are mentioned in various Ayurvedic classics and they are the most accepted varieties of Ayurvedic dosage forms due to its easy administration, palatability and long shelf-life.

Etymology

The word *Avaleha* has been derived from the root word *"lihaswadane"*, in which *'lih'* means substance which is licked and *'aswadane'* means that which has good taste.[2]

Definition

According to *Acharya Sharangdhara*, the semisolid mass obtained by continuous heating of *Kwathadi* basic *Kalpanas* is called *Rasakriya/ Avaleha*.[3]

Synonyms

According to the consistency various synonyms are given to this preparation namely *Avaleha, Leha, Lehya, Avalehya, Rasakriya, Ghana* etc.[4]

Ingredients of a typical *Avaleha*

The component drugs which are used in the preparation of *Avaleha* can be discussed under the following headings.

1. Aqueous Medium - *Kashaya, Swarasa* or any other liquid preparation.
2. Substrate - Sugar, sugar candy and jaggery which varies according to different formulations and sugar medium will act as a preservative.
3. *Aushada dravyas* - Powdered drugs which are rich in volatile principles that make *Avaleha* more palatable.
4. Lipid medium - *Ghrita* and *Tilathaila* for frying the pulp which keeps the *Avaleha* soft and also helps in preservation.

5. Additives - Honey, gingelly oil, salts, alkalies, milk and milk products, soup, *Bhasmas* according to formulations and possess specific time for addition.

Method of preparation

The equipments required in the method of preparation of *Avaleha* includes the drugs specified in the formulation, a wide-mouthed stainless steel vessel, a fine sieve and a strong spatula for mixing the medicine during preparation. For large scale production in factories, super-heated steam jacketed vessels are used for heating, electrically operated mixing machines are used for mixing purposes and sieving is done by mechanical sifters.

Process of preparation

The *Kashaya* or *Swarasa* is prepared and the sweetening agents like *Guda, Sarkara, Khanda* are dissolved and heated over mild fire in a clean stainless steel vessel. The blend should be filtered through a clean double layered cloth to remove the physical impurities present in the sweetening agent. The filtrate is again boiled and reduced over mild fire to a thicker thread-like consistency. Ghee or oils is added to the preparation just before attaining the *Paka lakshana*. The vessel is taken out of fire after attaining *Paka lakshana* and fine powder of medicinal drugs (*Prakshepa churna*) is added little by little and stirred well to a homogenous mixture and allow the mixture to cool. Honey is added after cooling and the final product is packed and preserved in dried, air tight, wide-mouthed inert containers. The details of *Avalehas* having special preparatory methods are detailed in Table no.1.

Table 1: *Avaleha* having special preparatory methods

Sl. No.	*Avaleha*	Method of preparation
1	*Manibadra Gulam*.[5]	*Anagnisidham* (in the absence of heat)- by pounding all the drugs together.
2	*Chyavanaprasa* [6]	*Amalaki* is made into a paste and is fried in ghee and oil, after removing the seeds
3	*Agastya Rasayana*[7]	*Hareetaki* paste is fried in ghee and oil
4	*Kushmanda Avaleha.*[8]	Small pieces of crushed *Kushmanda* after taking *Swarasa,* is fried in ghee until it becomes a golden brown colour
5	*Soorana Avaleha*.[9]	Same as *Kushmanda Avaleha*

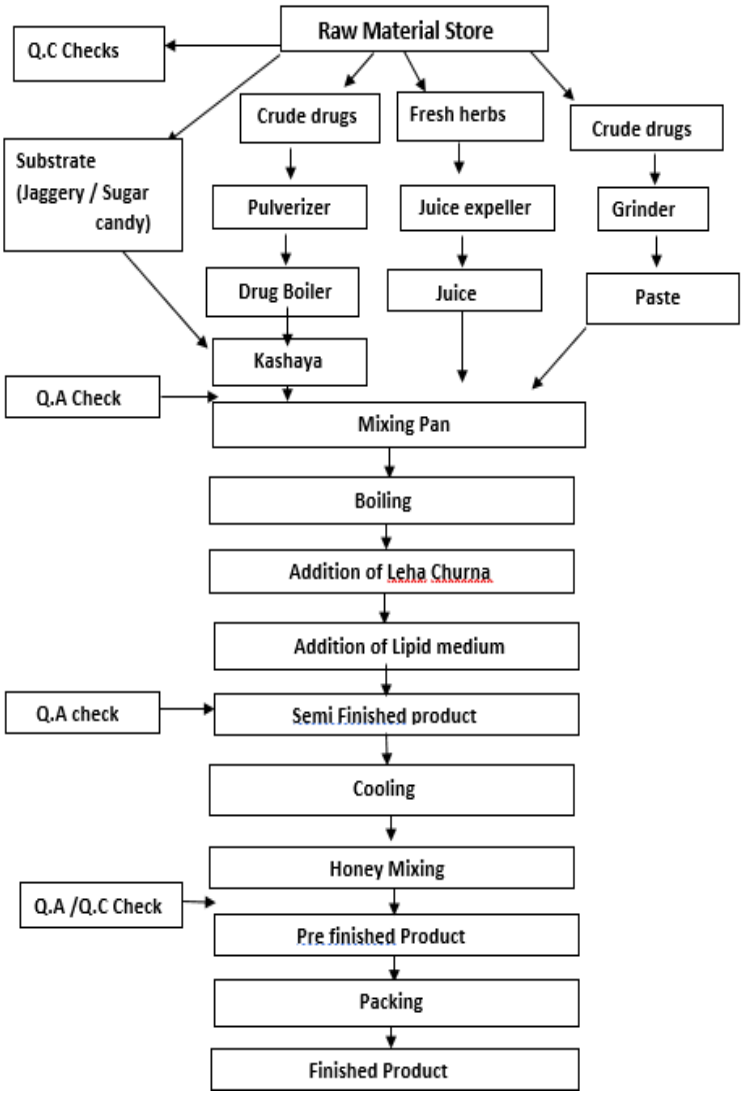
General precautions during *Avaleha* production

The general precautions during *Avaleha* production are discussed under three sections namely Pre-processing, Main process and Post-processing which is elaborated in Table.no.2 and Figure no.1

Table 2: Precautions to be during various stages of *Avaleha* production

Stages	Precautions
Pre-processing	1. Fresh raw drugs should be taken for the preparation of *Swarasa* 2. Wet drugs should be taken double the quantity of dry drugs in the formula. 3. *Kashaya* drugs should be added as coarsely powdered form and water should be potable. 4. Drugs which are used as *Prakshepa* should be finely powdered 5. Quality assured ghee and oil should be used
Main process	1. Maintain the intensity of fire throughout the procedure. 2. Lid should not be used to cover the vessel during the preparation of *Kashaya* 3. Pulp should be fried till it attains brownish black colour and the moisture content is lost. 4. Fried pulp is added at the stage of *Tantupaka* 5. Proper mixing should be done for the equal distribution of *Prakshepa churna* to the mixture
Post-processing	1. Honey should be added only after the product is cooled. 2. Packing material should be inert, wide-mouthed and free from contamination

Figure no.1 : Flow chart for preparation of Avaleha



Critical Control Points regarding *Avaleha Preparation (Avaleha Paka lakshana)*: The confirmatory tests for *Avaleha* preparation can be categorized into *Asannapakalakshana* (tests before attaining *Paka*) and *Sidhalakshana* (tests after the preparation). The tests are mainly intended to identify the optimal consistency of *Avaleha.* This peculiar consistency of *Avaleha* depends on the ratio between sugar and water in the preparation, which determines the stability of the product. (Table 3)

Table 3: Details of *Avaleha Paka Lakshanas*

Asannapaka lakshana		***Siddha lakshana***		**Reference**
Tantumatva	Thread like appearance due to proper consistency	*Peedithomudra*	Finger prints due to proper consistency of the product, which is also a sign of perfect preparation.	Sargadharasa mhitamadhya makhanda 8/3
Apsumajjana	Sinks in water due to proper consistency	*Gandhavarnar asodbhava*	Proper odour, colour, taste are essential elements in the end product which indicates the use of genuine ingredients for the preparation	
Sthiratva	Firm due to the proper consistency and	*Sukhamarda*	Soft to roll	

	powder fineness, so as to assess the stability of the preparation			
Darvipralepa	Sticks to the stirrer due to proper consistency	*Sukhasparsha*	Soft to touch	Bhava Prakasha Poorvakhanda 2/41
Tantulibhavet	Threadlike appearance due to Consistency	*Piditebhajate mudra*	Finger prints when pressed	
Kshiptonaplavate	Non-spreading	*Gandhvarnara sanvita*	Odour, colour, taste	
Kshiptastunishchala	Motile			
		Sukhamarda	Soft to roll	Bhaishajya Ratnavali
		Kharasparsha	Hard to touch due to the proper consistency and Powder fineness, so as to assess the stability of the preparation.	
		Peeditobhajte Mudra	Finger prints	
Na sarana	Non-spreading			As.Ka.6
Tantumatva	Thread like appearance			

Component Ratio and Consistency of *Avaleha*

When ratio of essential ingredients to be taken is not mentioned in the given preparation.[10]; the following ratio is to be taken. The ratio of ingredients is *Sita* or *Khandasarkara* (Sugar) - 4 parts, *Guda* (jaggery) - 2 parts, *Drava dravya* (Liquid media) - 4 parts and *Churna* (Powder - 1 part. The consistency of *Avaleha* varies accordingly and they are explained in Table no. 4.

Table 4: Consistency of different *Avaleha*

No.	Consistency	*Avaleha*
1.	Free flowing	*Agastyarasayana, Chyavanaprasa, Dasamoolahareetaki*
2.	Paste like	*Manibhadra Gulam*
3.	Semi solid	*Satavari Gula, Panchajeerakagula*
4.	Dry lumps like	*Haridrakhanda*
5.	Granule like	*Vyoshadivataka, Kooshmanda Rasayana*
6.	Bolus like	*Soubhagyasundimodaka*

Dose *(Matra)*

The dose of *Avaleha* varies from one *Karsha* (12gm) to 2 *Palas* (96gm) [11]. Dose should be decided after analyzing the *Rogibala* and *Rogabala*.

Anupana (Adjuvants)

Anupana improves the efficacy of the drug by augmenting its potency and facilitates its easy absorption. *Avaleha* is administered along with milk, sugar cane juice, *Panchamuli Kashaya, Vasa Kwatha* or other liquid substance.[12] Milk, *Yusa, Kasaya*, water and *Phala rasa* are to be used as vehicle as per the diseased condition.[13]

Avalehasevanakala

If the patient is having the disease in *Urdhwajatrugathabhaga, Leha* should be taken in evening time with proper *Anupana.* But if the disease is affected to *Adhobhaga, Leha* should be taken before food.[14]

***Saviryathaavadhi* (Shelf life)**

According to *Sharngadara Samhita*, shelf life of *Avaleha* is one year.[15]

Preservation

The *Leha* should be kept in wide mouthed glass or porcelain jar.

Qualities of *Avaleha* and Non-conformances in *Avaleha* production

The qualities of *Avaleha* over other medicaments are easy to administer, safe to use and are accepted by all age groups. They have pleasant and agreeable taste, high therapeutic efficacy and longer shelf life. The non-conformances of *Avaleha* are mentioned in table no. 5

Table 5: Non-conformances in *Avaleha*

Sl.No.	Causes of non-conformances	Non- Conformances
1	Lowered sugar level	Change in taste & shelf life
2	*Prakshepa churna* made out of exhausted spicy drugs	Palatability, change in odour
3	Contaminated *Prakshepa churna*	Microbial contamination & Shelf life
4	Improper *Paka*	Charring, Fermentation
5	Foreign matters in substrate	Microbial contamination & Shelf life
6	Fineness and quantity of *Prakshepa churna*	Palatability, consistency
7	Temperature control during addition of *Prakshepa churna*	Palatability, change in smell & taste, consistency
8	Improper mixing	Affects quality
9	Skipping of some process stages	Affects quality

Avalehakalpanas* used in various *Chikitsaprakarana

Table 6: *Avalehakalpanas* used in various *Chikitsaprakarana*

Prakarana	**Ashtanga Hridaya**	**Charaka Samhita**
Rakta Pitta	*Trivrit Lehya*[16] *Trivrit Modaka*	Nil
Kasa	*Agastya Rasayana*[17] *Kushmanda Avaleha*[18] *Vasishta Rasayana*[19] *Vyaghryadi Lehya*	*Chitrakadi Lehyam* [25] *Hareethaki Lehya* [26] *Padmakadi Lehya* [27]
Pandu	*Drakshavaleha*[20]	*Daatryavaleha* [28], *Silajatu Vataka* [29]
Arsas	*Chitrakadi Lehya*[21]	Nil
Gulma	*Danthi Hareethaki*[22]	*Danthi Hareethaki* [30]
Sopha	*Dasamula Hareethaki*[23]	-
Kushta	*Manibadra Gula*[24]	-

Confections and *Avaleha*

Sweet substances play crucial role in *Avalehakalpana* as they impart palatability and preservation. *Sarkara* (crystalline sugar), *Guda* (jaggery) and *Madhu* (honey) are the substances that take the role of sweet substances in *Avaleha* formulations. These substances are even though carbohydrate in nature, contain different forms of the same. Confectionery dose forms have a long history of use in therapeutic applications, yet there is no great presence on such dose forms in the open literature. The use of patient-friendly dose forms can increase compliance relative to traditional dose forms where difficulties in swallowing may prohibit the use of tablets and capsules in particular. Prolonged slow release in the oral cavity may also provide a biopharmaceutical benefit by preventing immediate dose availability and extending the duration of drug exposure.

Ingredients of Confectionaries

The ingredients of Confectioneries can be broadly classified into two – Essential ingredients and Optional ingredients. The Essential Ingredients include sugar and water. The optional ingredients include

1. Sweetening agents such as cane jaggery, palm jaggery, palm sugar, raw sugar, invert sugar, honey, sorbitol, liquid glucose, lactose, dextrose, and icing sugar.
2. Edible oils and fats
3. Edible flours and starches
4. Edible oilseeds flours and protein isolates
5. Edible molasses

6. Malt and malt extracts
7. Edible common salt
8. Vitamins and minerals
9. Enzymes
10. Acidulants, food grade, such as citric acid malic acid, tartaric acid, lactic acid, malic acid, tartaric acid and lactic acid.
11. Jellifying agents, such as gelatin (food grade), agar (food grade), and sodium carboxy methyl cellulose.
12. Permitted anti-oxidants, permitted preservatives, Permitted colouring matter, permitted flavouring agents.

Table 7: BIS standard of confectioneries[32]

Sl.No.	Tests	Value
1.	Ash sulphated, percent by mass	15
2.	Acid Insoluble ash, percent by mass	2
3.	Sulphur dioxide	350 mg/kg
4.	Arsenic	10 mg/ kg
5.	Lead	20 mg/kg,
6.	Copper	5 mg/kg
7	Zinc	5 mg/kg

Table 8: Comparison between Confections and *Avaleha*

Sl. No.	Confections	*Avaleha*	Examples of *Avaleha*
1.	Essential ingredients include sugar and water	Sugar and water	*Gandeera Rasayana*
2.	Sweetening agents (optional ingredients)	Jaggery, Sugar candy, Honey	*Chyavanaprasa, Agastya Rasayana*
3.	Edible oils, fats	Gingelly oil, ghee	*Chyvanaprasa, Kushmanda Avaleha*
4.	Edible flours and starches	*Thugaksheeri*	*Chyavanaprasa*
5.	Edible oil seeds	*Thila*	*Ashvagandadilehya*
6.	Edible salts	*Panchalavana*	*Kalyana Gula*
7.	Malt and Malt extracts	*Yava*	*Agastya Rasayana*
8.	Vitamins	*Amalaki*	*Chyavanaprasa, Brahma Rasayana*
9.	Edible molasses	*Ikshu rasa*	*Sathavari Gula*
10.	Tartaric acid	*Chincha*	*Chinchadi Lehya*

DISCUSSION

Bhaishajya Kalpana is the branch of Ayurveda, wherein standard raw drugs are transferred into a potent medicine. It includes various pharmaceutical procedures which involve identification and collection of authentic raw materials, application of standardized processing techniques, production of quality drug, packing and storage of the finished product. In this branch there are basically two types of formulations i.e. Primary formulations and Secondary formulations. The Secondary formulations include the preparations like *Avaleha Kalpana* (Medicated semisolid preparations), *Arista Kalpana* (fermentative preparations), *Sneha Kalpana* (Medicated fatty preparations) etc.

Avaleha contains an aqueous medium (*Kashaya, swarasa* etc), substrate (sugar, sugar candy, jaggery), *Oushada dravyas* (Powdered drugs),lipid medium (*Ghrita, Thila thaila* etc), and additives (Honey, gingelly oil, salts). The confirmatory tests for *Avaleha* preparation can be categorized into *Asannapakalakshana* (tests before attaining *Paka*) and *Sidhalakshana* (tests after the preparation) which are mainly used to identify the *Paka* of *Avaleha* and it depends on sweetening agent and water ratio. Dose is specified as one *Karsha* (12gm) to two *Palas* (96gm) based on the strength of the patient and severity of the disease. By analyzing various *Avaleha* preparations, the consistency varies from freely-flowing, paste-like, semisolid and granular, which depends upon the substrate and *Oushada churna* ratio.

Many of the *Avalehas* have unique methods of preparation, for example *Chyavanaprasa, Haridra-khanda, Agastya Rasayana* etc. There are several factors which affect the quality of the product such as lowered sugar level in substrate, exhausted

Prakshepa churna, improper *Paka* etc. *Avaleha* can be compared to confections mentioned in British pharmacopoeia. Both contains essential ingredients as sugar and water and optional ingredients as edible oils, honey, flours, starches, edible salts etc.

Avaleha are intend to provide better drug absorption through the oral cavity. The oral trans-mucosal route has significant potential for drug delivery both systemically and locally. The oral mucosa contains stratified squamous epithelia, which is similar to the skin. The absence of keratinized mucosa and presence of salivary glands maintains the moisture, making the oral mucosa more permeable and absorptive than the skin. The oral cavity is a highly-hydrated environment that facilitates drug dissolution and the small surface area of the oral membrane is also beneficial for sustained drug delivery of medicines like *Vyoshadi Vataka, Haridra Khanda, Taleesapatradi Vataka* etc. Oral absorption can also overcome hepatic first-pass metabolism and improve the bioavailability.

The oral cavity provides a stable and relatively chemically benign environment (pH ranging from 6.5 to 7) due to continuous secretion of saliva. The presence of salivary amylase and lipase in oral cavity helps in the assimilation of carbohydrates and lipophilic ingredients such as *Ghrita, Taila* in *Avalehas*. Salivary amylase/ptyalin is the carbohydrate digesting enzyme which converts starch into dextrose and maltose. The enzyme Maltase converts maltose further into glucose. Lingual lipase is the lipolytic enzyme which converts triglycerides into fatty acids and diacylglycerol.[32]

The next level of absorption takes place in stomach where gastric lipasehydrolyzes fats in to fatty acids and glycerol. Gastric amylase digests the starch and Pepsin converts proteins into proteases, peptones and polypeptides[33]. The enzymes like trypsin, chymotrypsin, pancreatic lipase etc. present in Pancreatic juices helps in digestion of proteins and fats. Proteolytic enzymes, amylolytic enzymes, lipolytic enzymes in succus entericus act on the partially digested *Avaleha*. The absorption of *Avaleha* is by facilitated by the presence of villi and microvilli in small intestine which increases the surface area of mucosa. From the lumen of small intestine, these substances pass through lacteal of villi and cross the mucosa and enter the blood directly or through lymphatics. It is one of the most common dosage form which has been employed in various disorders and is gaining popularity due to its easy administration, palatability and longer shelf life.

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