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RESEARCH ARTICLE

SHELF LIFE ASSESSMENT OF SHIRISHA ASHWAGANDHADI AVALEHA - A PRELIMINARY ASSESSMENT

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ABSTRACT

Background:*ShirishaAshwagandhadiAvaleha*is a herbo mineral formulation containing *AbhrakaBhasma*, *ShringaBhasma*, *Samirapannaga Rasa*, *Shirisha*, *Ashwagandha* and other herbal drugs. In general, shelf life of *Avaleha*is described as one yearin the classics of Ayurveda. As *ShirishaAshwagandhadiAvaleha* contains three metallic ingredients, its shelf life might be different than other *Avalehas*. Looking in to this, it is planned toevaluateshelf life of *ShirishaAshwagandhadiAvaleha*. **Materials and methods:***Avaleha*was prepared in departmental lab following classical guidelines.The samples were subjected toaccelerated stability study maintaining temperature and humidity 40±2ºC and 75±5%respectively. Relevant analytical parameters were analyzed at an interval of 0, 1, 3 and 6 months to check the degradation levels in the formulation. **Results:**Product was free from microbial contamination and heavy metals were within the prescribed limits. There were insignificant changes in physico-chemical profiles at different intervals. On extrapolation of the observations, the shelf life of *Avaleha* was found to be 8 years and 7 months. **Conclusion:**The shelf life of *ShirishaAshwagandhadiAvaleha* was found to be much longer than the given standards in official gazettes of Govt. of India.This increased shelf life may be because of the metalliccomponent present in the formulation.

Introduction:

The time period during which potency of drug remain unaffected due to environmental factors or from microbial contamination is termed as 'shelf life'. Shelf-life is the length of time, after which all substances starts to degrade in their qualities and become unsuitable for consumption or sale. In other words, shelf-life of a product assures potency of a drug. It is often mathematically modeled around a parameter such as concentration of a chemical compound, a microbiological index, or moisture content, etc.[i]

In major texts of Ayurveda, there is no clear statement about the shelf life of *Ayurvedic* dosage forms but brief information is given. Shelf life in elaborative manner finds mention in *Vangasena* and *SharangadharaSamhita*.[ii,iii]. In the year 2005, the Ministry of Health and Family Welfare published an amended rule 161-B, under Drugs and Cosmetics Act - 1940, where the shelf life period of ASU medicineswas defined.[iv, v] But the provided shelf life is general and there is a need to evaluate shelf life of individual formulations.Considering this,an attempt has been made to evaluate shelf life of *ShirishaAshwagandhadiAvaleha* (SA) with the help of modern analytical techniques.

Materials and methods:

Collection of raw materials:*ShirishaAshwagandhadiAvaleh a*is a compound herbo-mineral formulation composed based on the experiences of Ayurveda physicians. All the herbal drugs and *Madhu*(honey) were procured from the Pharmacy, Gujarat Ayurved University, Jamnagar. *Samirapannaga Rasa* was prepared in the Dept. of *Rasashastra*and *BhaishajyaKalpana,* Institute for Post Graduate Teaching and Research in Ayurveda, Jamnagar. *ShringaBhasma*was purchasedfrom ASFA pharmacy, Surat, Gujarat. *Guda*(jaggery) was procured from the local market, Jamnagar. All the herbal drugs were authenticated in the Pharmacognosy Laboratory, Institute for Post Graduate Teaching and Research in Ayurveda, Jamnagar. Composition formulation is stated at Table-1.

Pharmaceutical Preparation of formulation:*Avaleha*is prepared by following classical guidelines of*Avaleha*.[vi]

Shelf life evaluation

Sample quantity and packing: Samples were supplied in 4 transparent plastic bottles with transparent screw cap.Each bottle contains 100 grams of SA.

Storage conditions: Samples were stored at 40±2ºC and RH: 75±5%.

Frequency of withdrawal: The products were withdrawn from the container and analyzed initially, and at a gap of 1, 3 and 6 months.

Parameters: Basic analytical parameters including total solid content,[vii] moisture %,[viii] ash value,[ix] acid insoluble ash,[x] water soluble extractives,[xi] methanol soluble extractives,[xii] were evaluated at intervals specified earlier.Test for microbial contamination was done initially and at the end of 6 months of storage by following standard guidelines.[xiii]]Chromatographic profiles (HPTLC) wereevaluated out under 254, 366 and 540 nm initially and after 6 months of storage. Analysis for Heavy metals using AAS was carried out initially.[xiv]

Observations and Results:

The organoleptic characters of the SA are shown in Table 2. No changes in organoleptic characters were found in the drug at different levels of storage.Physico-chemical characters of SA at initial, 1, 3, 6-month interval are shown in Table 2. Microbial growth was found below prescribed limits in SA initially and after 6thmonth [Table 3]. Heavy metals were also found to be within the prescribed limits [Table 4]. HPTLC showed 5 spots at 254 nm with Rf values 5 spots at 366 nm and 6 spots at 540 nm. (Fig. 1-6). Rf values recorded were same for both samples (0, 6 months) [Table 5].

Based on the physico-chemical values, intercept and slope were calculated followed by expected time for 10% degradation for individual parameters. On extrapolation of these values; the shelf life of SA was found to be 8 years and 7 months [Table 6-8].

Discussion:

Shelf life or *SaviryataAvadhi* isconsidered as 'best before use date' after which one or more properties of the formulation shows considerable degradation. *Sharangadhara*opines that the *Avaleha*start to lose their therapeutic potency after a year, while*Yogaratnakara*opines the period as six months.[4]The Govt. of India Gazette specifies the shelf life of *Avaleha*as three years.[xv] In addition to this, potency of a dosage form always depends upon the composition, place, season, storageconditions etc. It infers that the shelf-life of medicinal preparations can be increased by taking specific care of all these factors. Earlier studies reported shelf life of *Rasayana Churna, Vasavaleha,* and *Kamsa Haritaki Avaleha*; but for SA, the same is not available.[xvi,xvii,xviii]The present study is a preliminaryattempt to know shelf life of SA.No changes in organoleptic characters were found at different levels of storage. SA was found to be Brownish black color in color with aromatic odor and bitter and astringent in taste. Color of drug was due to its componentsand jaggery.Insignificant differences were observed in basic physico-chemical profiles in the drugs at different stages of analysis. The moisture content was found to be increasing gradually with storage. Moisture is one of

the main parameters that determine the shelf life of a product, and is the main causative factor in product deterioration. Moisture in a product is sufficient to activate different enzymes, which slowly decompose the product resulting in its degradation.[xix] Microbial count and Heavy metals were within the prescribed limits indicating safety and quality of the product.

The changes in all these parameters were analyzed to evaluate the shelf life of this formulation that is found to be 8 years and 7 months indicating longer shelf life of the compound. This period is double to that of the period mentioned in the official gazettes for *Avaleha*.

In addition to the suitable environmental conditions, care taken in storing the formulation in ideal conditions and sterile containers; the formulation composition of SA might be a reason for the increased shelf life. The metallic fraction of SA i.e. *Samirapannaga Rasa, Anhraka Bhasma Bhasma, Shringa Bhasma* and a herbo-mineral component (*Sitopaladi Churna*) might be responsible in storing the therapeutic attributes of the formulation for a longer period.

Conclusion:

Shelf-life of SAis found to be 8 years and 7 months. This implies that the drug is more stable than the standard period laid down in official gazettes. This observation may be specific to SA, as earlier study with *KansaharitakiAvaleha* shows shelf life within standards. This may be due to the use of certain *Bhasma*and *KupipakvaRasayana*in the formulation. Studies involving many more *Avaleha*sare needed to substantiate the observations of the current study.

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Table 1: Formulation composition of SA

	Ingredients		Botanical name/ English name	Part used	Quantity
1	*KwathaDravya*	*Shirisha*	*Albizzia lebbeck* (L) Benth.	Dried St. bark	4 Kg.
2		*Vasa*	*Adhatoda vasica* Nees	Dried Leaf	4 Kg.
3		*Kushtha*	*Saussurea lappa* CB. Cl	Dried Root	4 kg.
4		*Kantakari*	*Solanum xanthocarpum* Sch. &Wendl.	Dried Whole plant	4 kg.
5		*PushkaraMoola*	*Inulara cemosa*Hk. f.	Dried Root	4 kg.
6		*Yashtimadhu*	*Glycyrrhiza glabra* L.	Dried Root	4 kg.
7		*Bibhitaki*	*Terminalia chebula* Roxb.	Dried Fruit	4 kg.
8		*Haridra*	*Curcuma longa* L.	Dried Rhizome	4 kg.
9		*Ajamoda*	*Trachyspermum ammi* (L) Sprengue.	Dried Fruit	4 kg.
		Potable water	-	-	144 ltr
		Reduced to 1/4th	-	-	36 ltr
	PrakshepaDravya	*Sitopaladi Churna*	Poly herbal formulation	-	3.55 kg.
10		*Ashwagandha*	*Withania somnifera* Dunal.	Dried Root	1.78 kg
11		*Abhraka Bhasma*	Calcined Mica	Mineral	445 gm.
12		*SameeraPannaga Rasa*	Arseno-mercurial compound	-	115 gm.
13		*Shringa Bhasma*	Calcined Deer horn	-	115 gm.
14	Sweetening agent	*Guda*	Jaggery	-	18 kg.

Table 2: Organoleptic and physico chemical parameters of SA

Organoleptic parameters				
Parameters	**Initial**	**1st month**	**3rd month**	**6th month**
Form	Brownish black colored semisolid material	Brownish black colored semisolid material	Brownish black colored semisolid material	Brownish black colored semisolid material
Taste	Bitter and astringent	OK	OK	OK
Color	Brownish black color	OK	OK	OK
Odor	Characteristic	Characteristic	Characteristic	Characteristic
Consistency	Semisolid	OK	OK	OK
Physico chemical parameters				

Moisture%	13.47	13.57	14.84	17.95
Total Ash	5.73	6.57	6.10	6.12
Acid insoluble Ash	2.69	2.97	2.38	2.84
Alcohol Soluble Ext	80.40	78.12	79.15	78.02
Water Soluble Ext	88.40	86.01	85.31	85.15
Total Tannins	2.10	--	--	1.50
Total Alkaloids	0.49	--	--	0.32
Total Saponins	9.20	--	--	4.42

Table 3: Total microbial growth in SA

Organism	**Initial**	**"6" months**	**Permissible Limits**
Total plate count (cfu/g)	1206 cfu/g	1481 cfu/g	10^5/g
Total fungal count (cfu/g)	Ab	Ab	10^3/g
E. coli	Ab	Ab	Absent
Pseudomonas aeruginosa	Ab	Ab	Absent
Staphylococcus aureus	Ab	Ab	Absent
*Salmonella*Spp	Ab	Ab	Absent

cfu : Colony Forming Units, Ab : Absent, g : Grams.

Table 4: Heavy metals in SA

Heavy metals	**SA**	**Permissible limits**
Lead	ND	10
Cadmium	ND	0.30
Arsenic	5.602ppm	3
Mercury	7,729ppm	1

ppm: parts per million, ND : Not Detected,

Table 5: R_f values recorded.

Drug	**Spot no.**	**R_f at 254 nm**		**R_fAt 366 nm**		**R_fAt 540 nm**	
		Tracck-1 (0 month)	**Track-2 (6 month)**	**Tracck-1 (0 month)**	**Track-2 (6 month)**	**Tracck-1 (0 month)**	**Track-2 (6 month)**
	1	1 0.09	0.09	0.05	0.05	0.09	0.09
	2	0.14	0.14	0.14	0.14	0.14	0.14
	3	0.26	0.26	0.32	0.32	0.26	0.26
	4	0.50	0.50	0.50	0.50	0.28	0.28
	5	0.58	0.58	0.58	0.58	0.36	0.36
	6					0.58	0.58

Table 6: Intercept and slope of SA for different parameters

Parameters	Intercept	Slope
Moisture %	13.03	0.77
Total Ash (%)	6.1	0.014
Acid Insoluble Ash (%)	2.73	0.0024
Alcohol Soluble extractive (%)	79.6	0.26
Water Soluble extractive (%)	87.33	0.44
Total Tannins	2.1	0.1
Total Alkaloids	0.49	0.028
Total Saponins	9.2	0.8

Table 7: Approximate period (in month) for 10% degradation of SA

Parameters	Initial	10% Degradation	Months required for 10% degradation
Moisture %	13.47	12.123	1.18
Total Ash (%)	5.73	5.157	67.36
Acid Insoluble Ash (%)	2.69	2.42	128.75
Alcohol Soluble extractive (%)	80.40	72.36	27.85
Water Soluble extractive (%)	88.40	79.56	17.66
Total Tannins	2.1	1.89	2.1
Total Alkaloids	0.49	0.441	1.75
Total Saponins	9.20	8.28	1.15
Mean Months			30.975

Table 8: Extrapolation of Shelf life

Drug	Mean Months for 10% degradation	Multiplication Factor	Shelf life	
			Months	Years
SA	30.975	3.33	103.15	8 Years 7 Months

Fig.1: Comparative HPTLC Plate @ 540 nm

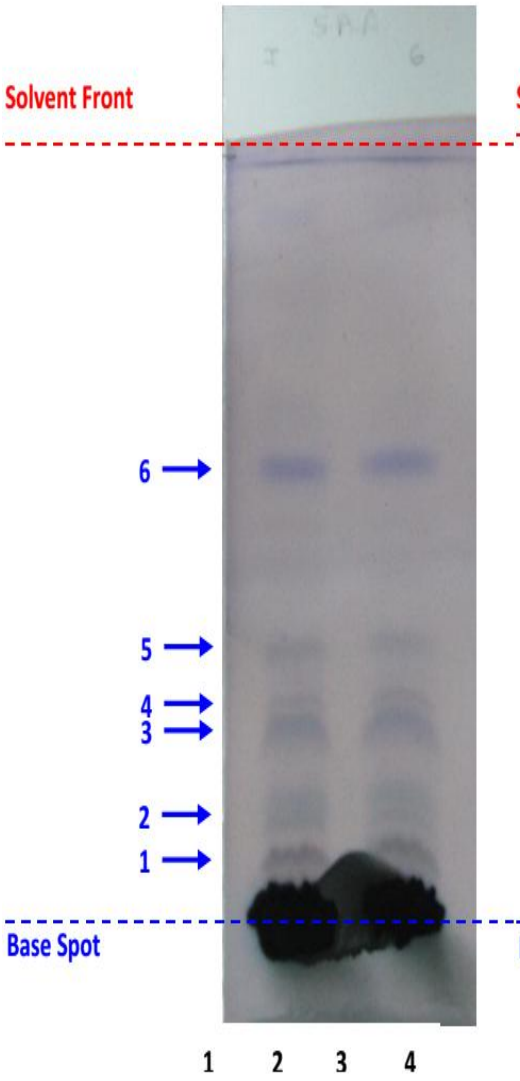

Fig.2: Comparative HPTLC Plate @ 366 nm

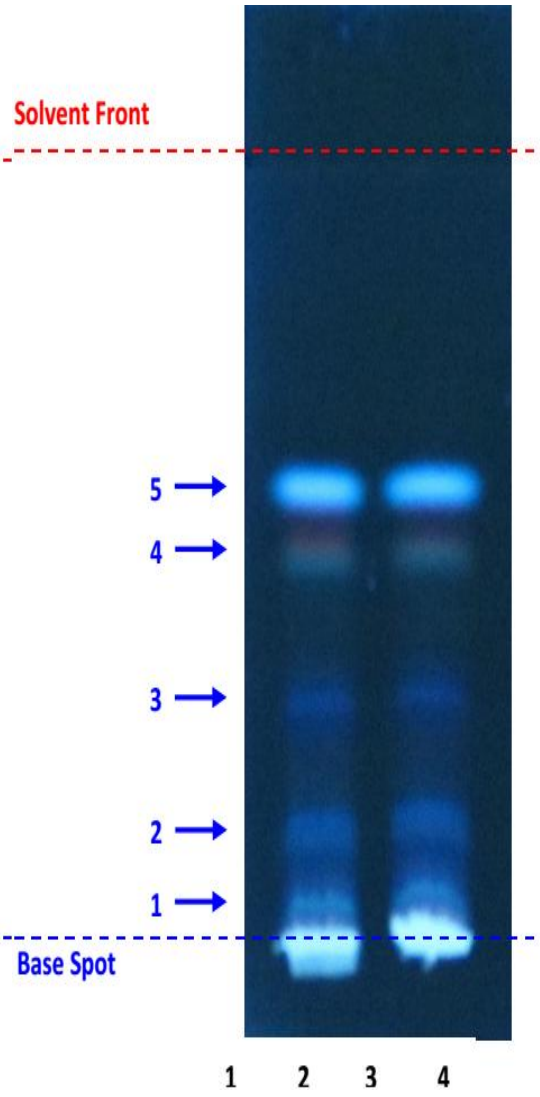

Fig.3: Comparative HPTLC Plate @ 254 nm

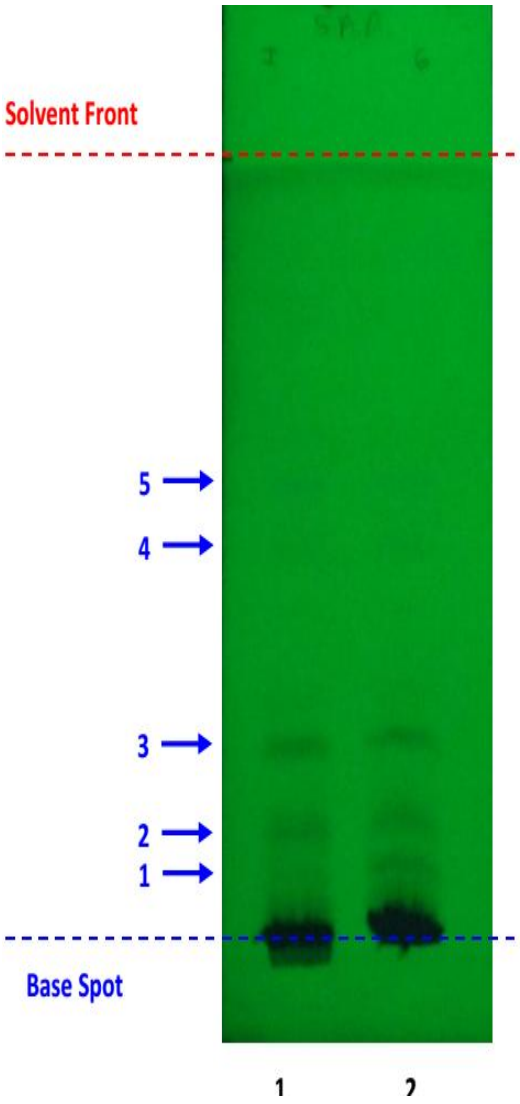

Fig.4: 3D overlay chromatogram @ 256 nm

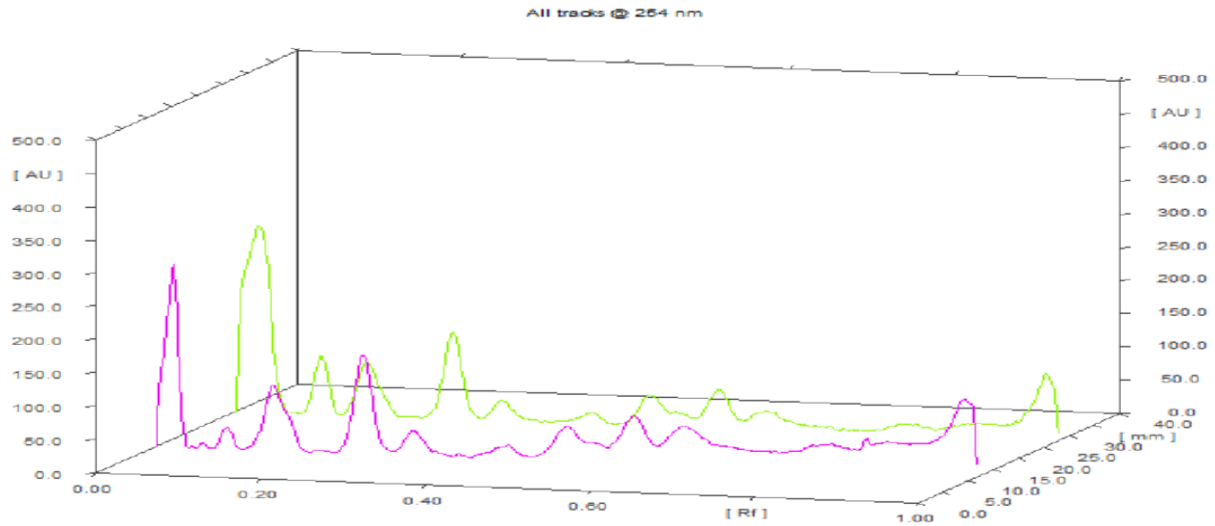

Fig.5: 3D overlay chromatogram @ 366 nm

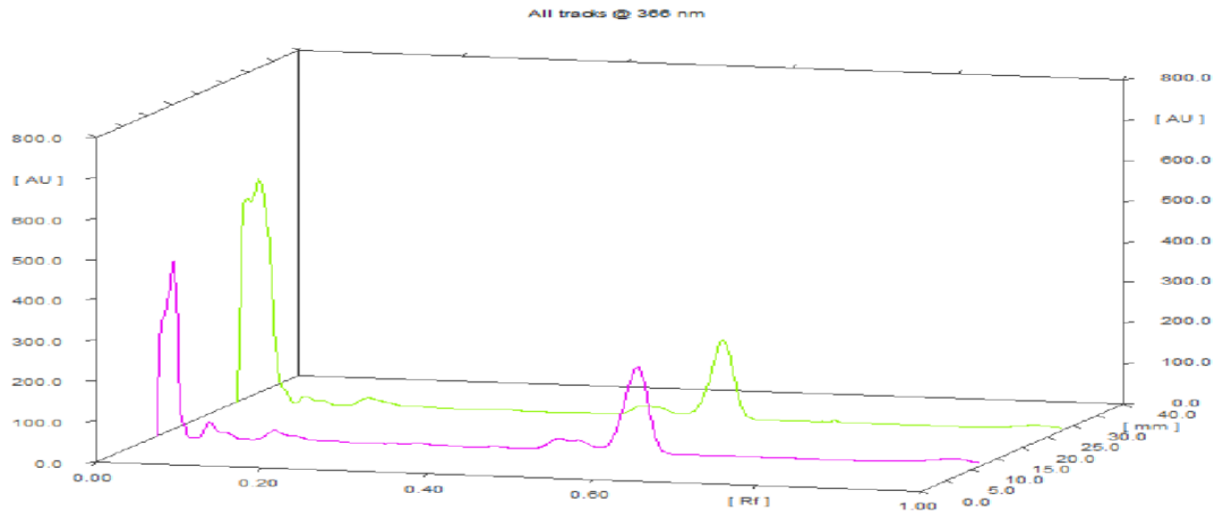

Fig.6: 3D overlay chromatogram @ 540 nm