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Research Article

SHELF-LIFE ASSESSMENT OF *DANTASHODHANA* PASTE (A POLYHERBAL TOOTHPASTE): A PRELIMINARY STUDY

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ABSTRACT

Objective: Shelf life is the period during which the potency (*Virya*) of a drug remains unaffected due to environmental factors or from microbial contamination. Considering the growing popularity of Ayurveda products, it becomes important to maintain the quality of all such products. Shelf life is one of the essential components under quality and needs to be evaluated for all products. *Dantashodhana* paste (DP) is a polyherbal toothpaste containing *Vyosha* (*Zingiber officinale* Roxb., *Piper nigrum* Linn., and *Piper longum* Linn.), *Trijata* (*Cinnamomum zeylanicum* Blume., *Elettaria cardamomum* Maton., *Cinnamomum* tamala (Buch.-Ham.) T.Nees and Eberm.), *Tejovati* (*Zanthoxylum armatum* DC.), *Saindhava* (rock salt), and other excipients.

Methods: DP was prepared with the following standard guidelines. The samples were subjected to accelerated stability study by maintaining temperature and humidity 40±2°C 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: DP was found to be free from microbial contamination. Heavy metals were within the prescribed limits for toothpaste complying the official standards. There were insignificant changes in physicochemical profiles at different intervals. On extrapolation of the observations, the shelf life of DP was found to be 12.16 years.

Conclusion: Shelf life of DP is found to be much longer than the standards specified in the D&C act. This prolonged shelf life may be contributed to care taken during drug preparation, storage, and properties of herbal drugs used in the formulation.

Keywords: Ayurveda, *Dantashodhana* paste, Polyherbal toothpaste, *Saviryata avadhi*, Shelf life.

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INTRODUCTION

One of the some misinterpretations among the common public about Ayurveda medicines is that Ayurveda medicines last lifetime and they have no expiry date; this is not always true. Ayurveda medicines also lose potency gradually with time. There are many categories of formulations, namely, *Vati*, *Gutika*, *Asava-Arista*, *Lepa*, and *Avaleha* which have a specific shelf-life period mentioned in Gazettes. The Gazette released in 2016 is the latest one for the shelf life of ASU medicines [1].

Although shelf-life periods are mentioned in classical textbooks, it needs to be evaluated with currently available techniques and parameters, and this becomes more important when formulation or dosage form is not mentioned in classics. For example, the shelf life of *Shirishadi Avaleha* was found same as mentioned in classics [2], while shelf-life period of *Shirisha Ashwagandhadi Avaleha,* which is an *Anubhuta* Yoga was found to be 8 years and 6 months that are much higher than the *Avaleha* [3].

Dantashodhana Choorna described in *Sushruta Samhita* contains seven herbal drugs and rack salt, the formulation is to be used as *Pratisarana* (gentle rubbing over the teeth and gums) [4]. For increased patient compliance and acceptance, this formulation was converted into *Dantashodhana* paste (DP) [5]. In the present study, an attempt has been made to evaluate its shelf life with the help of modern analytical techniques.

METHODS

All drugs were procured from the local market, Jamnagar, and authenticated in the Pharmacognosy Laboratory, Institute for Post Graduate Teaching and Research in Ayurveda, Jamnagar, and an article on pharmacognostical analysis was published [6]. Composition formulation is stated in Tables 1 and 2.

Preparation of formulation

As a specific method of preparation is not mentioned for the paste, the herbal part of DP was collected in *Yavakuta* (coarse powder) form except for *Saindhava* (rock salt) (Table 1); *Kwatha* (decoction) was prepared to add 16 times of water and reduced it to one-fourth. The contents were filtered through dry and clean cotton cloth. The filtrate was again subjected to heat to prepare *Ghana* (concentrated aqueous herbal extract). This *Ghana* and base materials for toothpaste were mixed in a proportion of 40:60, respectively (Table 2). Mixture was triturated properly in edge runner for 1 day until the formation of a homogenous paste. This paste was filled in non-rigid collapsible tube containers of 20 g each and containers were sealed carefully from both the sides (Fig. 1).

Sample quantity and packing for shelf-life evaluation

Samples in 25 tubes, each contains 20 g of DP.

Storage conditions

Temperature: 40±2°C and relative humidity: 75±5%.

Parameters

Basic analytical parameters, including fineness [7], pH [8], foaming index [9], spreadability [10], and heavy metals [11], were evaluated at intervals as specified earlier. Test for microbial contamination was done initially and at the end of 6 months of storage [12]. Chromatographic profile (high-performance thin-layer chromatography [HPTLC]) was evaluated out under 254, 366, and 540 nm initially and after 6 months of storage.

Frequency of withdrawal

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

RESULTS

No changes in organoleptic characters were noted in the drug at different levels of storage (Table 3). Physicochemical characteristics of DP at initial, 1, 3, and 6 months interval are presented in Table 4. Microbial growth was found below the prescribed limits in DP initially and after 6 months (Table 5). Heavy metals, including arsenic, lead, and mercury, were found in the amount of 1.245 ppm, 2.658 ppm, and 0.657 ppm, respectively, that are within the prescribed limits (Table 6). HPTLC showed three spots at 254 nm, one spot at 366 nm, and six spots at 540 nm. Rf values recorded were the same for both samples (0 and 6 months) (Table 7 and Figs. 2 and 3). Based on the physicochemical values, intercept and slope were calculated followed by expected time for 10% degradation for individual parameters (Tables 8 and 9) (Graphs 1-3). On extrapolation of these values, the shelf life of DP was found to be 12.16 years (Table 10).

Table 1: Drugs composition of *Dantashodhana Ghana* [4]

S. No.	Name	Botanical/English name	Proportion
1.	*Vyosha*		1 part
	Shunthi	*Zingiber officinale* Rosc.	
	Maricha	*Piper nigrum* Linn.	
	Pippali	*Piper longum* Linn.	
2.	*Trivarga*		1 part
	Twaka	*Cinnamomum zeylanica* Bl.	
	Ela	*Elettaria cardamomum Maton*.	
	Tamala	*Cinnamomum tamala* Nees.	
3.	*Tejovati*	*Zanthoxylum armatum* DC.	1 part
4.	*Saindhava*	Rock salt	1 part

Table 2: Ingredients of DP

No.	Name	Percentage
1.	*Dantashodhana Ghana*	27
2.	*Dantashodhana Kwatha*	18
3.	*Saindhava*	7.20
4.	Glycerin	12.60
5.	Sorbitol	12.60
6.	CMC	1.26
7.	SLS	3.24
8.	Calcium carbonate	18
9.	Methylparaben	0.02
10.	Propylparaben	0.02
11.	Saccharine	0.06
12.	Peppermint oil	0.5

SLS: Sodium lauryl sulfate, CMC: Critical micelle concentration, DP: *Dantashodhana* paste

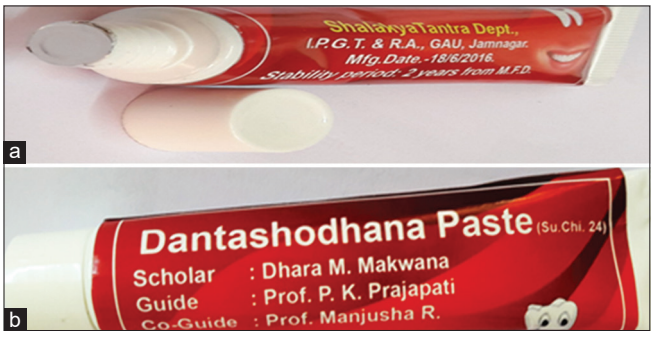


Fig. 1: (a and b) Packing of *Dantashodhana* paste in a non-rigid collapsible tube container

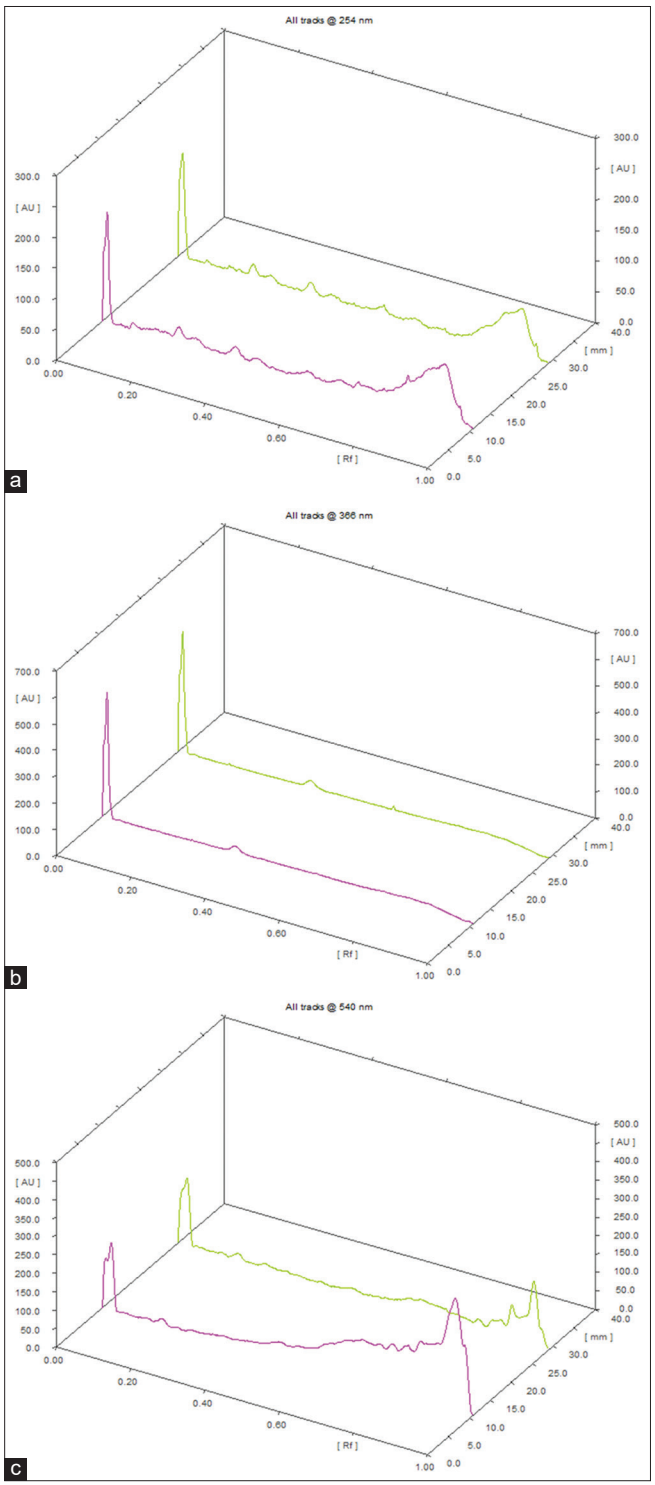


Fig. 2: Peak display in high-performance thin-layer chromatography, (a) peak display 254 nm, (b) peak display 366 nm, (c) peak display 540 nm

Table 3: Organoleptic parameters DP

S. No.	Parameters	Initial (October 1, 2016)	1st month (November 1, 2016)	3rd month (January 1, 2017)	6th month (April 1, 2017)
1.	Color	Blackish-gray	Blackish-gray	Blackish-gray	Blackish-gray
2.	Odor	Characteristic	Characteristic	Characteristic	Characteristic
3.	Consistency	Thick paste	Thick paste	Thick paste	Thick paste

DP: *Dantashodhana* paste

Table 4: Physicochemical parameters of DP

S. No.	Parameters	Initial (October 1, 2016)	1st month (November 1, 2016)	3rd month (January 1, 2017)	6th month (April 1, 2017)
1.	Fineness	Good	Good	Good	Good
2.	pH	6.87	7.03	7.08	7.10
3.	Spreadability	1.2 cm/10 g weight	1.25 cm/10 g weight	1.10 cm/10 g weight	1.2 cm/10 g weight
4.	Foaming index	175	178	175	175
5.	Gritty particles	Not present	Not present	Not present	Not present

DP: *Dantashodhana* paste

Table 5: Microbial load in DP

S. No.	Test	Initial (October 1, 2016)	6th month (April 1, 2017)
1.	Total plate count	<10 cfu/g	<34 cfu/g
2.	Total yeast and mold count	Absent	Absent
3.	*Escherichia coli*	Absent	Absent
4.	*Salmonella*	Absent	Absent
5.	*Staphylococcus aureus*	Absent	Absent
6.	*Pseudomonas aeruginosa*	Absent	Absent
7.	*Candida albicans*	Absent	Absent

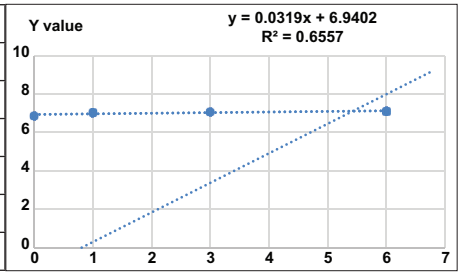
DP: *Dantashodhana* paste

Table 6: Heavy metal test (by AAS test)

Sr. no.	Test	Result (ppm)	Permissible limit as per API [14] (ppm)	BIS standards
1.	Arsenic	1.245	3	2
2.	Lead	2.658	10	20
3.	Mercury	0.657	1	Not mentioned
4.	Cadmium	0.197	0.3	Not mentioned

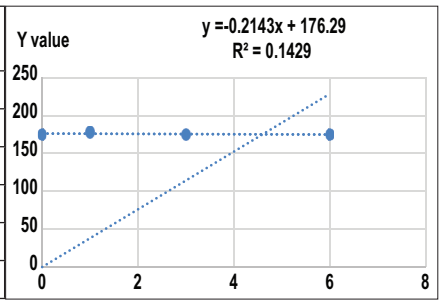
ppm: Parts per million, AAS: Atomic absorption spectroscopy, API: Active pharmaceutical ingredients, BIS: Bureau of Indian Standards

Month	pH
0	6.87
1	7.03
3	7.08
6	7.10
Intercept	6.9402
Slope	0.0319



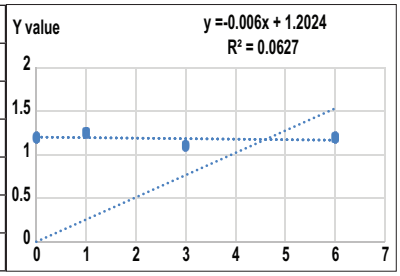
Graph 1: Slope of pH of *Dantashodhana* paste

Month	Foaming index
0	175
1	178
3	175
6	175
Intercept	176.29
Slope	−0.2143



Graph 2: Slope of F of *Dantashodhana* paste

Month	Spreadability
0	1.2
1	1.25
3	1.1
6	1.2
Intercept	1.20
Slope	0.214



Graph 3: Slope of spreadability of *Dantashodhana* paste

DISCUSSION

The present study is a preliminary attempt toward evaluating shelf life of DP. No changes in organoleptic characters were found at different levels of storage. DP was found to be blackish-gray with characteristic odor and thick consistency. Color of the formulation can be contributed to the use of *Ghana* and *Kwatha* in the formulation. Insignificant differences were observed in basic physicochemical profiles in the drugs at different stages of analysis.

Microbial count and heavy metals were within the prescribed limits as per BIS and API, indicating safety and quality of the product [13,14]. Stability study of the same drug with respect to baseline microbial count has already been published which concluded that DP does not show any microbial contamination with the change in climatic conditions [15]. Prevention of the contamination may be attributed to antimicrobial properties of formulation contents.

The changes in all these parameters (such as pH, spreadability, foaming ability, fineness, stability studies, and test for Hg, Pb, and As) were analyzed to evaluate the shelf life of the formulation that is found to be 12.16 years, indicating longer shelf life of the compound.

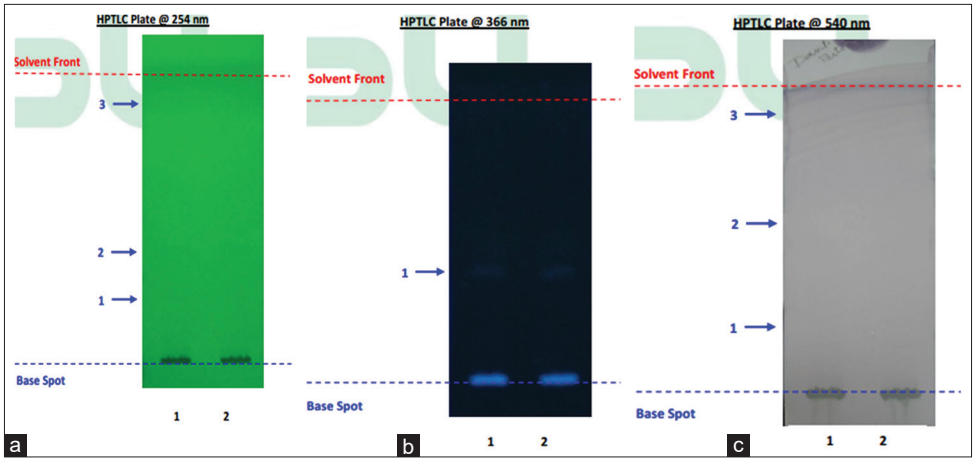


Fig. 3: High-performance thin-layer chromatography (HPTLC) study of *Dantashodhana* paste. (a) Comparative HPTLC plate at 254 nm, (b) comparative HPTLC plate at 366 nm, (c) comparative HPTLC plate at 540 nm

Table 7: HPTLC of DP

Drug	Spot no.	Rf at 254 nm		Rf at 366 nm		Rf at 540 nm	
		Track-2 (0 month)	Track-2 (6 months)	Track-2 (0 month)	Track-2 (6 months)	Track-2 (0 month)	Track-2 (6 months)
	1.	0.21	0.21	0.39	0.39	0.21	0.21
	2.	0.39	0.39			0.55	0.55
	3.	0.89	0.89			0.90	0.90

DP: *Dantashodhana* paste, HPTLC: High-performance thin-layer chromatography

Table 8: Intercept and slope of DP

S. No.	Parameters	Intercept	Slope
1.	pH (1% w/v)	6.94	0.032
2.	Spreadability	1.20	0.006
3	Foaming index	176.29	0.214

DP: *Dantashodhana* paste

Table 9: Approximate period for 10% degradation in DP

Parameters	Initial	10% degradation	Approximate months required for 10% degradation
pH (1% w/v)	6.87	6.183	23.66
Spreadability	1.2	1.08	20
Foam index	175	157.5	87.80
Mean month			43.22

DP: *Dantashodhana* paste

Table 10: Extrapolation of shelf life in DP

Drug	Months	Multiplication factor	Shelf life	
			Months	Years
DP	43.22	3.33	145.92	12.16

DP: *Dantashodhana* paste

CONCLUSION

The shelf life of DP was found to be 12.16 years. This higher stability is may be due to the use of *Ghana* preparation of herbal drugs. The present study is a preliminary study and further investigations are essential to ascertain actual cause behind the longer shelf life.

AUTHORS' CONTRIBUTIONS

Dhara Makwana carried out the test and collected all data. R Galib outlined the test and worked out all technical details, analytical and numerical calculations. Dhara Makwana and Parth Dave contributed to the preparation of the study drug (DP) and wrote the manuscript in consultation with R Galib. PK Prajapati and Manjusha Rajgopala were in charge of overall direction and planning.

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CONFLICTS OF INTEREST

The authors do not have any conflicts of interest.

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Nil.

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