

ACCELERATED STABILITY STUDIES OF KANTAKARI AVALEHA AND ITS GRANULES

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ABSTRACT

Introduction: *Kantakari Avaleha* (KA) is merely herbal medicine used to treat *Shwasa*, *Kasa*, *Hikka* and *Arati* since Vrinda Madhava period. It is observed that KA degrade early than the other *Avaleha* forms; however, the stability study of KA was not carried out till date. KA was modified to its granular form by aiming increase shelf life as well as increase palatability. **Aim:** To evaluate the accelerated stability of KA and its granules. **Materials and Methods:** Finished formulations of each KA and KAG were packed in three airtight food graded plastic containers separately. one pack from each sample were analyzed just after manufacturing and remaining two packs were kept in stability chamber at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\% \pm 5\% \text{RH}$, of which one pack was analyzed after the completion of three and another after 6 months. Organoleptic, physico-chemical, microbiological parameters along

with high-performance thin layer chromatography (HPTLC) fingerprinting were carried out.

Results: Organoleptic characters were not significantly changed at the end of the 6 month in accelerated stability Condition. HPTLC fingerprinting showed minimum changes and microbial studies were in confirmation to the World Health Organization guidelines.

Conclusion: KA and KAG confirmed to the International Conference on Harmonization Guideline for accelerated testing of the pharmaceutical product on said parameters and as per the Grimm's statement the shelf life of KA and KAG may last 13.05 and 14.48 months.

KEYWORDS: Accelerated stability study, shelf life, *Kantakari Avaleha*, *Kantakari Avaleha* granules.

INTRODUCTION

KA contains whole *Kantakari* plant as *Kwatha dravya*, 13 *Prakshepa dravya*, *Sharkara*, *Gritha* and *Tila tail* and *Madu*. Comparing to other *Avaleha* forms; in KA, *Prakshepa* and *Madura dravya* is equal quantity and oil amount is also approximately equal to the amount of *Prakshepa dravya*. Hence its method of preparation is also specific to itself, may be the reason of that *Kantakari Avaleha* has more chances of degradation. Granular dosage form is mostly liable to more shelf life, therefore *Kantakari Avaleha* was converted in to its granular dosage form. While doing this modification, only oil quantity was reduced by one forth and process of KA was changed. While KA preparation, *Prakshepa dravya*, *Kwatha* and oil content all together were heated over mild fire until achieved the *Avaleha* consistency. But in KAG preparation, *Prakshepa dravya* was stir fried and it was added to early prepared sugar syrup. Hence expected more shelf life of KAG than KA. Both the KA and KAG were subjected to confirm their shelf life since still there is no study conducted on stability of KA and its granules.

MATERIALS AND METHODS

Procurement of raw drugs

The fresh *Kantakari* was collected from periphery area of Jamnagar. Raw material were procured from the pharmacy, Gujarat Ayurved University, Jamnagar. *Sita* (Sugar Candy) was purchased from local market of Jamnagar. *Madhu* (Bee honey) was purchased from the outlet of Forest Department, Jamnagar. All the drugs were authenticated by the Pharmacognocny Laboratory, IPGT & RA, Jamnagar.

Kantakari Avaleha and *Kantakari Avaleha* Granules were prepared at Department of *Rasashastra* and *Bhaishajya Kalpana*, I.P.G.T & R.A, Jamnagar. The whole pharmaceutical study was carried out as mentioned below.

Formulation composition of KA and KAG granules is placed at Table 1.

Pharmaceutical procedure

Preparation of *Churna* (powder)^[1]

Guduchi, *Chavya*, *Chitraka*, *Musta*, *Karkatashringi*, *Shunthi*, *Maricha*, *Pippali*, *Dhanvayasaka*, *Rasna*, *Shati*, *Tugaksiri* (*Vamshalochana*) are the raw materials should be used as fine powder in this formulations. Each raw material was separately taken and removed physical impurities and dried under sunlight. They were Grinded by using Mini

Pulverizer and sieved through # 72. The powder which was not passed through # 72 sieve was subjected to grind again by using mixture grinder and sieved then to obtain fine powder. Packed each powder separately in airtight polyethylene containers.

Preparation of *Kantakari Kwatha* (decoction)

Fresh *Kantakari Panchanga* was taken, and removed physical impurities, washed with potable water and then cut with cutter and crushed by using wet grinder. Crushed *Kantakari Panchanga* was taken in a stainless steel vessel. Then water was added it and subjecting to heating process and reduced water into 1/4th of its initial volume. Then filtered through a clean cotton cloth to obtain *Kwatha*.

Preparation of *Kantakari Avaleha* ^[2,3]

The specific classical method mentioned for *Kantakari Avaleha* in Sarangadhara Samhita was followed for the preparation of *Kantakari Avaleha*. According to that; added *Sita* (sugar candy) in *Kantakari Kwatha* and stirred over heating until dissolve the sugar for 10 minutes. Temperature of homogenous mixture was around 80°C. Then the mixture of sugar and *Kwatha* was filtered through double cloth to remove physical impurities of sugar candy. Then added the powdered ingredients named as *Churna Dravya* (Sr.no.2-13 in Table 2) with *Ghrita* and *Taila* together to the filtrate. Heating process was maintained between 90- 95°C with stirring, till it attains the consistency of *Leha* confirmed by the formation of soft bolus, which does not disperse in water. Then stopped heating process and allow for self-cooling up to around 60°C temperature. After that added fine powders of *Vamsalochana*, *Pippali* and stirred properly to get uniform mixture and allow them cooling to room temperature. *Madhu* was added at 30°C temperature and mixed thoroughly to obtain homogeneous blend. Final product was stored in airtight containers.

***Kantakari Avaleha* granules**

KAG was prepared as per the developed method which confirmed by the scholar, after many experimental batchers. For this preparation, oil quantity was reduced up to 25% of quantity (Table no 3) mentioned in the basic formula. In this method, *Churna Dravya* (Sr.no.2-13 in Table 3) was stir fried with *Ghrita* and *Tila Taila* to obtained oily mass. Oily mass of *Churna dravya* was added in earlier prepared sugar candy syrup and then heating process was carried out for 20 minutes. After self-cooling (60°C) added fine powders of *Vamshalochana*, & *Pippali*. *Madhu* was added at the 30°C temperature and mix thoroughly to obtain a

homogeneous hard mass. This mass was passed through 10 # sieve by rubbing over it for convert into granular form. These granules were stored in air tight containers.

Storage

Air tight food graded plastic container of 150 ml capacity was procured from the local market was used for storage purpose. About 100 g of drug formulation was filled into the container, and tightly closed with its plastic lid.

Methodology of accelerated stability testing

Formulations were filled with three packs of KA and three packs of KAG and labeled properly including the formulation name, date of preparation, date of commencement of thermal /humidity challenge, and date of withdrawal. The accelerated stability study was carried out for the period of 6-months. Temperature was regulated at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ with relative humidity (RH) $75\% \pm 5\%$. Total three packs each were analyzed for the stability evaluation of KA and KAG. One pack each was tested for various analytical parameters at the time of manufacture, that is, 0 month, and other packs were kept in stability chamber (Osworld photostability chamber^[4] OPSH G-4 1258 with temperature ranges of $5\text{--}60^{\circ}\text{C}$ with resolution $+0.1^{\circ}\text{C}$, accuracy of $\pm 0.2^{\circ}\text{C}$, and uniformity of $\pm 1^{\circ}\text{C}$) for thermal/humidity challenge. Each second packs of both the formulations were removed from stability chamber at the completion of a 3rd month, and the third packs were opened at the completion of 6 months and analyzed.

Analytical parameters

Organoleptic characters such as color^[5] odor^[6] and taste^[7] were assessed on all packs. Physico-chemical analysis was done by testing loss on drying^[8] total ash^[9] water soluble extractives^[10] Alcohol soluble extractive^[11] Total Sugar (%)^[12] Assay of Solasodine (by Gravimetry) and pH of 10% solution^[13] KA and KAG samples were also evaluated for the total bacterial count, total fungal count, and the specific pathogens, that is, *Escherichia coli*, *Salmonella* spp., *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.^[14] Qualitative densitometric high-performance thin layer chromatography (HPTLC) fingerprinting was carried out to evaluate the changes in KA and KAG. Water and dichloromethane (1:1) extract of KA and KAG were used for TLC application. The analysis was performed on $2.5\text{ cm} \times 10\text{ cm}$ silica gel 60 F254 plates using Linomat 5 (Camag Switzerland) automated spray-on band applicator equipped with a 100 μl Hamilton syringe. Band length was 8 mm, distance from

the plate edge was 12.5 mm, and distance from the bottom of the plate was 10 mm. Twin trough chamber (Camag Switzerland) was saturated for 20 min at room temperature prior to the plate development. Toluene:ethyl acetate:formic acid (7:2.5:0.5) combination was used as a solvent system for the mobile phase. Migration was 8 cm. After development, the plate was evaluated under ultraviolet (UV) 254 nm, 366 nm and 540 nm; further the plate was derivatized with anisaldehyde sulfuric acid and kept in oven at 110°C to evaluate under visible light using CAMAG TLC Visualizer and scanned using CAMAG TLC SCANNER 3.^[15]

Evaluation parameters

Values which obtained in initial month and after 6 months of storage of stability chamber were subjected to calculate intercept and slope. From the above data, approximate 10% degradation was calculated and was extrapolated to get shelf life. Real-time aging factors 3.3 were used for extrapolation of shelf life as Jamnagar is included to climatic Zone IV of ambient temperature and humidity 30°C/70% RH. Number of months when degradation occurred was calculated using the following formula.^[16]

$$\text{Months when 10\% degradation occurs} = \frac{[\text{0 month Assay value} - \{(\text{0 month assay value} \times 10)/100\}] - \text{Intercept}}{\text{Slope}}$$

RESULTS

No change was observed in both the formulations of KA and KAG in organoleptically. (Table 4). The results of different physicochemical parameters are given in (Table 5, 6). Microbial study of initial month and 6 month of both the KA and KAG are shown in table 7. Total plate count (NMT 10⁵ cfu/g) of KA was reduced to 2230 cfu/g from 4164 cfu/g at the end of the 6 month and for KAG, it was reduced from 2886 cfu/g to 1976 cfu/g. Total yeast and mold count of KA is 324 cfu/g at the starting month and it is 2955 cfu/g in KAG. Total yeast and mold was absent in both the samples at the end of the 6 month. All the other pathogenic microbes like *E. coli*, *Salmonella* were not seen at the initial stage either six month.

High-performance thin-layer chromatography profile represented in Figures 1-3 that showed 08 spots at 254 nm, 05 spots at 366 nm, and 09 spots at 540 nm respectively for KA. Only one spot out of five spots (0.19) was disappeared in 366nm track and all the other spots were not shown any changes in other two tracks of @254nm and @ 540nm.(table 8). HPTLC profile of KAG was shown 08 spots in @254nm track, 07 spots @366nm and 09 spots in @

540nm track. No changers had seen in any of the three tracks at the end of the 6 month. (table 9), (figure 4,5,6.).

Based on these values, intercept, slope (table 10) and approximate time for 10% degradation (table 11) of each KA and KAG samples were calculated. As per the final results, the shelf life of KA was found to be 13.05 month and KAG was 14.48 month.[Table12].

DISCUSSION

Finished product of KA and KAG was not shown any significant change in their organoleptic characteristics in accelerated thermal/humidity conditions. Alteration in color usually occurs due to pH changes or light exposure.^[17] In this study, there was no change in color, which correlates with an insignificant change in pH and confirms to criterion on the storage condition. Organoleptic characters such as color, smell, taste, structure, weight, properties, Clarity, cleanliness and freshness etc., were the only tool in ancient period used by Ayurvedic scholars to evaluate the stability and shelf life of single or compound formulations.^[18]

As per the WHO, Ministry of AYUSH, and other food and drug regulations, physico-chemical stability data are also essential to decide the shelf life of drugs. Hence, further physico-chemical and microbial evaluations were carried out to confirm the shelf life of these products.

Moisture content of KA was increased in 41.37% from initial weight in KA at the end of 6 month and moisture percentage of KAG was increased in 28.89 %. It may be the reason of excessive *Prakshepa dravya* in this formula are hygroscopic in nature and absorb more moisture from the atmosphere. Comparatively less percentage change of KAG may because of stir-fried *Prakshepa* has less chance of absorb moisture from the environment. pH of KA had changed 21.69 % at the 6 month and the pH change of KAG was 11.06 %. The pH value is one of the main factors influencing the quality of medicine. It controls many chemical and microbiological reactions. Higher percentage variation of pH value in this study indicates the less stability in this product. Total Ash value of KA was increased by 26.94 % and in KAG it was increased by 14.48% during 6 month stability study. Alcohol soluble extractive reduced 8.65% from KA sample and 7.19% from KAG. Water soluble extractive of KA was changed by 6.48 % and in KAG it was changed 13.78%. Total Sugar percentage was reduced in KA by 10.66% and in KAG, sugar content was reduced by 19.45 %. 28.68% of assay of Solasodine was reduced in KA and it was reduced by 12.38 % in KAG.

CONCLUSION

Both the samples of KA and KAG was organoleptically not exhibited any different during 6 month in accelerated chamber. And there was no pathogenic microbes till the study carried out. The duration of time wherever a product be able to stable and safe to be used, are called as expiry date.^[19] Thus here it seems to have much time for expiry date. But the shelf life replicate the time when a product resolve work both safely and effectively. The amount of time a product can maintain its identity, strength, therapeutic effect in a stable condition under certain environmental conditions, equates to its shelf life.^[20] As same as in Auyrveda it is mentioned as the *Savirya Avadhi* which means the time period of the remaining it's *Virya* (Potency) of the product.^[21] According to the graph 1, alcohol soluble extract of both the samples KA and KAG remained in good condition for long time. Alcohol soluble ext. of both the sample may long lasted around 25 month. Extracts indicate the potency of medicine, and it is good sign for long term stability of *Kantakari Avaleha* and granules. Only one spot was changed in KA at the end of 6 month HPTLC profile and KAG has not shown any different during study period. This is also positive image for the stability of these products.

But Moisture, pH, assay of solasodine and total plate count are the most affected factors for *Kantakari Avaleha* and moisture, total sugar and total plate count are the most affected factors for *Kantakari Avaleha* granules for their degradation. (Graph: 1). It is clear that many of the parameters might be controlled by upholding the moisture content may show less changers. Though, loss on drying of both the products were in below 10 % at the initial stage, but it was augmented within short time of period. Comparatively KA exhibited higher change in moisture than KAG.

While comparing both the drugs, modified dosage form of KAG was not exhibited much long stability as estimated though comparatively all the parameters, especially moisture content, were highly changed in KA than KAG. Total sugar content reduction was comparatively higher in KAG than KA. It denotes that, sugar content reduction may interfere to the degradation of KAG. The reason for sugar content reduction of KAG may because of reduction of oil content or otherwise by bio chemical changers transpire in process modification.

Thus all the results shown comparatively similar shelf life of KA and KAG id east 13.05 month shelf life of KA and 14.48 month of KAG.

As per revised Rule 161-B; vide G.S.R. No. 789 (E) [b] shelf life of *Avaleha* is 3 years with developed conditions. But it can be vary minimum 6 month (Yoga Ratnakara)^[22] on wards as per the classics. As per the previous studies done resently, *Trivrit Avaleha* had shown 1 year and 6 months stability, *Kamsaharitaki Avaleha* shown 1 year and 11 months, *Shirishavaleha* prepared by water had 1 year and 4 month stability, *Shirishavaleha* prepared by *Kanji* 2years shelf life. *Shirisha Ashwagandhadi Avaleha* (metallic component present) shown maximum shelf life of 8 years and 7 months. Those data shows that, shelf life is depending on the formulation composition^[23] as one variable.

Limitations and further recommendations

Since the accelerated stability studies alone do not serve as the sole basis to calculate drugs shelf life; it should be supported by long-term and real-time studies. Biologically active molecules in the formulation should be identified and its thermal/ humidity, and light dependent quantitative variation with time should also be evaluated. Further, degradation products in the samples should be detected by appropriate physico-chemical, biochemical, and immunochemical methods to avoid drug-induced adverse effects.

While processing KA, it can be heated further more step than that of *Avaleha* consistency stage and until the mild oily layer separated. Then the Outer oil layer appearing of KA may be act as a protective layer from its oxidization.

By closing the container with sealed cap, it may be increased the Shelf life of both the products.

Table 1: Composition of *Kantakari Avaleha* and *Kantakari Avaleha* granules.

No	Ingredient	Botanical Name	Parts used	Qty.inClas.c	Metric
1	<i>Kantakari</i>	<i>Solanum xanthocarpum</i> Schrad. & Wendl.	Whole plant	<i>Tula</i>	4800 g
2	Water	-	-	<i>Drona</i>	12288 ml
3	<i>Guduchi</i>	<i>Tinospora cordifolia</i> Miers	Stem	1 <i>Pala</i>	48 g
4	<i>Chavya</i>	<i>Piper chaba</i> Trel. & Yunc.	Stem	1 <i>Pala</i>	48 g
5	<i>Chitraka</i>	<i>Plumbago zeylanica</i> Linn.	Root	1 <i>Pala</i>	48 g
6	<i>Musta</i>	<i>Cyperus rotundus</i> Linn.	Rhizome	1 <i>Pala</i>	48 g
7	<i>Karkatahringi</i>	<i>Pistacia integerrima</i> J.L. Stewart ex Brandis	Gall	1 <i>Pala</i>	48 g
8	<i>Shunthi</i>	<i>Zingiber officinale</i> Roscoe.	Rhizome	1 <i>Pala</i>	48 g
9	<i>Maricha</i>	<i>Piper nigrum</i> Linn.	Fruit	1 <i>Pala</i>	48 g
10	<i>Pippali</i>	<i>Piper longum</i> Linn.	Fruit	1 <i>Pala</i>	48 g
11	<i>Dhanvayasaka</i>	<i>Alhagi camelorum</i> Fisch	Whole plant	1 <i>Pala</i>	48 g

12	<i>Bharangi</i>	<i>Clerodendrum serratum indicum</i> Moon	Root	1 Pala	48 g
13	<i>Rasna</i>	<i>Alpinia galangal</i> Willd.	Rhizome	1 Pala	48 g
14	<i>Shati</i>	<i>Hedycium speciatum</i> Ham ex smith	Rhizome	1 Pala	48 g
15	<i>Sita</i>	Sugar Candy	-	20 Pala	960 g
16	<i>Madhu</i>	Bee honey	-	8 Pala	384 g
17	<i>Ghrita</i>	Ghee	-	8 Pala	348 g
18	<i>Taila Tila</i>	Sesame oil	-	8 Pala	384 g
19	<i>Vamsha lochana</i>	<i>Bambusa arundinacea</i> (Retz.)	-	4 Pala	192 g
20	<i>Pippali</i>	<i>Piper longum</i> Linn.	Fruit	4 Pala	192 g

Table 2: Ingredients and their quantity of *Kantakari Avaleha*.

No	Ingredients	Quantity
1	<i>Kantakari Kwatha</i>	6640
2	<i>Guduchi</i>	104g
3	<i>Chavya</i>	104g
4	<i>Chitraka</i>	104g
5	<i>Musta</i>	104g
6	<i>Karkatashringi</i>	104g
7	<i>Shunthi</i>	104g
8	<i>Maricha</i>	104g
9	<i>Pippali</i>	104g
10	<i>Dhanvayasaka</i>	104g
11	<i>Bharangi</i>	104g
12	<i>Rasna</i>	104g
13	<i>Shati</i>	104g
14	<i>Ghrita</i>	2074g
15	<i>Taila Tila</i>	830ml
16	Sugar Candy	830 g
17	<i>Madhu</i>	830 g
18	<i>Vamshalochana</i>	415g
19	<i>Pippali</i>	415g

Table 3: Ingredients and their quantity of *Kantakari Avaleha granules*.

Sl. No.	Ingredients	Quantity
1	<i>Kantakari Kwatha</i>	6645
2	<i>Guduchi</i>	104 g
3	<i>Chavya</i>	104 g
4	<i>Chitraka</i>	104 g
5	<i>Musta</i>	104 g
6	<i>Karkatashringi</i>	104 g
7	<i>Sunthi</i>	104 g
8	<i>Maricha</i>	104 g
9	<i>Pippali</i>	104 g
10	<i>Dhanvayasaka</i>	104 g
11	<i>Bharangi</i>	104 g

12	<i>Rasna</i>	104 g
13	<i>Shati</i>	104 g
14	<i>Ghrita</i>	622.5ml
15	<i>Taila Tila</i>	622.5ml
16	Sugar Candy	2074g
17	<i>Madhu</i>	830g
18	<i>Vamshalochana</i>	415g
19	<i>Pippali</i>	415g

Table 4: The organoleptic parameters of KA and KAG observed at the initial, 1, 3 , and 6 month interval of the study.

Sample	Organoleptic parameters	0 month	1 month	3 months	6 months
KA	Description	Dark Brown colour	Dark Brown colour	Dark Brown colour	Dark Brown colour
	Odour	Characteristic	Characteristic	Characteristic	Characteristic
	Taste	Characteristic	Characteristic	Characteristic	Characteristic
	Consistency	Semisolid	Semisolid	Semisolid	Semisolid
KAG	Description	Dark brown colour	Dark brown colour	Dark brown colour	Dark brown colour
	Odor	Characteristic	Characteristic	Characteristic	Characteristic
	Taste	Characteristic	Characteristic	Characteristic	Characteristic
	Consistency	Granular	Granular	Granular	Granular

Table 5: Physicochemical parameters of KA.

Parameters	0 month	Accelerated stability study		
		1st month	3rd month	6th month
pH (1 % solution)	6.13	5.20	4.92	4.80
T Sugar content	9.34	8.73	8.63	5.48
Total Ash (% w/w)	4.75	5.57	5.88	6.03
Alcohol soluble extractive (%)	52.36	51.79	51.25	47.83
Water soluble extractive (%)	52.90	52.34	50.55	49.53
Total Sugar (%)	38.36	37.98	35.09	34.27
Assay of Solasodine (by Gravimetry)	1.28	0.99	0.96	0.90

Table 6: Physicochemical parameters of KAG.

Parameters	0 month	Accelerated stability study		
		1st month	3rd month	6th month
pH (1 % solution)	5.33	5.22	4.81	4.74
Moisture content	5.78	5.68	8.33	7.45
Sugar content	5.78	5.68	8.33	7.45
Total Ash (% w/w)	8.24	9.35	9.40	9.68
Alcohol soluble extractive (%)	50.59	48.90	48.48	46.95
Water soluble extractive (%)	64.52	61.33	60.95	55.63

Total Sugar (%)	45.86	40.46	38.80	36.94
Assay of Solasodine (by Gravimetry)	1.05	0.99	0.97	0.92

Table 7: Microbial limit test of KA and KAG.

Parameters	0 month		6 months	
	KA	KAG	KA	KAG
Total plate count (NMT 105 cfu/g)	4164 cfu/g	2886 cfu/g	2230 cfu/g	1976 cfu/g
Total yeast and mold count (NMT 103 cfu/g)	324 cfu/g	2955 cfu/g	Absent	Absent
<i>E. coli</i>	Absent	Absent	Absent	Absent
Salmonella (absent)	Absent	Absent	Absent	Absent
<i>Staphylococcus aureus</i> (absent)	Absent	Absent	Absent	Absent
<i>Pseudomonas aeruginosa</i> (absent)	Absent	Absent	Absent	Absent

Table 8: HPTLC profile of *Kantakari Avaleha*.

	@254nm		@366nm		@ 540nm	
	Track 1	Track 2	Track 1	Track 2	Track 1	Track 2
01	0.19	--	0.19	--	0.16	0.16
02	0.35	0.35	0.35	0.35	0.19	--
03	0.42	0.42	0.47	0.47	0.24	0.24
04	0.47	0.47	0.57	0.57	0.35	0.35
05	0.57	0.57	0.69	0.69	0.47	0.47
06	0.69	0.69			0.57	0.57
07	0.78	0.78			0.69	0.69
08	0.88	0.88			0.78	0.78
09					0.88	0.88

Track 1 KA at initial level Track 2 KA after 6 months

Table 9: HPTLC profile of *Kantakari Avaleha* granule.

	@254nm		@366nm		@ 540nm	
	Track 1	Track 2	Track 1	Track 2	Track 1	Track 2
01	0.14	0.14	0.14	0.14	0.14	0.14
02	0.21	0.21	0.34	0.34	0.21	0.21
03	0.34	0.34	0.48	0.48	0.34	0.34
04	0.42	0.42	0.57	0.57	0.42	0.42
05	0.48	0.48	0.62	0.62	0.48	0.48
06	0.57	0.57	0.71	0.71	0.57	0.57
07	0.71	0.71	0.77	0.77	0.62	0.62
08	0.77	0.77			0.71	0.71
09					0.77	0.77

Track 1 KA at initial level Track 2 KAG after 6 months

Table 10: Intercept and Slope of KA and KAG.

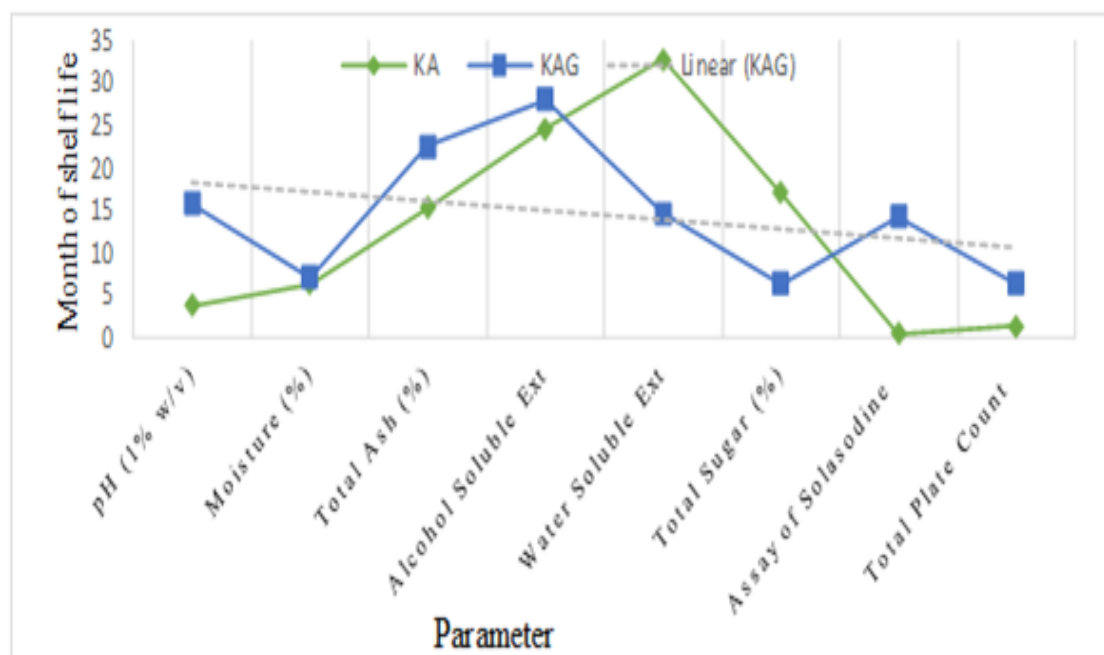
Parameters	Intercept	Slope		
	KA	KAG	KA	KAG
pH (1% w/v)	5.72	5.2821	-0.18	-0.1029
Moisture (%)	9.59	5.95	-0.62	0.35
Total Ash (%)	5.10	8.70	0.18	0.19
Alcohol Soluble Ext (%)	52.66	50.07	-0.75	-0.54
Water Soluble Ext (%)	52.78	63.95	-0.58	-1.34
Assay of Solasodine	1.16	1.03	-0.06	-0.02
Total Sugars (%)	38.26	43.69	-0.73	-1.27
Total Plate Count	4164	2886	-322.33	-151.67

Table 11: Approximate period for 10% Degradation in KA and KAG.

Parameters	Initial		10% Degradation		Approximate Months required for 10% degradation	
	KA	KAG	KA	KAG	KA	KAG
pH (1% w/v)	6.13	5.33	5.52	4.80	1.13	4.71
Moisture (%)	9.34	5.78	8.41	5.20	1.91	2.14
Total Ash (%)	4.75	8.24	4.275	7.42	4.58	6.75
Alcohol Soluble Ext	52.36	50.59	47.12	45.53	7.38	8.40
Water Soluble Ext	52.90	64.52	47.08	58.07	9.82	4.39
Total Sugar (%)	38.36	45.86	34.52	41.27	5.11	1.90
Assay of Solasodine (by Gravimetry)	1.28	1.05	1.15	0.95	0.13	4.25
Total Plate Count	4164	2886	3747.6	2597.4	1.29	1.9
Mean Months					3.92	4.35

Table 12: Extrapolation of shelf life in *kantakari Avaleha* and its Granules.

Drug	Months	Multiplication Factor	Shelf life
			Months
KA	3.92	3.33	13.05
KAG	4.35	3.33	14.48



Graph 1: Shelf life in *Kantakari Avaleha* and its granules by different parameters.

Figure 1- HPTLC- KA -Plate @254nm

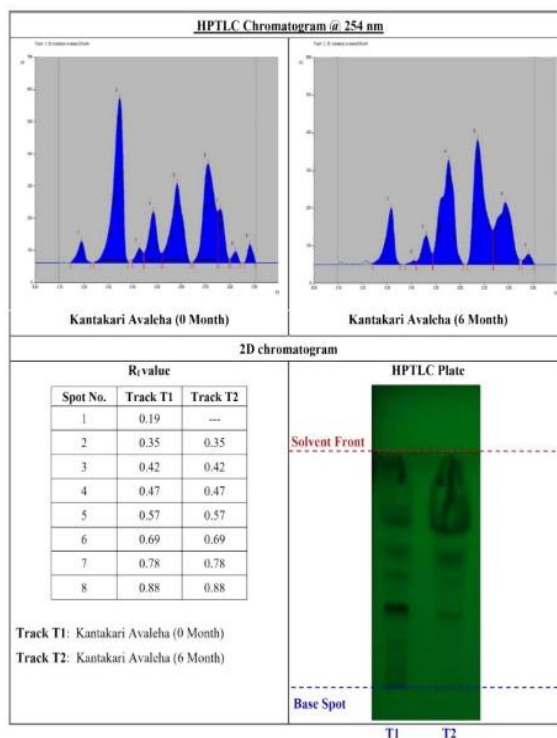


Figure 2- HPTLC –KA-Plate @254nm

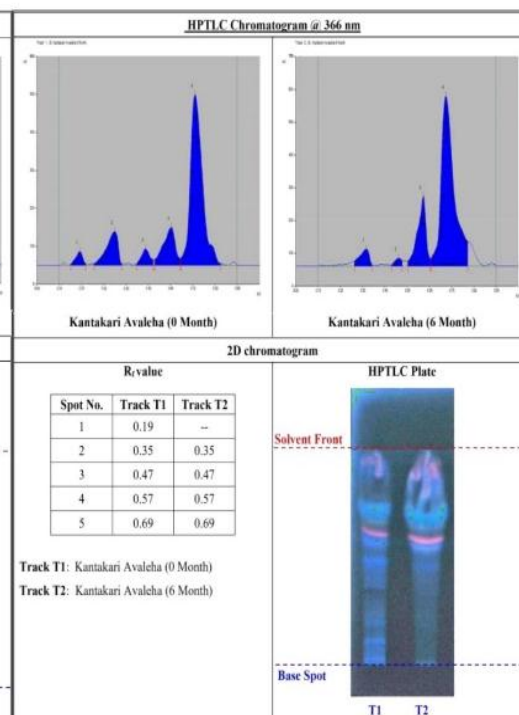


Figure 3- HPTLC- KA -Plate @540 nm

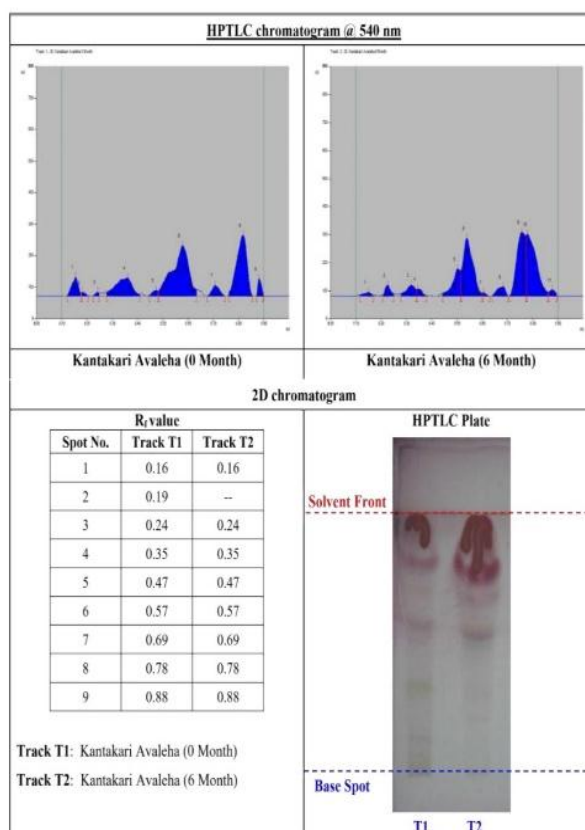


Figure 1, 2, 3: HPTLC of KA.

Figure 4- HPTLC- KAG -Plate @254nm

Figure 5-HPTLC-KAG-Plate @254nm

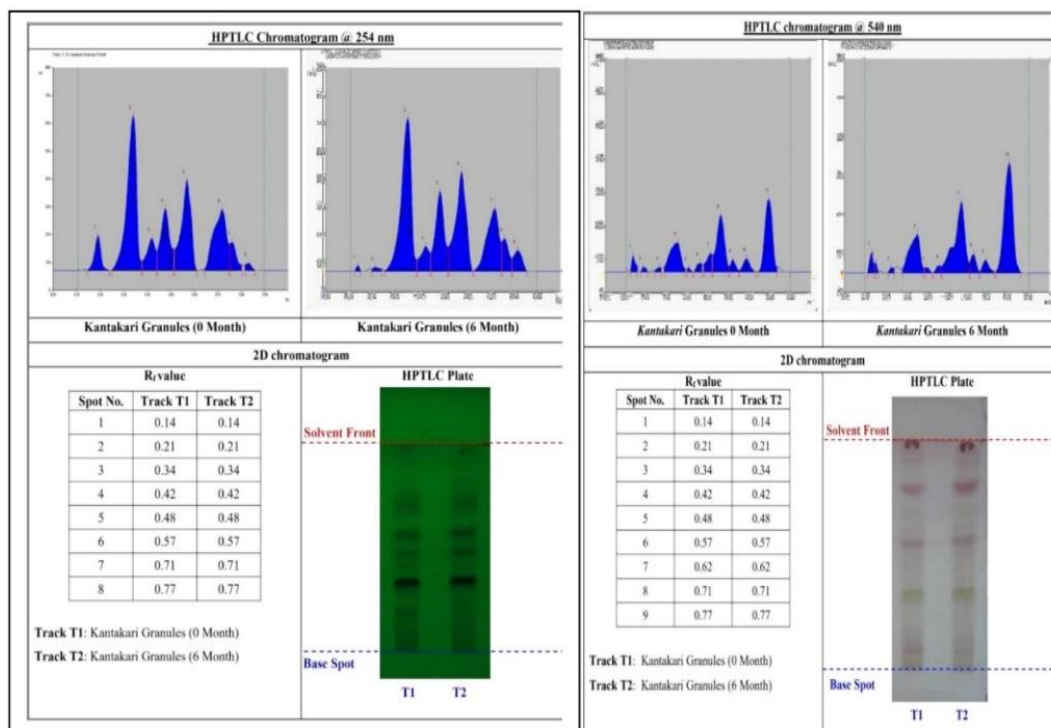


Figure 6- HPTLC- KAG -Plate @540 nm

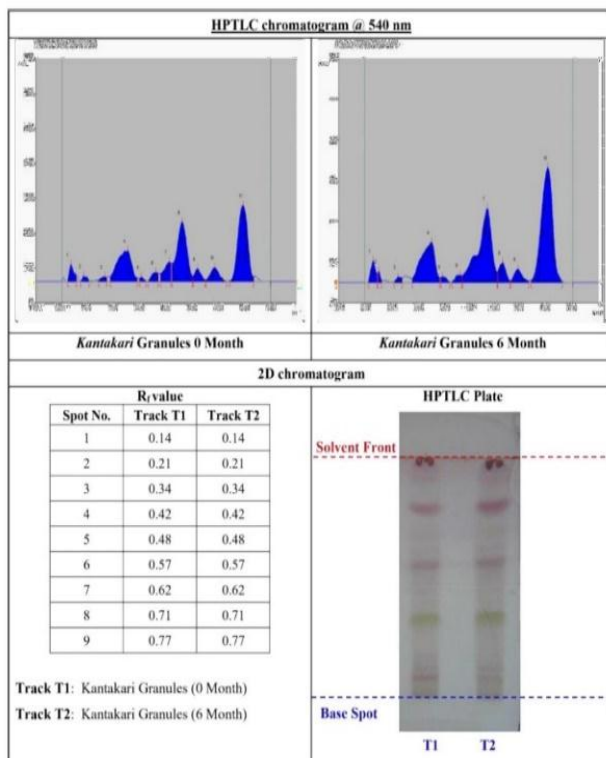


Figure 4, 5, 6: HPTLC of KA.

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