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Accelerated stability studies of *Sufoofe Sailan*: A Unani formulation

Seema Rani, Khaleequr Rahman, Peerzada Mohammad Younis

Department of Ilmul Saidla, National Institute of Unani Medicine, Bengaluru, Karnataka, India

Abstract

Introduction: *Sufoofe Sailan* (SS) is a polyherbal powder preparation used in Unani medicine to treat gynecological diseases. It is observed that SS degrade early as it is in the form of powder; however, the stability study of SS was not carried out till date. **Aim:** To evaluate the accelerated stability of SS. **Materials and Methods:** Finished formulation of SS was packed in three airtight transparent polyethylene terephthalate containers. One pack was analyzed just after manufacturing and remaining two packs were kept in stability chamber at 40°C ± 2°C/75% ± 5% 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 showed no significant change in accelerated stability condition. All physico-chemical parameters showed changes <5%, HPTLC fingerprinting showed minimum changes and microbial studies were in confirmation to the World Health Organization guidelines. **Conclusion:** SS 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 SS may last 20 months.

Key words: Accelerated stability study, shelf life, *Sufoofe Sailan*, Unani system of medicine

Introduction

Sufoof (powder) is an intimate mixture of dry finely divided drugs, chemicals which have been triturated and sieved and may be intended for internal or external use. In view of their greater specific surface area *Sufoof* disperse and dissolve more readily than compacted dosage forms.[1] However, at the same time major drawbacks are in its stability, in comparison to other oral solid dosage forms. *Sufoof* is predisposed to various changes in physico-chemical properties and gives rise to microbiological growth as well that result in its degradation and decomposition. These changes can reduce the efficacy of the drug and may be hazardous for health if consumed. Apart from chemical reaction problems; changes in organoleptic characters such as cohesion, crystal growth, moisture absorption, etc., may cause lumping of powders that lead to degradation.[2] These changes all together can have a serious impact on the pharmacological effect, as well as on patient compliance.

Address for correspondence: Dr. Seema Rani, Department of Ilmul Saidla, National Institute of Unani Medicine, Kottegepalya, Magadi Main Road, Bengaluru - 560 091, Karnataka, India.
E-mail: seema.malik786@gmail.com

Many Unani physicians have mentioned the shelf life of *Sufoof*. According to Arzani, *Sufoof* has the shelf life of 3 months[3] while others have mentioned the shelf life of *Sufoof* up to one year.[4] As per the Drugs and Cosmetics Rules, 1945, rule 161B (Amendment, dated 24 November, 2005) the shelf life of *Sufoof* is 2 years and of *Sufoof* containing *Namakiyat* (salt) as 1-year.[5] On the other hand, National Formulary of Unani Medicine (NFUM) states that the stability of *Sufoof* containing *Maghziyat* (kernels) is <6 months.[6] All these comments about the stability of *Sufoof* are empirical and need to be scientific. Therefore, it is very essential to establish the shelf life of a *Sufoof* by stability studies on modern scientific parameters.

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Unani formulation, *Sufoofe Sailan* (SS) is used to treat *Sailanur Rahem* (leucorrhea), *Uqr* (sterility), *Surate Inzal* (premature ejaculation), etc.[6] This formulation is easily affected by the environmental factors and usually spoils soon with time. As till date no study was conducted to establish the shelf life of SS, the present study was conducted to develop the method and evaluate shelf life through accelerated stability testing.

Materials and Methods

Procurement of raw drugs

All plant materials used for the formulation of SS were purchased from the raw drug trader during February to July 2013. All the plant materials were confirmed, and a sample of each plant material used was submitted to the drug museum, with voucher specimen no. 19/IS/Res./2014, for future reference. *Gule Dhawa* (*Woodfordia fructosa* L. Kurz.) and *Gule Fofal* (*Areca catechu* L.) were further certified by Herbarium curator, Department of Botany, and specimen was deposited in their museum with accession number 2968 and 2969, respectively.

Preparation of *Sufoofe Sailan*

As *A. catechu* flower was purchased in fresh form, dried in hot air oven at 60°C for 2 h. All plant material were stored in airtight glass containers. All ingredients were rinsed with running tap water, and shade dried at 60°C in hot air oven prior to use. All ingredients were powdered separately in the electric grinder and sieved through no. 80 mesh. These powdered ingredients were weighed separately in the ratio mentioned in NFUM and mixed rigorously in an electric kitchen mixer to get homogenous powder [Table 1].[6]

Storage

Container closure system of 250 ml capacity, made up of transparent polyethylene terephthalate, procured from the local market was used for storage purpose. About 200 g of drug formulation was filled into the container, covered with aluminum foil and tightly closed with red polypropylene threaded cap. Precautions were taken while packaging these samples.

Methodology of accelerated stability testing

The formulation was filled with three packs 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°C ± 2°C with relative humidity (RH) 75% ± 5%. Total three packs were analyzed for the stability evaluation of SS. One pack 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 OPSH G-4 1258 with temperature ranges of 5–60°C with resolution +0.1°C, accuracy of ±0.2°C, and uniformity of ±1°C) for thermal/humidity challenge. The second pack was removed from stability chamber at the completion of a 3rd month, and the third pack was opened at the completion of 6 months and analyzed.

Table 1: Ingredients of *Sufoofe Sailan*

Drug name	Botanical name	Part used	Proportion (%)
Gule dhawa	*Woodfordia fructosa* L. Kurz.	Flower	12.5
Gule fofal	*Areca catechu* L.	Flower	12.5
Mochras	*Bombax malabaricum* Dc.	Gum	12.5
Gond molsri	*Mimusops elengi* L.	Gum	12.5
Nabat safaid	Sugar	Crystals	50

Analytical parameters

Organoleptic characters such as color,[7] odor,[8] and taste[9] were assessed on all packs. Physico-chemical analysis was done by testing loss on drying, total ash, acid insoluble ash, water soluble ash, pH of 1% and pH of 10% solution, extractive values[10] bulk and tapped density, Hausner's ratio, compressibility index,[11] total alkaloids,[12] total glycosides,[13] and total tannins.[14]

Qualitative densitometric high-performance thin layer chromatography (HPTLC) fingerprinting was carried out to evaluate the changes in SS. Water and dichloromethane (1:1) extract of SS was used for TLC application. The analysis was performed on 2.5 cm × 10 cm silica gel 60 F_{254} 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) 200 nm, 254 nm, and 366 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.[14]

SS 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*.[15]

Results

SS prepared as per the method described in NFUM and tested for organoleptic characters, various physico-chemical parameters and microbial lode at 0, 3, and 6 months at accelerated stability conditions. Overall, insignificant difference in organoleptic characters at 0, 3, and 6 months were observed. Overall changes in different physico-chemical parameters were also <5% till the end of 6 months, while microbial analysis was in confirmation to World Health Organization (WHO) guidelines [Tables 2-5].

Discussion

Organoleptic parameters

Finished product of SS was light brown (7.5YR5/6), odorless, pleasant and sweet, solid/hard powder without any clumping, and did not show any significant change in their organoleptic characteristics in accelerated thermal/humidity conditions. Alteration in color usually occurs due to pH changes or light exposure.[16] 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.

Table 2: Organoleptic and physico-chemical analysis *Sufoofe Sailan*

Parameter	0 month	After 3rd month	After 6th month
Organoleptic characters			
Appearance	Solid powdered	Solid powdered	Solid powdered
Color	Light brown/7.5YR5/6	Light brown/7.5YR5/6	Light brown/7.5YR5/6
Odor	Odorless	Odorless	Odorless
Taste	Sweet and pleasant	Sweet and pleasant	Sweet and pleasant
Physical characters			
Bulk density (g/ml)	0.48±0.01	0.45±0.02	0.48±0.01
Tapped density (g/ml)	1.29±0.01	1.31±0.01	1.31±0.00
Hausner's ratio	0.63±0.009	0.60±0.04	0.63±0.02
Compressibility index (%)	23±1.0	23.25±0.75	24±2.0
LOD* (%)	4.7±0.03	4.76±0.02	4.85±0.01
Ash value (%)			
Total ash	2.57±0.02	2.53±0.01	2.47±0.01
Acid insoluble	1.19±0.00	1.15±0.00	1.14±0.02
Water soluble	0.77±0.01	0.75±0.01	0.76±0.02
Chemical characters			
pH 1% solution	4.76±0.00	4.85±0.00	4.86±0.00
pH 10% solution	5.23±0.00	5.25±0.00	5.31±0.00
Extractive value (%)			
Aqueous	22.18±0.09	21.13±0.38	22.12±0.17
Alcohol	10.32±0.04	10.16±0.08	10.08±0.05
Petroleum ether	0.45±0.01	0.43±0.014	0.43±0.02
Chloroform	1.19±0.02	1.18±0.01	1.14±0.01
Secondary metabolites (%)			
Alkaloids	2.58±0.00	2.55±0.01	2.50±0.01
Glycosides	0.72±0.01	0.71±0.00	0.70±0.00
Tannins	10.39±0.03	10.31±0.01	10.22±0.02

All values are presented as±SEM, *Loss of weight on drying. SEM: Standard error of the mean, LOD: Loss on drying

Table 3: Total bacterial and fungal count in drug samples of ACS

Sample (month)	Total bacterial count(cfu/g/ml)	WHO limit	Total fungal count (cfu/g/ml)	WHO limit	Inference
0	30,000	10^5/g	20	10^3/g	Within limit
3	4000	10^5/g	1	10^3/g	Within limit
6	70,000	10^5/g	120	10^3/g	Within limit

WHO: World Health Organization, ACS: Accelerated stability study sample

Table 4: Presence of pathogenic bacteria in ACS

Sample (month)	*Escherichia coli*	*Salmonella*	*Staphylococcus aureus*	*Pseudomonas aeruginosa*
0	Absent	Absent	Absent	Absent
3	Absent	Absent	Absent	Absent
6	Absent	Absent	Absent	Absent

ACS: Accelerated stability study sample

Organoleptic characters such as *Rang* (color), *Boo* (smell), *Maza* (taste), *Saakht* (structure), *Vazan* (weight), *Sifat* (properties), *Safai* (clarity), *Jila* (cleanliness), and *Tazgi* (freshness), etc., were the only tool in ancient period used by Unani scholars to evaluate the stability and shelf life of single or compound formulations. Until afore mentioned characters of the drug were in predefined order, it was considered that shelf life is maintained, and any changes were attributed to the loss of its shelf life.[17]

However, only organoleptic characters are not enough to prove the shelf life in the contemporary era to meet the quality standards of herbal drugs and formulations as chemical degradation ordinarily cannot be detected by the naked eye examination. Only excessive chemical degradation occasionally is accompanied by observable physical changes. In addition, some physical changes not necessarily related to chemical potency. Thus, commonly

Table 5: *Rf* and color of bands of ACS at 0, 3, and 6 months study under UV 254 nm, 366 nm and after spraying anisaldehyde sulfuric acid and number of peaks, peak area, and height at 200 nm

Day	Under UV 254 nm		Under UV 366 nm		After spraying anisaldehyde sulfuric acid		Number of peaks at 200 nm and their peak area and height			
	Rf	Color	*Rf*	Color	*Rf*	Color	Number of peaks	*Rf*	Area	Height
0 month	0.04	Dark	0.05	Purple	0.04	Green	12	0.04	10,034.43	544.60
	0.11	Light	0.09	Brown	0.07	Blue		0.09	8342.76	523.45
	0.17	Light	0.15	Blue	0.17	Blue		0.11	6221.90	487.23
	0.22	Dark	0.18	Blue	0.19	Orange		0.17	5984.38	421.35
	0.27	Dark	0.26	Brown	0.23	Yellow		0.26	4320.97	400.18
	0.32	Light	0.35	Blue	0.32	Brown		0.32	4007.31	390.32
	0.46	Light	0.40	Orange	0.36	Blue		0.40	3456.74	287.43
	0.51	Dark	0.45	Yellow	0.41	Purple		0.46	3458.53	220.10
	0.62	Light	0.55	Blue	0.48	Blue		0.55	2513.10	127.23
	0.69	Dark	0.63	Brown	0.67	Black		0.62	1854.12	104.21
			0.68	Orange				0.79	604.72	18.91
			0.89	Brown				0.89	431.56	16.23
3rd month	0.04	Dark	0.05	Purple	0.04	Green	12	0.04	10,021.32	512.26
	0.17	Light	0.07	Red	0.07	Blue		0.09	7869.62	493.14
	0.22	Dark	0.12	Purple	0.19	Orange		0.11	6221.90	487.23
	0.27	Dark	0.15	Blue	0.23	Yellow		0.17	5984.38	421.35
	0.32	Light	0.18	Blue	0.32	Brown		0.26	4320.97	400.18
	0.51	Dark	0.26	Brown	0.36	Blue		0.32	4007.31	390.32
	0.62	Light	0.35	Blue	0.41	Purple		0.40	3458.74	287.43
	0.69	Dark	0.40	Orange	0.48	Blue		0.46	3408.53	220.10
	0.79	Light	0.45	Yellow	0.67	Black		0.55	2513.10	127.23
			0.50	Brown	0.85	Purple		0.62	1854.12	104.21
			0.55	Blue				0.69	1563.87	84.94
			0.63	Brown				0.79	604.72	18.91
			0.79	Purple						
			0.84	Red						
6th month	0.04	Dark	0.05	Purple	0.04	Green	10	0.04	10,021.32	512.26
	0.17	Light	0.09	Brown	0.07	Blue		0.09	7869.62	493.14
	0.22	Dark	0.15	Blue	0.19	Orange		0.11	6221.90	487.23
	0.27	Dark	0.18	Blue	0.23	Yellow		0.17	5984.38	421.35
	0.51	Dark	0.26	Brown	0.41	Purple		0.26	4320.97	400.18
	0.62	Light	0.40	Orange	0.48	Blue		0.40	3397.43	273.02
	0.69	Dark	0.50	Brown	0.67	Black		0.46	3408.53	220.10
			0.55	Blue	0.72	Brown		0.55	2513.10	127.23
			0.63	Brown	0.85	Purple		0.62	1854.12	104.21
			0.68	Orange				0.79	604.72	18.91
			0.71	Blue						
			0.84	Red						

UV: Ultraviolet, ACS: Accelerated stability study sample

it should be assumed that a product that has undergone a physical change not explained in the labeling may also have undergone a chemical change, and such products should not be dispensed.[18]

WHO, Ministry of AYUSH, and other food and drug regulatory agencies mentioned that the 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 this product's shelf life.

Physico-chemical parameters

Bulk and tapped density

In this study, the percentage change in bulk density, tapped density, Hausner's ratio, and compressibility index were <5% [Table 2], thus, it is in confirmation to the International Conference on Harmonization (ICH) guideline for stability studies.[19]

It is mentioned that Hausner's ratio and compressibility index are the simple, fast, and popular method of powder flow

characteristics. The flow characteristics of solid particulate depend on the size, shape, size distribution of particles, and moisture content. The increase in the moisture content of a powder decreases its ability to flow smoothly due to the increased thickness of the adsorbed liquid layer, which increases the strength of liquid bridges formed between particles.[20]

Aulton discussed that Hausners ratio of <1.25 indicates good flow, whereas >1.5 indicate poor flow.[21] According to the scale of flowability, compressibility index and Hausner's ratio of test drug formulation lies between 21–25 and 1.26–1.34, respectively, means it have a passable flow character.[22]

Loss on drying

The percentage of change of weight loss on drying from 0 month was 1.34%, and 3.19% at 3 and 6 months, respectively, which showed that there was no significant change in moisture content. Probably, moisture content did not vary as this formulation was subjected to stability chamber in airtight containers, which were of good standard quality and prevent moisture adsorption.

The presence of excessive amount of water in plant drugs causes hydrolysis of constituents, other biochemical reactions and the growth of bacteria and fungi. However, the water content in plant drugs can vary between 8% and 14%.[23] It was assumed that the test drug contain very less amount of water, hence there was no significant physico-chemical changes and microbial growth.

Ash values

The percentage change of total ash, acid insoluble, and water soluble ash value at 3 and 6 months was 1.55%, 2.85%, 2.97% and 3.76%, 4.20%, 1.29%, respectively, in accelerated stability condition from 0 month. As these changes were <5%, it confirms to the ICH guideline.[24]

pH values

In the present study in all samples, pH was between 4.7 and 5.31 only. Percentage change in pH of 1% solution from 0 to 3 and 6 months was 1.93% and 2.16%, respectively. Percentage change in pH of 10% solution from 0 to 3 months and 6 months was 0.31% and 1.52%, respectively. As these changes were below 5%, to be considered as insignificant as per the ICH guidelines.

The pH value is one of the main factors influencing the quality of medicine. It controls many chemical and microbiological reactions. Researcher found that when the pH value is low (presence of acidic substances), the bacterial count could be low whereas at neutral or higher pH the level of contamination of the herbal preparations could observed to be higher. This suggests that a neutral or alkaline pH favors high contamination levels of the herbal preparations.[25] As the pH of the test formulation was 5.31 or less and microbial count was also within the normal limit as per WHO guidelines, it is in accordance with the observations of previous research work.[25]

Extractive values

The percentage change at 6 months from 0 month in aqueous, alcoholic, pet ether, and chloroform extractive values of samples were 0.27%, 2.32%, 4.44%, and 4.20%, respectively.

Secondary metabolites

The percentage change in total alkaloid from 0 month was 1.16% and 2.96% at 3 and 6 months, respectively. Percentage change in total glycoside at 0–3 months was 0.92%, and 0–6 months it was 2.76%. Percentage change in total tannin was 0.83% at 0–3 months and 1.66% at 0–6 months. As all these changes in the quantitative estimation of secondary metabolites were not more than 5%, it confirms to ICH stability guideline.

High-performance thin layer chromatography

Rf values and color of bands under 254 nm, 366 nm and after spraying anisaldehyde sulfuric acid analyzed are shown in Figures 1-6, and different samples were compared under UV 200 nm for numbers of peaks, peak area, and peak height

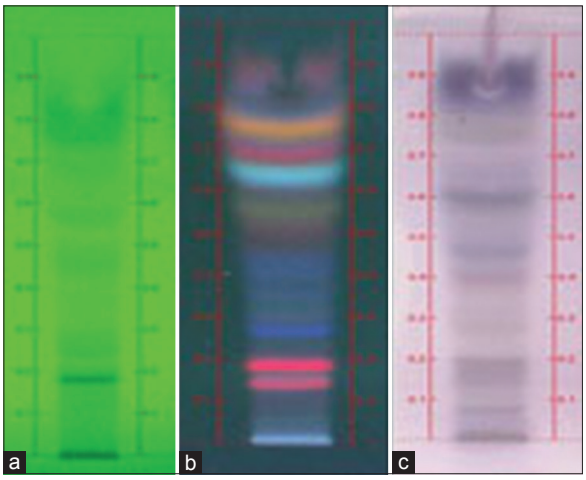

Figure 1: High-performance thin layer chromatography of *Sufoofe Sailan* at 0 month of accelerated stability study sample (a) under UV 254 nm, (b) under UV 366 nm, (c) derivatized with anisaldehyde sulfuric acid under white light

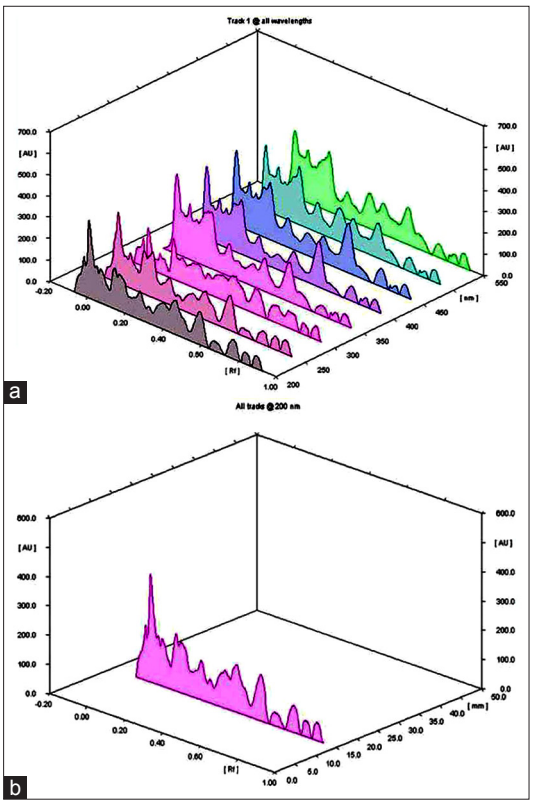

Figure 2: High-performance thin layer chromatography densitometric scan of *Sufoofe Sailan* at 0 month (a) at multiple wave length, (b) at ultraviolet 200 nm

which are summarized in Table 5, and graphical presentation of densitometric scan is shown in Figures 1-6.

HPTLC study of accelerated stability study samples showed that they were not identical as some new peaks appeared, and some peaks were missing in later day's sample, however, no major changes were observed. Yet, it is advisable to identify the missing peaks to confirm whether they were of the pharmacologically active component and likewise new peaks should be identified as it may be the toxic substance.

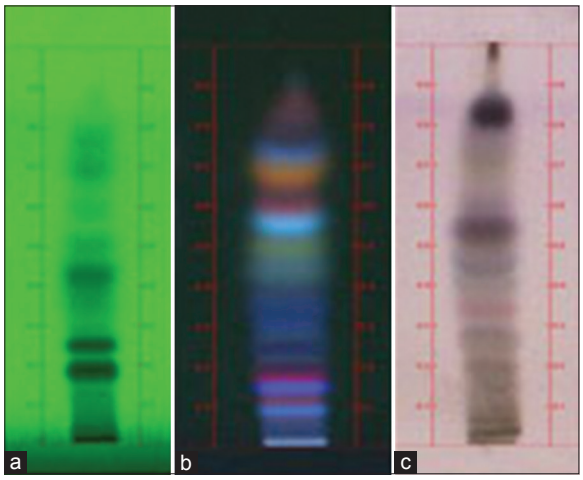

Figure 3: High-performance thin layer chromatography of *Sufoofe Sailan* at 3 month of accelerated stability study sample (a) under UV 254 nm, (b) under UV 366 nm, (c) derivatized with anisaldehyde sulfuric acid under white light

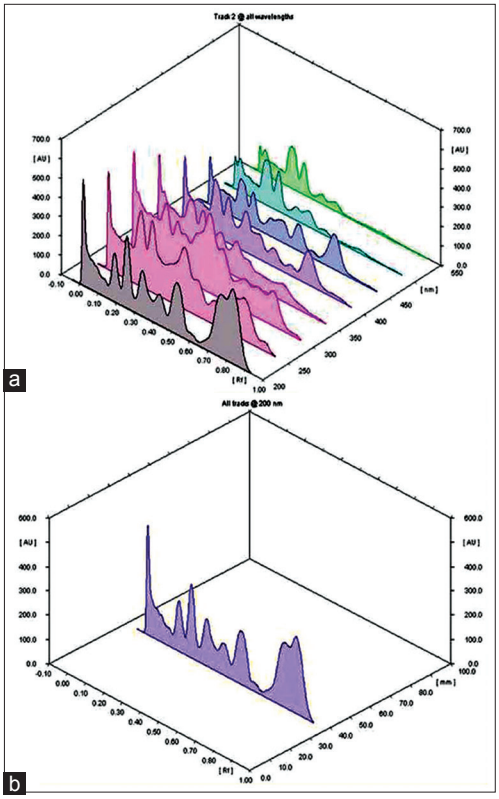

Figure 4: High-performance thin layer chromatography densitometric scan of *Sufoofe Sailan* at 3rd month (a) at multiple wave length, (b) at ultraviolet 200 nm

Microbial analysis

Total bacterial count was 30000 cfu/g/ml at 0 month, 4000 cfu/g/ml at 3rd month, and 70,000 cfu/g/ml at 6th month. Total fungal count was 20 cfu/g/ml, 1 cfu/g/ml, and 120 cfu/g/ml at 0, 3, and 6 months, respectively. Further pathogenic bacteria that is, *E. coli*, *Salmonella*, *S. aureus*, and *P. aeruginosa* were absent in the present study samples. Thus, all packs confirm to the microbial standards set by WHO,[26] API,[27] and other guidelines [Table 4]. The drop in total bacterial and fungal count from 0 to 3 months was possibly due to thermal condition

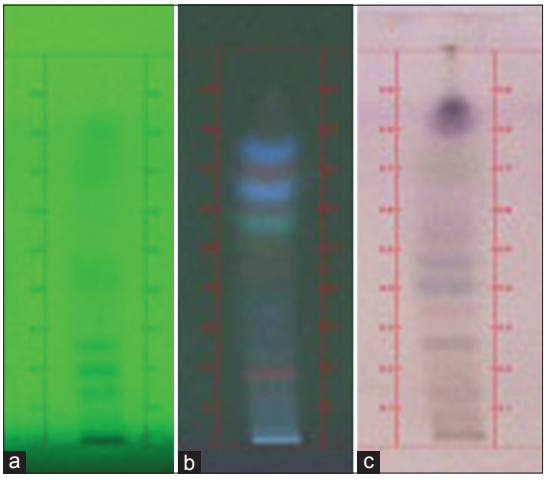

Figure 5: High-performance thin layer chromatography of *Sufoofe Sailan* at 6 month of accelerated stability study sample (a) under UV 254 nm, (b) under UV 366 nm, (c) derivatized with anisaldehyde sulfuric acid under white light

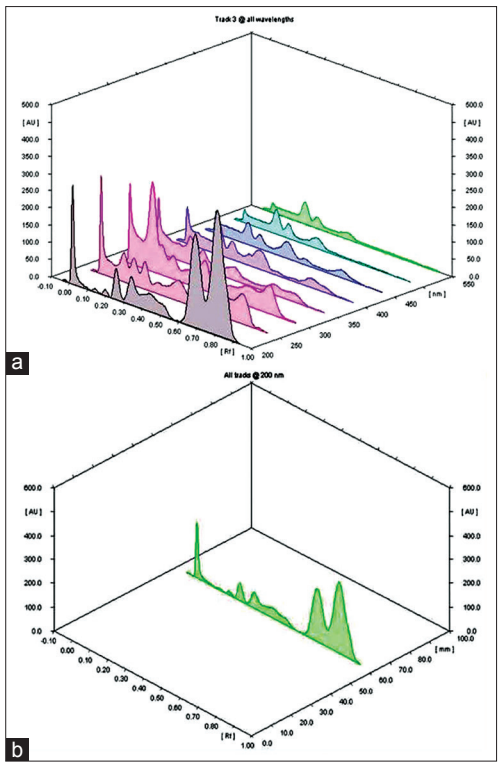

Figure 6: High-performance thin layer chromatography densitometric scan of *Sufoofe Sailan* at 6th month (a) at multiple wave lengths (b) at ultraviolet 200 nm

of stability chamber because of which microbes may die further increase in microbial count during 3–6 months may be due to the growth from spores, which are usually difficult to die in comparison to the fully grown microbes. However, this total bacterial and fungal count were under the limits set by WHO.

Micro-organisms require readily accessible water in appreciable quantities for growth.[28] Researcher established that only moisture does not have a significant effect, but the water activity is the key to determine if microorganisms will grow or not.[29] Drying at a specific temperature decreases the total microbial count in plant material as it lowers the water activity.[30] In the present study, before preparing the formulation, raw drugs were rinsed with running drinking water for few minutes, dried at 60°C stored in airtight containers, and all precautions were taken to avoid contamination during processing. Thus, the finished samples had very low moisture (4–5%). Further, the pH of samples was ranging from 4.7 to 5.31. Probably these factors played an important role in keeping total microbial lode in the prescribed limit.

To confirm the shelf life/stability of product, change in the assay from its initial value should not vary more than 5% and meet the acceptance criteria such as appearance, physical, and chemical attributes, etc., However, even 90% of labeled potency is commonly considered as the minimum acceptable potency level.[31] In the present study, to assess the physico-chemical parameters of the test drug formulation, 5% variation limit was fixed, that is, as per the ICH guidelines.

It has been proposed that 3 months at 40°C/75% RH is roughly equivalent to 24 months at room temperature (25°C).[32] According to this rule, it can be affirmed that SS will be stable for 4 years at room temperature. According to the "Shelf life Recommendations for Supplements Guidelines for Manufacturers," if a study was carried out at 10°C temperature above the ambient temperature, an estimate of shelf life equals to × 2 accelerated storage time.[5] As the formulation was tested at 40°C temperature, which is 10°C above the room temperature, that is, 30°C/70% RH (climatic zone IV-for India), and the accelerated storage time was 6 months. Hence, as per this regulation SS will be stable for 1-year.

However, the most popular concept in this regard is Grimm's statement. Grimm mentioned that, predictive factor for zone IV was 3.3 of the accelerated study period. It means if the product is stable for 6 months at 40°C/75%RH, its shelf life will correspond to 20 months at 30°CC/70% RH (climatic zone IV).[33]

As per the Drug and Cosmetics Rules, 1945, rule 161B (Amendment, dated November 24, 2005) the shelf life of all *sufoof* are 2 years,[5] which is near to the shelf life calculation carried out according to Grimm's statement (i.e. 20 months).

Thus, in the view of above interpretations, it can be safely affirmed that SS has the shelf life of 20 months at room temperature. However, ICH Harmonised Tripartite Guideline regarding the evaluation for stability data mentioned that if no significant change at accelerated condition is found the retest period or shelf life would depend on the nature of the long-term data.[34]

Strength

This is the first of its kind of study, where SS was evaluated under accelerated stability storage condition. Organoleptic and physico-chemical, microbiological parameters, as well as HPTLC fingerprinting, was carried out in this study, to evaluate the stability/shelf life of the test drug formulation.

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.

Conclusion

Accelerated stability study of *Sufoofe Sailan* showed that there was no considerable variation in the formulation at 3rd and 6th month when compared with 0 month sample in all the parameters tested. Organoleptic characters were acceptable. The percentage of change at 6 months in physico-chemical parameters were <5%, and the total microbial count was within the limit offered by WHO. Thus, SS confirms to the ICH Harmonised Tripartite Guideline for accelerated stability testing of the pharmaceutical product. As per the Grimm's statement, the shelf life of SS was calculated 20 months at room temperature. However, additional long-term or real-time stability study should also be carried out.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

यूनानी योग सुफूफे सैलान की त्वरित स्थिरता का अध्ययन

सीमा रानी, खलीकुर रहमान, पीरजादा मोहम्मद यूनीस

सुफूफे सैलान यूनानी चिकित्सा में स्त्री रोगों के इलाज के लिए एक ज्ञात दवा है। अवलोकन से देखा गया है कि सुफूफे सैलान बहुत जल्द खराब हो जाता है क्योंकि यह दवा चूर्ण के रूप में उपलब्ध है। सुफूफे सैलान की स्थिरता का अध्ययन आज तक नहीं किया गया था, इसलिए वर्तमान अध्ययन का उद्देश्य सुफूफे सैलान के त्वरित स्थिरता का मूल्यांकन करना था। इस परीक्षण में तैयार सुफूफे सैलान तीन पात्रों में भरा गया जो हवा बंद पारदर्शी पॉलीइथीलीन टेराफ्थेलेट से निर्मित थे। एक पात्र की दवा का तैयारी के तुरंत बाद विश्लेषण किया गया और शेष दो पात्रों को ४०+२° सेंटीग्रेड तापमान और ७५+५% आर्द्रता (आर.एच.) पर स्थिरता कक्ष में रखा गया। इन दो पात्रों का तीन महीने और छह महीने के बाद विश्लेषण किया गया। विश्लेषण में आरगनोलेपटिक, भौतिक–रासायनिक, एच.पी.टी.एल.सी. फिंगर प्रिंटिंग के साथ सूक्ष्मजीवविज्ञानी मापदंडों में परिवर्तन का मूल्यांकन किया गया। आरगनोलेपटिक विशेषता पर त्वरित स्थिरता हालत में कोई महत्वपूर्ण परिवर्तन नहीं दिखा। सभी भौतिक–रासायनिक मापदंड, एच.पी.टी.एल.सी. फिंगर प्रिंटिंग और माइक्रोबियल अध्ययन दवा उत्पाद के अंतर्राष्ट्रीय सम्मेलन और विश्व स्वास्थ्य संगठन के दिशानिर्देश के मापदंडों की पुष्टि में थे। दवा में परिवर्तन ५% से कम देखा गया। इस प्रकार ग्रिम के अनुशंसा के अनुसार यह पुष्टि होती है कि सुफूफे सैलान का जीवन २० महीने है।