Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 14 (1), 2023; 239-243

Evaluation of Accelerated Stability study of KVGAP'S Nutricare powder - An Ayurvedic Neutraceutical Product

Research Article

Purushotham KG[1], Shruthan K[2*], Harshitha M[3], Pavana KB[2], Nayak N Gopalakrishna[2], Rathan Kumar KT[4]

1. Professor and Head, 2. Assistant Professor, 3. Professor,
Department of Rasashastra and Bhaishajya Kalpana, KVG Ayurveda Medical College and Hospital,
4. Analytical Chemist, KVG Ayurveda Pharma and Research Centre,
Ambatedaka, Sullia, Karnataka. India.

Abstract

Accelerated stability study of KVGAP'S Nutricare Powder was conducted as per the standard guidelines. 3 pilot batches of KVGAP'S Nutricare Powder were manufactured in KVG Ayurveda Pharma and Research centre, Sullia by following methods and procedures used for commercial scale production batches. Samples were stored at accelerated temperature 40 ± 2°C and relative humidity 75 ± 5%. The reference samples for the above study were stored at a temperature less than 10°C. The samples were withdrawn from the stability chamber at the intervals of 0, 3, and 6 months and evaluated for organoleptic characters, physicochemical parameters, TLC, microbial analysis, test for specific pathogen. Results showed no significant change in odor, taste and appearance of Nutricare Powder after storing for 6 months under accelerated conditions. Physicochemical profiles (moisture content, total ash, acid-insoluble ash, *p*H, water- soluble extractive, alcohol-soluble extractives and acid-insoluble ash,) of the samples during the study period of 6 months didn't show much difference. Microbiological analysis of the samples showed no signs of microbial growth and specific pathogens were absent in all the samples. After extrapolating the data, shelf life of Nutricare Powder (Reference samples) was found to be 6.12 years and accelerated study samples were found to be 4.49 years. Thus, it can be established that Nutricare Powder is having shelf life of 4.49 years and product remains stable in accelerated temperature conditions.

Key Words: Accelerated stability study, KVGAP'S Nutricare Powder, Shelf life.

Introduction

Stability study of Ayurvedic proprietary medicines is mandated by regulatory agencies, thus compelling the Ayurvedic pharma industry to perform the stability testing for their proprietary medicines. Objective of stability study is to ensure better customer reliance of the products by ensuring the quality, efficacy and safety of the products throughout its shelf life and also to determine the shelf life of the products. The stability depends on various factors like the nature of the product, the ingredients of the products, the packaging material etc. Stability studies are carried out to demonstrate that the medicine will remain suitable for consumption during shelf period when stored under the condition(s) mentioned on the packaging. The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of variety of environmental factors such as temperature, humidity and light, to establish a retest period for drug substance or a shelf life for drug products.(1). Considering these factors, accelerated stability testing of KVGAP'S Nutricare Powder was conducted as per the guidelines of Ayurvedic Pharmacopeia of India Part 1 , Vol 8 and laboratory guide for the analysis of Ayurveda and Siddha formulations.(2,3) KVGAP'S Nutricare Powder is an natural nutritional supplement manufactured in KVG Ayurveda Pharma and Research centre. It contains following ingredients: *Godhuma, Rajika, Ela, Shatpushpa, Marica, Jeeraka, Shunti and Twak*. It was advised to consume KVGAP'S Nutricare Powder as a Drink prepared by boiling One tea spoon of powder in 1 cup of milk. It is indicated as Nutritive and carminative.

*** Corresponding Author:**

Shruthan K
Assistant Professor,
Department of Rasashastra and Bhaishajya Kalpana,
KVG Ayurveda Medical College and Hospital,
Ambatedaka, Sullia. Karnataka. India.
Email Id: kshruthan @gmail.com

Methodology

Test drug

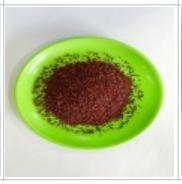
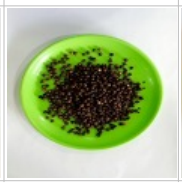
KVGAP'S Nutricare Powder was manufactured in KVG Ayurveda Pharma and Research Centre, Ambatedaka, Sullia adhering to strict GMP guidelines.

Table No 1: Showing Ingredients, Parts used, Quantity of ingredients of KVGAP'S Nutricare powder

Each 5 gm of KVGAP'S Nutricare Powder contains :

SL No	Botanical Name - Sanskruth Name	Part Used	Qty	UoM
1	*Triticum sativa - Godhuma*	Seed	3588.5100	mgm
2	*Elusine coracana - Ragika*	Seed	717.7000	mgm
3	*Eletteria cardomom - Ela*	Seed	119.6100	mgm
4	*Anethum sowa - Shatapushpa*	Seed	239.2300	mgm
5	*Piper nigrum - Maricha*	fruit	119.6100	mgm
6	*Cuminum cyminum - Jeeraka*	fruit	71.7700	mgm
7	*Zingiber officinale - Shunti*	Rhizome	71.7700	mgm
8	*Cinnamomum Zeylanicum - Twak*	Stem bark	71.7700	mgm

Fig 1: Showing Ingredients of KVGAP'S Nutricare Powder

Godhuma	*Rajika*	*Ela*	*Shatapushpa*	*Marica*	*Jeeraka*	*Shunti*	*Twak*
							

Selection of batches

3 pilot batches of KVGAP'S **Nutricare Powder** were manufactured by following methods and procedures used for commercial scale production batches. Pilot batches were manufactured at 1/10th of the commercial batch size. The overall quality of the pilot batches were representative of the commercial batches.

Container and Closure system

The stability studies were conducted on the dosage form packaged in the container and closure system proposed for marketing (including as appropriate, any secondary packaging and container).

Storage Conditions

The accelerated stability study was conducted as per the ICH guidelines. The samples are stored in stability chambers and temperature maintained during the study period was 40 ± 2 °C, while the relative humidity was 75 ± 5%.

The reference samples for the above study were stored at a temperature less than 10⁰c.

Frequency of withdrawal of the Sample

The samples were withdrawn from the stability chamber at the intervals of 0, 3, and 6 months and evaluated for relevant parameters.

Parameters for Evaluation Organoleptic characters

- Color
- Odor
- Taste
- Appearance

Physicochemical parameters

- *p*H (4)
- Moisture content/ loss on drying (5)
- Total ash (6)
- Acid insoluble ash (7)
- Water soluble extractive (8)
- Alcohol soluble extractive (9)

TLC (10)

Microbial analysis (11)

- Total viable aerobic count
- Total fungal count
- Total Enterobacteriaceae count

Test for specific pathogen (12)

- Staphylococcus aureus
- Escherichia coli
- Pseudomonas aeruginosa
- Salmonella Species

Results

Table No.2: Showing Physicochemical parameters of KVGAP'S Nutricare Powder: Reference Samples

Parameters	0 Month			%	S.D (+-)	S.E (+-)	t value	p value	Remarks
PH	5.96	3 months	5.99	-0.45	0.096	0.068	-0.48	**>0.05**	**NS**
		6 months	5.33	10.51	0.124	0.088	8.74	**<0.05**	**S**
Moisture content/ loss on drying	1.39	3 months	2.38	41.75	0.593	0.419	2.90	**<0.05**	**S**
		6 months	1.90	26.91	0.540	0.382	1.64	**>0.05**	**NS**
Total ash	1.97	3 months	2.30	14.34	0.737	0.521	0.77	**>0.05**	**NS**
		6 months	2.71	27.32	0.549	0.388	2.33	**>0.05**	**NS**

Acid insoluble ash	0.56	3 months	0.44	21.85	0.289	0.204	0.48	**>0.05**	**NS**
		6 months	0.68	21.37	0.488	0.345	-0.42	**>0.05**	**NS**
Water soluble extractive	10.79	3 months	10.05	6.80	0.300	0.212	0.71	**>0.05**	**NS**
		6 months	7.73	28.31	1.466	1.036	3.61	**<0.05**	**S**
Alcohol soluble extractive	6.43	3 months	5.36	16.60	1.891	1.337	0.95	**>0.05**	**NS**
		6 months	3.61	43.78	0.824	0.583	5.91	**<0.05**	**S**

Table 03: Showing Physicochemical parameters of KVGAP'S Nutricare Powder: Accelerated temperature samples

Parameters	0 Month			%	S.D (+-)	S.E (+-)	t value	p value	Remarks
PH	5.96	3 months	5.30	11.07	0.110	0.08	11.37	**<0.05**	**S**
		6 months	5.50	7.72	0.195	0.14	3.98	**<0.05**	**S**
Moisture content/ loss on drying	1.39	3 months	2.34	69.03	0.250	0.18	2.96	**<0.05**	**S**
		6 months	1.90	36.81	0.844	0.60	1.45	**>0.05**	**NS**
Total ash	1.97	3 months	2.11	7.42	0.440	0.31	0.51	**>0.05**	**NS**
		6 months	2.71	37.58	0.724	0.51	2.02	**<0.05**	**S**
Acid insoluble ash	0.56	3 months	0.69	23.51	0.849	0.60	0.33	**>0.05**	**NS**
		6 months	0.51	8.45	0.756	0.53	0.14	**>0.05**	**NS**
Water soluble extractive	10.79	3 months	9.23	14.40	1.709	1.21	1.69	**<0.05**	**S**
		6 months	8.43	21.82	1.530	1.08	2.34	**<0.05**	**S**
Alcohol soluble extractive	6.43	3 months	1.97	69.29	1.967	1.39	4.70	**<0.05**	**S**
		6 months	6.43	0.00	2.724	1.93	0.00	**0.00**	**NS**

Table No. 04: Showing comparative result of physicochemical parameters of KVGAP'S Nutricare Powder

Parameters	Reference Samples Group A	Accelerated Samples Group B	SE	T Value
pH	5.76	5.59	0.045	5.132
Moisture content/ loss on drying	1.89	1.88	0.211	0.057
Total ash	2.32	2.26	0.174	0.415
Acid insoluble ash	0.56	0.59	0.152	-0.235
Water soluble extractive	9.52	9.48	0.036	0.073
Alcohol soluble extractive	5.13	4.94	0.553	0.385

Chart No. 01: Physicochemical parameters of KVGAP'S Nutricare Powder: Reference Sample

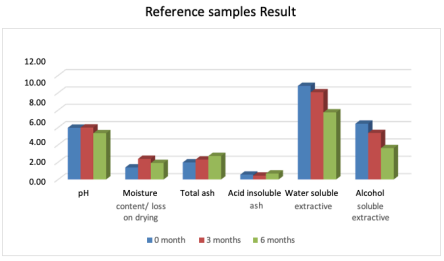


Chart No. 02: Showing Physicochemical parameters of KVGAP'S Nutricare Powder Accelerated temperature samples

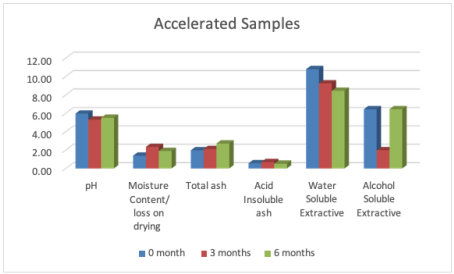
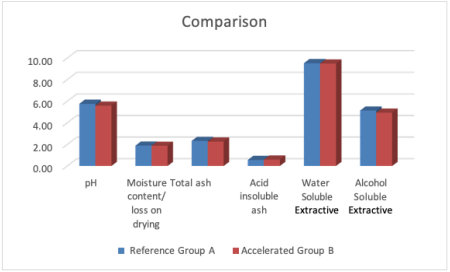


Chart No. 03: Showing Comparison of Physico-chemical parameters of KVGAP'S Nutricare Powder



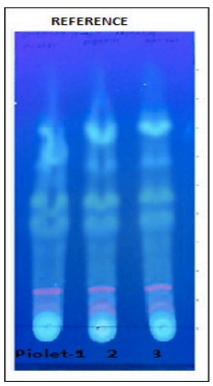
TLC

Solvent of extraction:
Ethanol;

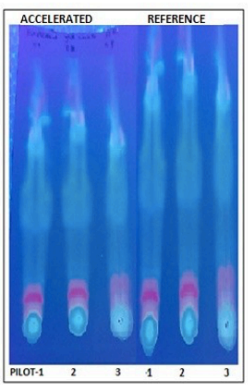
Mobile Phase:
Toluene: Ethyl acetate: Formic acid (8 : 2: 0.1);

Detection:
Under UV at 366nm;

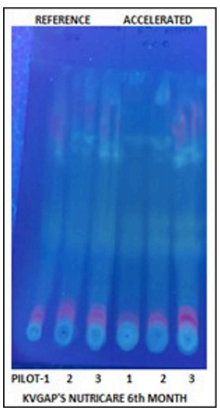
Applied volume:
20µl



KVGAP'S NUTRICARE - 0 MONTH



KVGAP'S NUTRI CARE- 3rd MONTH



KVGAP'S NUTRICARE 6th MONTH

Microbiology report of KVGAP'S Nutricare powder

Table No 05 : Showing the Microbial Analysis report of KVGAP'S Nutricare Powder (Reference samples)

Sl. No	Parameters	0 Month	3 months	6 months	Specifications	Test Method
1	Total viable aerobic count	NIL	NIL	NIL	$<10^5$ $cfug^{-1}$	API Part 1 vol 8, first edition 2011
2	Total fungal count	NIL	NIL	NIL	10^3 g-1	API Part 1 vol 8, first edition 2011
3	Total Enterobacteriaceae count	NIL	NIL	NIL	10^3 g-1	API Part 1 vol 8, first edition 2011

Table No 06: Showing the specific pathogens report of KVGAP'S Nutricare Powder (Reference Samples)

Sl. No	Parameters	0 Month	3 months	6 months	Specifications	Test Method
1	Staphylococcus Aureus	NIL	NIL	NIL	absent	API Part 1 vol 8, first edition 2011
2	Escherichia Coli	NIL	NIL	NIL	10 g^{-1}	API Part 1 vol 8 , first edition 2011
3	Pseudomonas aeruginosa	NIL	NIL	NIL	Absent	API Part 1 vol 8 , first edition 2011
4	Salmonella Species	NIL	NIL	NIL	Absent	API Part 1 vol 8 , first edition 2011

Microbiology Report of Accelerated study samples

Table No 07: Showing Microbial analysis report of KVGAP'S Nutricare powder (Accelerated Temperature Samples)

Sl. No	Parameters	0 Month	3 months	6 months	Specifications	Test Method
1	Total viable aerobic count	NIL	NIL	NIL	$<10^5$ $cfug^{-1}$	API Part 1 vol 8, first edition 2011
2	Total fungal count	NIL	NIL	NIL	10^3 g-1	API Part 1 vol 8, first edition 2011
3	Total Enterobacteriaceae count	NIL	NIL	NIL	10^3 g-1	API Part 1 vol 8, first edition 2011

Table No 08: Showing Specific pathogens report of KVGAPS Nutricare Powder (Accelerated Temperature Samples)

Sl. No	Parameters	0 Month	3 months	6 months	Specifications	Test Method
1	Staphylococcus Aureus	NIL	NIL	NIL	absent	API Part 1 vol 8, first edition 2011
2	Escherichia Coli	NIL	NIL	NIL	10 g^{-1}	API Part 1 vol 8 , first edition 2011
3	Pseudomonas aeruginosa	NIL	NIL	NIL	Absent	API Part 1 vol 8 , first edition 2011
4	Salmonella Species	NIL	NIL	NIL	Absent	API Part 1 vol 8 , first edition 2011

Table No 09: Showing Approximate Period for 10% Degradation in Reference Samples

Parameters	Initial	10% Degradation	Approximate months for 10% Degradation
pH	5.76	5.24	7.36
Moisture content/ loss on drying	1.89	1.72	114.40
Total ash	2.32	2.11	3.31
Acid insoluble ash	0.56	0.51	2.53
Water soluble extractive	9.52	8.66	2.90
Alcohol soluble extractive	5.13	4.67	1.84
Mean Months			22.06

Table No 10 : Shelf Life (Reference samples)

Months	Multiplication Factor	Shelf Life (Months)	Years
22.06	3.33	73.45	6.12

Table No 11: Approximate Period for 10% Degradation in Accelerated temperature Sample

Parameters	Initial	10% Degradation	Approximate months for 10% Degradation
pH	5.59	5.08	35.16
Moisture content/ loss on drying	1.88	1.70	48.20
Total ash	2.26	2.06	2.78
Acid insoluble ash	0.59	0.53	4.25
Water soluble extractive	9.48	8.62	4.92
Alcohol soluble extractive	4.94	4.49	1.82
Mean Months			16.09

Table No. 12: Shelf Life (Accelerated samples)

Months	Multiplication Factor	Shelf Life (Months)	Years
16.19	3.33	53.91	4.49

Discussion

Stability study of Ayurvedic formulations can establish better patient compliance and legisilatory requirements. Hence stability study of KVGAP'S Nutricare Powder was conducted as per ICH Guidelines. Results showed no significant change in odour, taste, and appearance of Nutricare Powder after storing for 6 months under accelerated conditions. Physicochemical profiles (moisture content, Total ash, acid-insoluble ash, *p*H, water-soluble extractive, alcohol-soluble extractives and acid-insoluble ash,) of the samples during the study period of 6 months didn't show much differences. Microbiological analysis of the samples showed no signs of microbial growth and specific pathogens were absent in all the samples. The observations were indicative of proper care taken during the manufacturing procedure and packing thus making the product free from contamination and extending the shelf life of the product. Approximate Period for 10% degradation of each parameter were calculated for both Reference sample group and accelerated sample groups. Mean month for 10% degradation of samples were calculated. This value was multiplied by multiplication factor 3.33 to calculate the Shelf life of Reference samples and Accelerated samples. After extrapolating the data, shelf life of Nutricare Powder (Reference samples) was found to be 6.12 years and accelerated study samples were found to be 4.49 years. The Shelf life of Ayurvedic *churnas* as per the 161-B rule of Drug and cosmetic act is 2 years. KVGAP'S Nutricare Powder remains stable for 4.49 years thus indicative of proper manufacturing procedure followed and proper packing of the products.

Conclusion

Accelerated stability study of KVGAP'S Nutricare Powder was conducted as per ICH Guidelines. It was found that KVGAP'S Nutricare Powder is having shelf life of 4.49 years which is more than the prescribed shelf life of 2 years for *Churnas* as per the regulatory requirements. Thus, it can be established that strict adherence to standard operative procedures, proper packing can enhance the shelf life of the formulation and product remains stable in accelerated temperature conditions.

Acknowledgement

- Shubhashree B T. MSc (Chemistry) - Analytical Chemist, KVG Ayurveda Pharma and Research centre, Ambateadka, Sullia.
- Vidhyamadhavi K. Msc (Biochemistry) - Biochemist, KVG Ayurveda Pharma and Research centre, Ambateadka, Sullia.

References

1. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 227p
2. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 227-229p
3. Lavekar G.S, Padhi MM, Verma S C, Singh Arjun (editors). Laboratory guide for the analysis of ayurveda and siddha formulations. New Delhi: Central council for research in Ayurveda and Siddha; 2010**.** 129-133 p.
4. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 194p.
5. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 193p.
6. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 193p.
7. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 194p.
8. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 194p.
9. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 194p.
10. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 220p.
11. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 208-210 p.
12. Ayurvedic Pharmacopeia of India, Part 1, Vol 8. 1st edition. Delhi; Govt of India; 2011. 211-213p.

*****