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Research Article

THE ACCELERATED STABILITY STUDY OF *CONSTALAX CHURNA*- AN AYURVEDIC FORMULATION

Gajanan B. Bhagwat[1], Swapna S Kadam[2]*, Madhuri Hivarale[3]

[1]R&D Manager, *[2]Consultant, [3]Quality analyst, Healing Hands Clinical Research & Development, Mangalmurti Complex, Near Hirabaug, Tilak Road, Pune, Maharashtra, India.

ABSTRACT

Constalax churna, greenish brown powder with characteristic odor and bitter salty taste was evaluated for its stability, as per ICH guidelines Q1A (R2) at accelerated conditions (Temperature: 40 °C ± 2, Relative Humidity : 75% ± 5). The real time stability is estimated at temperature: 25 °C ± 2 &relative humidity 60% ± 5.The study sample was observed for changes in different parameters like physico-chemical, organoleptic and microbial load for 6 month under accelerated conditions and for real time stability study observed for one year. Real time stability was comparatively estimated to evaluate actual degradation rate of *Constalax Churna* with respect to accelerated conditions. Up to six months of storage at accelerated condition, no change was observed in organoleptic parameters like colour, odour and taste of *Constalax Churna*. Changes in of different physico-chemical parameters were taken into account to evaluate intercept and slope. Extrapolated shelf life of *Constalax Churna was* calculated with 10% degradation rate from physico-chemical parameters at accelerated condition 40 °C ± 2 and 75% ± 5 RH. The present evaluation supports that the *Constalax Churna* was appropriate at accelerated condition up to 6 month storage. From this accelerated stability study it could be extrapolated that shelf life of *Constalax Churna* is 25.42 months (2.11years) for climatic zone I & II countries. Real time stability data of *Constalax Churna* showed very good stability up to 2 years.

KEYWORDS: *Constalax Churna*, Accelerated stability, Real time Stability, Shelf life, Ayurvedic formulations.

INTRODUCTION

The tradition of Ayurveda in India has been well documented and Ayurvedic formulations are used effectively in health practice since long time. Ancient Ayurvedic literature have mentioned the importance of Shelf life of the Ayurvedic formulations. Not only shelf life but some of the authentic Ayurveda books have also described in detail about the factors responsible for degradation of the formulation and also the time period after which the formulation becomes unfit to use. Ayurvedic Formulary of India also has given the time period from the date of manufacture within which the formulations should be consumed for best results. [1]

Ayurvedic drugs have different constituents with different concentrations which make the formulation complex in nature. The stability, purity and quality of finished Ayurvedic formulation depends upon the complete evaluation of all constituents.

Stability study provides evidence on how quality of a drug substance or product varies with time under influence of variety of environmental factors such as, temperature, humidity and light and also to establish a retest period for the drug substance or product and recommended storage conditions. So we can say stability study is necessary as an assessment of product quality. [2] Each product has specific shelf-life based on its characteristics (physical and chemical) as well as environmental and biological factors. Accelerated stability study can be helpful to predict reliable shelf life of drugs. [2,3] Stability testing of herbal drugs is a challenging risk, because the entire herb or herbal product is regarded as the active matter, regardless of whether constituents with defined therapeutic activity are known. [4]

The purpose of a stability testing is to provide proof on how the quality of the herbal products varies with the time under the influence of environmental factors such as temperature, light, oxygen, moisture, other ingredient or excipients in the dosage form, particle size of drug, microbial contamination, trace metal contamination, leaching from the container and to establish a recommended storage condition and shelf-life.[5,6] Accelerated stability and real time stability are the two types of evaluations available. Real time study requires longer time period to conduct.

In routine practice of Ayurveda, powdered form (*Churna*) formulations are widely used for treatment. The potency of *Churna* forms is best up to two months as per the Ayurvedic pharmacology[7] after which they start degrading gradually thus losing their efficacy. However, it doesn't lose the potency to treat the element to that stage that it can't be utilized for salutary uses. The storage condition is one of the important aspects affecting shelf-life of the formulation. Detailed precise guidelines about shelf life estimation or stability of the pure Ayurvedic products are not given till date in any Government organization except a Gazette notification issued by Government of India on 20th October, 2009 with slight modification in the earlier draft notification issued on 26th November, 2005.[8,9] In present research work, evaluation of accelerated stability study was conducted to find out the shelf-life of *Constalax Churna.*

METHODOLOGY

CONSTALAX is an Ayurvedic multiherbal formulation (*Churna*) in powdered form. Ingredients are dried powders of *Sonamukhi* (*Casia Augustifolia*), *Sunthi* (*Zingiber Officinale*), *Saunf* (*Foeniculum Vulgeri*), *Baalhirada* (*Terminalia Bellerica*), *Ajwain* (*Ptychotis Ajowan*) and *Narikellavan* (*Cocos Nucifera)* fried with Rock salt) in specific proportion. All these constituents have been reported as effective laxative in authentic Ayurvedic literature. [10,11]

For evaluation of stability, a freshly prepared formulation, *Constalax Churna*, was considered. *Constalax Churna* was packed in airtight food grade plastic container having aluminum foil covering.

Parameters of evaluation

As per ICH guideline Q1. A (R2)[12] evaluation of accelerated stability and real time stability study was conducted. The study sample was stored under specific conditions as mentioned below,

For Accelerated stability: Temperature: 40°C ± 2, Relative Humidity (RH): 75 % ± 5.

For Real time stability: Temperature: 25 °C ± 2, Relative Humidity (RH): 60 % ± 5.

The change was observed during 6 months for accelerated stability and 1 year for real time stability study at an interval of 0,1,3,6 and 12 months. Real time stability was comparatively carried out to evaluate the actual degradation rate of *Constalax Churna* with respect to accelerated condition. 10% degradation was set to extrapolate of the accelerated stability data at the acceptable point. Real time aging factor 5 and 3.3 were used for extrapolation of shelf life.

The parameters considered for evaluation of stability were 1. Organoleptic characters like colour, odour and taste, 2. Physico-chemical parameters like Loss on drying, pH, Total ash, Water soluble, extractive value, bitter residue, total saponin and total tannin.3. Microbial load.

Assessment of Organoleptic Parameters

The nature of the Ayurvedic formulation indicated by its colour while taste and odour of the formulation are very susceptible indicators.

Color: *Constalax Churna* in quantity of 5 grams was taken into watch glasses. A perfectly white background was used and the sample was observed for colour with naked eye in white tube light.

Odour: Sample of 2 gram Constalax Churna was smelled for odour test

Taste: A pinchful of Constalax Churna was tasted on taste buds of tongue.

Loss of drying

Loss on drying was determined by weighing about 2gm of the *Constalax Churna* in previously weighed dried petridish (tarred evaporating dish) and dried in an oven at 105^{0}C, till two consecutive weights, which do not differ by more than 5mg. The weight after drying was noted and loss on drying was calculated. The percentage was expressed as % w/w with reference to air dried sample. [13]

pH

For pH determination 1 g of *Constalax Churna* mixed with 100 ml distilled water in a 100 ml volumetric flask. The solution was sonicated for about 10 minutes. The pH was measured with the help of digital pH meter.

Water soluble extractive value

About 5 gm accurately weighed *Constalax Churna* was macerated in a glass-stopper conical flask. 100 ml chloroform water was added and macerated for 6 hours, shaking frequently and then allowed to stand for 18 hours then after 24 hrs it was filtered rapidly and 20 ml of the filtrate was transferred in a tarred flat bottom evaporating dish with a pipette and evaporated to dryness on a boiling water bath. Then evaporating dish was dried at 105 ^{0}C for 6 hrs and then cooled and weighed. From the weight of the residue the percentage of water soluble extractive was calculated and expressed as % w/w with reference to air dried sample. [13]

Total ash

The ash value was determined by incinerating about 5g of the granulation air-dried material, in a previously weighed crucible at gradually increasing heat up to 450 ^{0}C until it is carbon free. Then cooled in a desiccator and weighed. The percentage of total ash was calculated and expressed as % w/w of air dried material. [13]

Total Tannin

For blank preparation: In a 500 ml conical flask 300 ml of distilled water was taken and 25 ml of indigo sulphonic acid solution was added to it and mixed well. It was titrated against 0.02M KMnO4 solution till stable golden yellow color was developed. The burette reading was noted.

For sample preparation: Accurately weighed about 0.05 g of *Constalax churna* was taken in to a 500 ml conical flask and 250 ml of distilled water was added and mixed well, and then sonicate it for 10 min. 25 ml of the indigo sulphonic acid solution was added and mixed well. Titrated against 0.02M KMnO4 solution till stable golden yellow color was developed. The burette reading was noted. The percentage of total tannin was calculated using following factor. 1 ml of 0.02M KMnO4 is equivalent to 0.00415g of tannin substance. [14]

Bitter residue

One gram of accurately weighed *Constalax churna* was taken in a 150 ml conical flask and 50 ml of methanol was added. It was refluxed for half an hour on a water bath. Then it was filtered and the methanol extract was collected in a 250 ml beaker. The residue was extracted for another two cycles of extraction. Three methanol extracts were pooled and evaporated to obtain approximately 5 ml thick paste. The concentrated extract was shaken with three successive cycles of 25 ml hot water or till all the water soluble matter is extracted or dissolved. These water washed extracts were pooled and transferred it to a separating funnel. This aqueous extract was extracted with minimum 4 cycles of 25 ml of petroleum ether (60-80 ^{0}C). This extract was washed with 25 ml of ethyl acetate. Ethyl acetate extraction was repeated for three more cycles. The ethyl acetate extracts were pooled and transferred to a pre-weighed evaporating dish and evaporated to dryness. From the weight of the residue the percentage of bitter residue was calculated and expressed as % w/w with reference to air dried sample. [15]

Estimation of Total Saponin

Five grams of *Constalax Churna*, accurately weighed, taken in a conical flask and 50 ml 90%v/v methanol was added to it. It was mixed well and refluxed for half an hour. It was filtered after cooling. The residue washed with 90%v/v methanol till became almost colorless. Methanol extract was combined and evaporated on a water bath to obtain a thick paste like residue. The residue was treated with 25 ml petroleum ether (60-80 ^{0}C). Petroleum ether layer was separated and discarded. The residue was treated with 25 ml chloroform. Chloroform layer was separated and discarded. The residue was treated with 25 ml ethyl acetate. Ethyl acetate layer was separated and discarded. Then 5 ml 90%v/v methanol was added in residue. It was shaken well to dissolve the residue completely. Then solution poured drop wise into a beaker containing 25 ml acetone with constant stirring to obtain precipitate. The flask containing the residue rinsed with minimum volume (about 2 ml) of 90%v/v methanol. Transferred the organic layer and dry the residue to constant weight. The percentage of total saponin was calculated and expressed as % w/w with reference to air dried sample. [16]

Microbial load

Microbial load was carried out as per standard procedure mentioned in Indian Pharmacopoeia.[17] It included Total bacterial count, Total Fungal Count, Presence of Escherichia coli, Salmonella spices, Pseudomonas aeruginosa and Staphylococcus aureus. Pure culture of Escherichia coli (NCIM: 2065; ATCC: 739), Salmonella Spp. (NCIM: 2257 NCTC: 6017), Pseudomonas aeruginosa (ATCC 9027), Staphylococcus aureus (ATCC 6358) were obtained from National Collection of Industrial Microorganisms, Pune. The media used for the microbial limit test were of HiMedia Pvt. Ltd.

RESULTS

The results of evaluation of stability study of *Constalax Churna* are shown in Tale No.1. It was analyzed on 0, 1, 3 and 6 months at accelerated conditions [Temperature: 40°C ± 2, Relative Humidity (RH): 75% ± 5] which was maintained up to 6 months. There was no change observed in color, odour and taste of formulation up to storage of 6 months at accelerated condition (Table 1).

Loss on drying (LOD - moisture content); total ash (TA - total inorganic content); pH (acidity), Total ash, water soluble ash (WSA); Bitter residue, Total saponin and Total tannin were the selected Pharmacopoeial constants for the analysis.

Variation in Pharmacopoeial constants was found linear; it was found to decrease from initial to 3rd month and decreasing more again during 6th month. Total Ash and Water Soluble Extractive value showed a slight decrease from initial to 6th month in contrast to pH which tends to increase on storage.

The therapeutically beneficial constants like Water Soluble Extractive value, Total Saponin; Total Tannin has shown substantial decrease in percentage. Extrapolated results at 10 % degradation and months when 10 % degradation occurs was calculated using the reported formula by calculating the slope and intercept values for the above deviations.[18] Results of different physicochemical parameters were taken in consideration to evaluate intercept and slope (Table 2).

Results of microbial load of Constalax Churna were complying with Ayurvedic Pharmacopeia limits at initial month and up to 6 months (Table 1). The extrapolated shelf life of Constalax Churna was calculated with 10% degradation rate from physicochemical parameters at accelerated condition 40°C ± 2 and 75% ± 5 RH (Table 3).

DISCUSSION

Constalax Churna finished formulation was green brownish in colour, with characteristic odor, bitter and salty, uniform solid powder without any tufts. The product did not show any considerable change in Organoleptic parameters in accelerated thermal or humidity conditions. Alteration in color usually occurs due to pH changes or light exposure.[19] In our study, no change in color was observed which correlates with an insignificant change in pH and confirms to criterion on the storage condition.

Organoleptic 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. [20]

Nevertheless, merely organoleptic parameters are not adequate to prove the shelf life in the present-day time. To assess the quality standards of herbal drugs and formulations other parameters are evaluated 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 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. [21]

As per the guidelines of Ministry of AYUSH, other food and drug regulatory agencies as well as WHO, the physico-chemical and microbial stability data is essential to decide the shelf life of formulations.

Other Physico-chemical Parameters

Loss on drying

The percentage of change of weight loss on drying from 0 month was 5.7%, 6.2% and 6.5% at1, 3 and 6 months, respectively, which showed that there was no significant change in moisture content. Perhaps, the moisture content did not differ 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%.[22] 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, at 1, 3 and 6 months was 14.32, 14.41%, 14.38%, respectively, in accelerated stability condition from initial month. As these changes were <5%, it confirms to the ICH guideline. [23]

pH values

The pH value of 1% solution was 5.08, 5.8 and 6.1 at 1, 3 and 6 months respectively. As these changes were below 5%, to be considered as insignificant as per the ICH guidelines.

The value of pH is the predominant factor influencing the quality of product. Many chemical and microbiological reactions are controlled by pH. Researcher found that in presence of acidic substances i.e., with low pH value, the bacterial count would be less while the chances of higher bacterial count would be more with neutral or higher pH. This suggests that a neutral or alkaline pH favors high contamination levels of the herbal preparations. [24] The pH of the Constalax formulation was 6.1 or less and microbial count was also within the normal limit as per WHO guidelines, similar findings were mentioned in previous research work. [24]

Extractive values & presence of acidic substances

The change in percentage of Water soluble extractive value was from 49.54%, 48.12%, 47.34%, 47.11% from initial month, at 1, 3 & 6 months respectively. Change in Bitter residue was from 3.89% to2.90 %.

Percentage change in total saponin was 1.04 % at 0–3 months and 1.66% at 0–6 months and in total tannin was 0.8% from initial to 3 months and 1.2% in 0 to 6 months.

All these changes in Extractive values and quantitative estimation of secondary metabolites were not more than 5%, so it confirms to ICH stability guideline.

Microbial analysis

The study sample showed absence of pathogenic bacteria like E*. coli*, *Salmonella*, *S. aureus*, and *P. aeruginosa*. Thus, Constalax Formulation confirms to the standards set by WHO [25], API. [26]

In the beginning, from 0 to 3 months, slight increase in total count was seen. That was mostly because of destruction of bacteria due to the thermal conditions of stability chamber. Further increase in total count was on account of spores present.

However, these total bacterial count and fungal count were under the prescribed limits of WHO. Low pH and moisture content of the study sample might be responsible for low or controlled microbial load.

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. [27]

For evaluation of stability of *Constalax Churna*, the test drug formulation, 5% variation limit was fixed as per the ICH guidelines to assess the physico-chemical parameters. It has been proposed that 3 months at 40°C/75% RH is roughly equivalent to 24 months at room temperature (25°C). [28]

As per the consideration, it can be affirmed that SS will be stable for 3.3 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. [29] 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 the study sample 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). [30]

Thus, in the view of above interpretations, it can be safely affirmed that *Constalax Churna* has the shelf life of 25 months at room temperature.

Table 1: Results of different parameters of *Constalax Churna* at 40 °C ± 2 and 75% ± 5 RH in different intervals

Sr. No	Parameter	Initial Month	1st Month	3rd Month	6th Month
01	Colour	Green Brownish Colored	Complies	Complies	Complies
02	Odour	Characteristic	Complies	Complies	Complies
03	Taste	Bitter & Salty	Complies	Complies	Complies
04	Loss on drying (% w/w)	5.1	5.7	6.2	6.5
05	pH value (1% w/v solution)	5.06	5.08	5.8	6.1
06	Total ash (%w/w)	14.29	14.32	14.41	14.38
07	Water soluble extractive value (%w/w)	49.54	48.12	47.34	47.11
08	Bitter residue (%w/w)	3.89	3.72	3.40	2.90
09	Total saponin (%w/w)	17.26	16.88	16.22	15.66
10	Total tannin (%w/w)	26.60	25.50	24.20	23.60
11	Total bacterial count (CFU/g)	30×10^3	51×10^3	25×10^4	33×10^5
12	Total yeast and mould (CFU/g)	20×10^1	22×10^1	32×10^2	60×10^3
13	*E. coli*	Absent	Absent	Absent	Absent
14	*P.areuginosa*	Absent	Absent	Absent	Absent
15	*S.spp*	Absent	Absent	Absent	Absent
16	*S.aureus*	Absent	Absent	Absent	Absent

Table 2: Intercept and slope of different physico-chemical parameters of *Constalax Churna*

Condition: 40 °C ± 2 and 75% ± 5 RH						
Parameters	**Initial Month**	**1st Month**	**3rd Month**	**6th Month**	**Intercept**	**Slope**
LOD	5.1	5.7	6.2	6.5	5.33	0.21
pH value	5.06	5.08	5.8	6.1	5.03	0.18
Total ash	14.29	14.32	14.41	14.38	14.31	0.02
Water soluble extractive value	49.54	48.12	47.34	47.11	48.91	0.36
Bitter residue	3.89	3.72	3.40	2.90	3.89	0.16
Total saponin	17.26	16.88	16.22	15.66	17.17	0.26
Total tannin	26.60	26.2	25.8	25.4	26.48	0.19

Table 3: Extrapolated shelf life of *Constalax Churna* from different physico-chemical parameters

Condition: 40 °C ± 2 and 75% ± 5 RH			
Parameters	**Result at Initial Month**	**Result at 10% Degradation**	**Months when 10% degradation occurs**
LOD	5.1	4.59	0.98
pH value	5.06	4.55	4.80
Total ash	14.29	12.87	9.70
Water soluble extractive value	49.54	44.58	7.52
Bitter residue	3.89	3.50	2.42
Total saponin	17.26	15.53	3.52
Total tannin	26.60	23.94	6.47
Mean Months at accelerated condition			5.04
Extrapolated shelf life of *Constalax Churna*			25.42

CONCLUSION

The present investigations supports that the *Constalax Churna* was appropriate and stable under accelerated conditions of storage up to 6 months. From the accelerated study this can be extrapolated that the average shelf life of *Constalax Churna* is 25.42 months (2.11 years). Real time stability data of *Constalax Churna* showed very good stability up to 2 year.

LIMITATIONS

The main limitation of the study is absence of qualitative evaluation by densitometric high-performance thin layer chromatography (HPTLC) fingerprinting. by long-term and real-time studies should be carried out as the accelerated stability studies are not enough to determine drugs shelf life.

It is recommended that the formulation should be evaluated further by applying appropriate biochemical, immunological methods for degradation products in formulation so as to prevent drug-induced adverse effects.

CONFLICTS OF INTEREST

There are no conflicts of interest.

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***Address for correspondence**
Dr. Kadam Swapna S
Consultant, Healing Hands Clinical Research & Development, 111, Mangalmurti Complex, Near Hirabaug, Tilak Road, Pune, Maharashtra, India.
Mobile: 9482687176
Email: swapnahh@gmail.com