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Evaluation of accelerated stability study of ayurvedic formulation – Trasina®

Dr. Soumendra Darbar[1*], Biswanath Roy[2]
1 Ph. D, FIC, Principle Investigator, Research and Development Division, Department of Science, Faculty of Science, Jadavpur University, Kolkata, West Bengal, India
[2] Research and Development Division, Dey's Medical Stores, Kolkata, West Bengal, India

Abstract
Background: Pharmaceutical product's stability testing is a complex series of processes that requires a lot of money, effort, and scientific knowledge to incorporate quality, efficacy, and safety into a medicine formulation.
Aim & Objective: The goal of the current study is to assess how accelerated storage conditions will affect prepared capsules. The objective of the study is to assess the effects of accelerated storage conditions on formulated Trasina® capsule.
Materials & Methods: To test for stability under accelerated conditions (Temperature: 40°C ± 2, Relative Humidity: 75% ± 5) in accordance with ICH recommendations Q1A (R2). For six months under expedited circumstances, the study sample was monitored for changes in various parameters such the physical, chemical, and microbiological load.
Results: No physical changes in taste, colour, or odour were noticed after up to six months of accelerated storage. Disintegration time of the capsule throughout the period within the prescribe standard. Additional variables like pH, total ash, acid soluble ash, and loss on drying were all within the established standard range. Bacterial count overall is significantly lower than expected.
Conclusion: According to the current stage-I stability study analysis, Trasina® capsules were suitable for storage up to six months under accelerated conditions.

Keywords: Trasina®, shelf life, ayurvedic formulations, accelerated stability

Introduction

In order to assess how herbal medicines maintain their qualities under controlled storage circumstances that are impacted by light, heat, moisture, oxygen, and other physical and chemical variables, stability testing is used [1]. The stability profile of pharmaceutical items is typically investigated at accelerated temperature and humidity, and the experimental results can be highly useful in predicting the quality and efficacy within the self-life term. It is common practise to investigate the stability of pharmaceutical preparations under accelerated temperature and humidity settings [2-5]. The experimental results can then be used to determine a product's shelf life or expiration date by adopting specific suppositions or criteria [6]. By using this technique, the shelf life of any drug product may be quickly anticipated.

Natural-ingredient based ayurvedic medications are more popular due to the perception that they are safer and have fewer adverse effects than synthetic alternatives. The ancient literature contains extensive documentation of the polyherbal formulation (PHF) concept. The therapeutic potential of the polyherbal formulation is better and more extensive than that of the single herb [7,8]. Ayurveda, the traditional Indian medical system, classifies some Indian medicinal plants as medhyarasayanas, or medicines, with the reputation of enhancing memory and intelligence [9]. Trasina is a herbal combination of these plants. Shilajit, *Withania somnifera*, *Tinospora cordifolia*, *Eclipta alba*, *Ocimum sanctum*, and *Picrorrhiza kurroa* are all components of the herbal supplement Trasina. In 1997, Bhattacharya *et al*. reported that the formulation has a memory-enhancing effect. According to studies, subchronic application of Trasina on mouse models for 21 days simulated some biochemical characteristics linked to Alzheimer's disease (AD) [10-12]. The current study aims to investigate the accelerated stability of herbal capsules for the purpose of quality and efficacy of the product, which are typically used to modulate the immune system and reduce stress.

Materials and methods

Composition of Herbal Formulation

Trasina capsule mainly composed of (Fig. 1) *Withania somnifera* 80 mg; *Ocimum sanctam* 190 mg; *Tinospora cordifolia* 10 mg; *Picrorrhiza kurroa* 10 mg and *Eclipta alba* 10 mg.

Storage condition and evaluation parameters

In this study (Accelerated stability study) we strictly follow ICH guideline Q1. A (R2). (8) Storage condition of Accelerated stability stated below:
Temperature: 40 °C ± 2, Relative Humidity (RH): 75 % ± 5
The change was observed during 6 month for accelerated stability.
The following parameters were considered for evaluation of stability study.

- Physical characters like colour, odour and taste
- Chemical parameters like disintegration, loss on drying, pH, total ash and acid soluble ash,
- Microbial load

Examination of colour, odour and taste

Colour: Five-gram Trasina was taken into watch glasses and placed against white background in white tube light. It was observed for their color by naked eye.

Odour*:* Two-gram Trasina was smelled.

Taste: A pinch of Trasina was taken and examined for it's taste on taste buds of the tongue.

Determination of loss on drying

To measure loss on drying, 2gm of the powdered material was weighed in a dried petri dish (a tarred evaporating dish) and dried at 105–110ºC until two subsequent weights did not differ by more than 5mg. The weight after drying was recorded, and drying loss was computed. In relation to an air-dried sample, the percentage was stated as % w/w [13].

Determination of total ash

Around 1 g of the powdered, air-dried material was used in a previously weighed crucible, and its ash value was calculated by incinerating it at a temperature that was gradually increased up to 500–600ºC until it was carbon free. Then desiccated to cool, and weighed. Calculated as a proportion of the weight of the air-dried material, total ash was represented as % w/w [13].

Determination of water-soluble extractive value

A conical flask with a glass stopper was used to macerate about 5 g of precisely weighed Trasina. 100 mL of chloroform water was added, then the mixture was macerated for 6 hours while being frequently stirred. After standing for 18 hours, it was quickly filtered, and 20 mL of the filtrate was transferred in a tar-lined flat-bottom evaporating dish and evaporated to dryness on a boiling water bath after 24 hours. The dish that was evaporating was then dried at 105 °C for 6 hours, chilled, and weighed. With relation to an air-dried sample, the proportion of water-soluble extractive was computed from the residue's weight and reported as% w/w [13].

Microbial load

Microbial load was performed in accordance with the recommended protocol described in the Indian Pharmacopoeia [14].

Determination of pH

Put 1 g of Trasina powder, precisely weighed, in a 100 mL volumetric flask, and filled the rest of the way with distilled water. During roughly 10 minutes, the solution was sonicated. Using a digital pH metre, pH was measured.

Results

In the accelerated stability study, Temperature: 40°C ± 2, Relative Humidity (RH): 75% ± 5 was maintained up to 6 months. The product was analyzed on 0, 3 and 6 month. No change was noticed in colour, odour and taste of Trasina (3 consecutive batches) up to storage of 6 months at accelerated condition (Table 1-3). Results of microbial load of Trasina (3 consecutive batches) was complies with Ayurvedic Pharmacopeial limits at initial month and up to 6 month (Table 1-3).

The all chemical parameters like loss on drying, total ash, acid soluble ash and pH were within the pharmacopial lime at initial month and up to 6 month (Table 1-3). Disintegration time of the three consecutive batches of Trasina were also within the pharmacopial lime at initial month and up to 6 month (Table 1-3).

Discussion

Stability testing aims to create a re-test period for the drug substance or a shelf life for the drug by providing data on how the quality of a drug substance or drug product changes over time under the effect of various environmental conditions including temperature, humidity, and light. The goal of stability is to guarantee that the product stays within the parameters set up to maintain its identity, strength, quality, and purity throughout the life. It can be understood as the amount of time, under specified circumstances, during which a product is stored, during which all of its significant qualities will continue to fall within the predetermined range. Pharmaceutical items undergo stability testing primarily to verify the efficacy and quality of the active ingredients, determine the shelf life or expiration date, and confirm the label claim. Each dosage form's stability data includes a few factors that collectively make up the stability profile. Pharmaceutical items' storage requirements and shelf life are determined by this stability profile. The creation of the final product's stability programme assess the quality of the product as well as efficacy of the medicine. The design of the stability program for the finished product should be based on the knowledge of the behavior and properties of the drug substance and the dosage form [14-16].

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On the basis of the data obtained from the accelerated stability study i.e. initial, 3 month and 6 month of the three consecutive batches stated that all the chemical parameters those are studies within the pharmacopial lime at initial month and up to 6 month. Degradation of rate of the product within the limit and also not noticeable. No considerable change was observed in organoleptic characters and microbial load even after 6 months accelerate study.

Conclusion

The present investigation supports that the herbal capsule Trasina® complies all the standard testing parameters during the accelerated condition up to 6 month storage. No such abrupt changes and variation were noted throughout the study period. So, it may by conclude that the quality of the herbal capsule Trasina® in the initial stage remain same after the accelerated study period.

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Conflict of interest
No conflict of interest

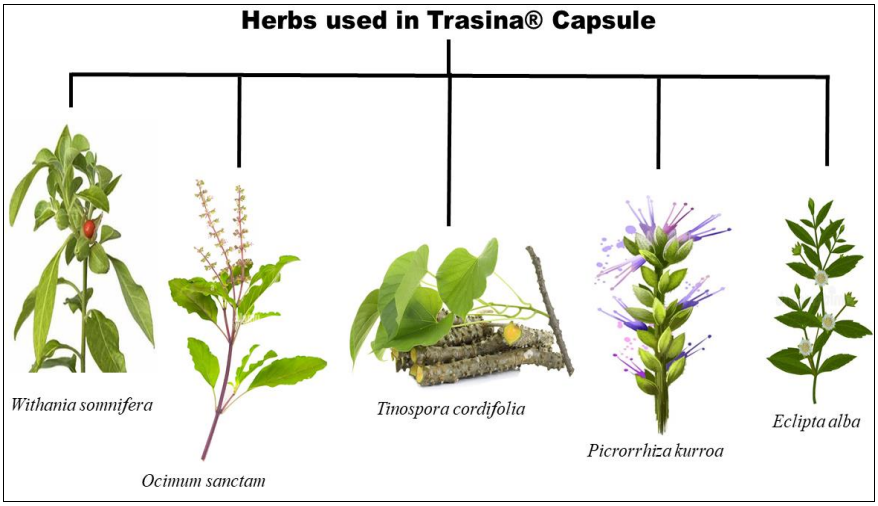

Fig 1: Major ingredients in Trasina®

Table 1: Results of different parameters of Trasina® (Batch No.: TR 364) at 30 °C ± 2 and 75% ± 5 RH in different intervals

Name of the Formulation: Trasina®				
Batch No.: TR 364				
Environmental Condition: Temperature - 30°C, Relative Humidity-75%				
Description	**Requirements**	**Initial**	**After 3 Months**	**After 6 months**
Appearance	Green and Yellow coloured capsule	Complies	Complies	Complies
Capsule size	0	Complies	Complies	Complies
Disintegration	NMT 30 min.	10.36	10.45	10.35
Loss on drying at 105°C	NMT 10% w/w	2.07% w/w	2.13% w/w	2.41% w/w
Total Ash at 450°C	NMT 10% w/w	13.47% w/w	13.54% w/w	13.10% w/w
Acid soluble ash	NMT 10% w/w	1.99% w/w	1.55% w/w	1.62% w/w
pH	6.0 – 8.0	6.15	6.34	6.32
Total Bacterial Count	NMT $1x10^5$ cfu/gm	245 cfu/gm	405 cfu/gm	370 cfu/gm

Table 2: Results of different parameters of Trasina® (Batch No.: TR 365) at 30 °C ± 2 and 75% ± 5 RH in different intervals

Name of the Formulation: Trasina®				
Batch No.: TR 365				
Environmental Condition: Temperature - 30°C, Relative Humidity-75%				
Description	Requirements	Initial	After 3 Months	After 6 months
Appearance	Green and Yellow coloured capsule	Complies	Complies	Complies
Capsule size	0	Complies	Complies	Complies
Disintegration	NMT 30 min.	11.27	10.40	10.38
Loss on drying at 105°C	NMT 10% w/w	2.15% w/w	2.30% w/w	2.34% w/w
Total Ash at 450°C	NMT 10% w/w	10.94% w/w	13.48% w/w	13.38% w/w
Acid soluble ash	NMT 10% w/w	1.08% w/w	1.59% w/w	1.57% w/w
pH	6.0 – 8.0	6.35	6.54	6.50
Total Bacterial Count	NMT $1x10^5$ cfu/gm	340 cfu/gm	335 cfu/gm	340 cfu/gm

Table 3: Results of different parameters of Trasina® (Batch No.: TR 366) at 30 °C ± 2 and 75% ± 5 RH in different intervals

Name of the Formulation: Trasina®				
Batch No.: TR 366				
Environmental Condition: Temperature - 30°C, Relative Humidity-75%				
Description	Requirements	Initial	After 3 Months	After 6 months
Appearance	Green and Yellow coloured capsule	Complies	Complies	Complies
Capsule size	0	Complies	Complies	Complies
Disintegration	NMT 30 min.	9.48	9.37	10.00
Loss on drying at 105°C	NMT 10% w/w	2.08% w/w	2.38% w/w	2.30% w/w
Total Ash at 450°C	NMT 10% w/w	11.09% w/w	11.10% w/w	11.12% w/w
Acid soluble ash	NMT 10% w/w	1.34% w/w	1.40% w/w	1.32% w/w
pH	6.0 – 8.0	6.48	6.42	6.47
Total Bacterial Count	NMT $1x10^5$ cfu/gm	235 cfu/gm	610 cfu/gm	190 cfu/gm

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