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Stability and shelf-life studies in Ayurvedic medicine: *Triphala*

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Abstract
Triphala is a globally recognized polyherbal Ayurvedic medicine with abundant antioxidants. It is believed to boost the immune system, improve digestion, and address chronic ulcers. The tablets are specially designed for oral consumption and contain herbal ingredients known for their specific medicinal benefits. Storage conditions can significantly affect the shelf life of herbal tablets; therefore, it is essential to assess the stability of these tablets. According to ICH guidelines, *Triphala* tablets endured accelerated stability studies at 40 °C and a relative humidity (RH) of 75%±5 over a period of 6 months, with assessments conducted at the 2nd, 4th, and 6th months. Various parameters, including organoleptic characteristics, physico-chemical properties, proximate composition, active phytochemical content, and microbiological load, were monitored during these intervals. The results of these analyses were taken into consideration when estimating the shelf life of *Triphala* Tablets. The extended shelf life estimate was determined by applying an accelerated deterioration rate of 10% for physico-chemical parameters. As a result, it was established that the *Triphala* tablets have an estimated shelf life of 4 years and 3 months.

Keywords: *Triphala*, Shelf life, immune booster, gallic acid, a polyherbal formulation, stability examination

1. Introduction
When assessing the quality of herbal products over time, stability testing is crucial as it considers diverse environmental factors, such as humidity, sunlight, air, and climate. This testing is instrumental in establishing guidelines for shelf life and storage. The Ayurvedic healing approach involves diverse dosage forms, adding complexity to standard quality control. Herbal tablet forms, known for their rigid structure in round, oval, or square shapes, include additives like disintegrants, lubricants, glidants, and binders to preserve tablet integrity and potency. Ayurvedic tablets, created for oral use, often feature beneficial medicinal herbal components. The term "Stability" denotes a product's ability to stay within defined limits under specific storage conditions. Essential for determining shelf life, stability studies, including accelerated and real-time analyses, are prevalent in the pharmaceutical sector. Accelerated stability testing is particularly valuable for insights into the shelf life of herbal medicines. The concentration and presence of active phytochemical components have a direct impact on the quality, effectiveness, and shelf life of herbal products. It is crucial that variations in bioactive components do not exceed ±5% of the initial concentration. Storage conditions significantly influence the shelf life of *Triphala* tablets, and assessments help ascertain the duration for which the tablets can uphold their intended quality and therapeutic properties. This ensures they remain secure and efficacious for consumers over time.
Triphala, a significant and widely utilized remedy in traditional Indian medicine for over a millennium, finds mention in key Ayurvedic texts such as the Charaka Samhita and the Sushruta Samhita. This preparation, composed of three crucial fruits, is known as the "three myrobalans" or fruits of *Terminalia chebula* Retz (Combretaceae), *Terminalia bellirica* Linn. (Combretaceae), and *Emblica officinalis* Gaertn. (Euphorbiaceae) and these therapeutic herbs is renowned for its diverse health benefits [1, 2]. Chebulin, ellagic acid, 2, 4-chebulyl-d-glucopyranose, Arjunglucoside I, Arjungenin, Chebulinic acid, gallic acid, ethyl gallate, punicalagin, terflavin A, terchebin, luteolin, and tannic acid are among several biologically active compounds found in *T. chebula* extract, according to a chemical study. The majority of *T. bellerica* chemical components are tannins, which mostly consist of β-sitosterol, gallic acid, ellagic acid, ethyl gallate, galloyl glucose, and chebulagic acid [3]. Quercetin, phyllaemblic chemical compounds, gallic acid, tannins, flavonoids, pectin, and vitamin C have all been

found to be abundant in *P. emblica* fruit [4]. the presence of antioxidants, such as gallic acid, is typical in phenolic compounds like Tannic Acid (*Terminalia chebula*, *Terminalia* bellerica) and Quercetin (*Emblica officinalis*). These fruits contain specific substances indicative of certain biological characteristics. Hence, in the present research, the stability of *Triphala* was determined by evaluating the stability of gallic acid. It must retain its quality and purity to preserve safety and efficacy due to the substantial number of tannins it contains, including ellagic acid and gallic acid. **[5,6].** *Triphala* possesses a spectrum of therapeutic effects, including anti-bacterial, anti-fungal, anti-viral, and anti-allergic properties. The nutrients within *Triphala* confer cardiotonic benefits, contributing to lowered cholesterol levels, blood pressure management, and improved blood circulation. Additionally, *Triphala* exhibits immunomodulatory characteristics, enhancing the body's immune system [7-10]. Traditional Ayurvedic healers frequently utilize the antioxidant-rich *Triphala* formulation to address various ailments such as anemia, jaundice, constipation, asthma, fever, and chronic ulcers [11-14]. *Triphala* has a longstanding history of use as a laxative for digestive issues, persistent constipation, colon cleansing, and poor food absorption [11, 13]. In a mouse model of OVA-induced AR, gallic acid, a component of *Triphala*, was found to reduce nasal inflammation by modifying the immune response toward Th1. Treatment with gallic acid resulted in elevated levels of Th1-related cytokines such as interferon (IFN) and IL-12 in nasal larval fluid (NALF), while inhibiting the increase of Th2 cytokines like IL-4, IL-5, IL-13, and IL-17. Patients treated with gallic acid showed histological improvements, including thickening of the nasal mucosa, goblet cell hyperplasia, and eosinophil infiltration [15]. Traditional medications derived from T. chebula fruits have been used to treat diseases affecting the upper respiratory tract, GI tract, urinary tract, and skin [16]. Gallic acid's positive effects in Allergic Rhinitis, according to a study [17], were attributed to its ability to suppress the release of pro-inflammatory cytokines and histamine through the modulation of cyclic adenosine monophosphate (cAMP), intracellular calcium regulation, NF-B, and a p38 mitogen-activated protein kinase (p38 MAPK)-dependent mechanism. Gallic acid, a primary plant component of *Triphala*, is believed to significantly contribute to the polyherbal Ayurvedic formulation's anti-cancer properties by inhibiting the growth of cancer cells [18].

2. Materials and Methods

2.1 Test Product Details

The *Triphala* tablets were made by Vijayani Nutraceutical Pvt. Ltd. in compliance with traditional methods, and subsequently, accelerated stability tests were carried out on the batches B-1 (VNL 21–054), B-2 (VNL 21–068), and VNL 21–121. Data from formal stability studies should be provided on at least three primary batches of the drug substance. The batches should be manufactured to a minimum of pilot scale by the same synthetic route as, and using a method of manufacture and procedure that simulates the final process to be used for, production batches. The overall quality of the batches of drug substance placed on formal stability studies should be representative of the quality of the material to be made on a production scale.

2.2. Sample quantity and packing

The weight of each tablet typically ranges from 460.0 to 510.0 mg, and there are 60 tablets in 120 ml plastic bottle.

2.3 Storage conditions in the stability chamber

The accelerated stability study was carried out in a stability chamber (Remi Elektrotechnik Ltd, Model: SC-35 PLUS) following the ICH guidelines Q1A (R2). Samples were stored at a temperature of 40 °C±2 °C, with a relative humidity of 75%±5%, and this condition was maintained for a period of 6 months.

2.4 Frequency of withdrawal

The impact of the intervention was evaluated at study intervals of 0, 2, 4, and 6 months over a 6-month period. In the accelerated stability study, a degradation level of 10% was established as the acceptable threshold.

3. Parameters of evaluation

Evaluations were conducted on the organoleptic qualities (taste, odour, colour, and appearance). Weight variation, disintegration time, pH, and the number of extractives soluble in alcohol and water were among the physical-chemical properties evaluated. As previously noted, proximate composition criteria, including moisture, ash, protein, fat, carbs, active ingredients, and microbial load, were assessed at predetermined intervals.

3.1 Analysing organoleptic characteristics

A skilled analyst assessed the appearance, colour, taste, and odour of the *Triphala* Tablets. To visually observe and evaluate colour, the tablets were arranged on a watch glass against a white background. The sample was smelled to determine its odour, and its taste was evaluated by placing it on the taste receptors of the tongue.

3.2 Determination of disintegration time test

The disintegration time test was conducted using a microprocessor-based digital digester (Lab India, Model: Tablet Disintegration Tester DT 1000). Insert one tablet into each tube within the basket, and if instructed, include a disk in every tube. Activate the equipment, utilizing either water or the specified medium as the immersion fluid, while keeping the temperature at 37±2°. After 30 minutes, raise the basket from the fluid and inspect the tablets, ensuring that each tablet has undergone complete disintegration [19].

3.3 Determination of pH

One gram of the crushed tablet powder (weight 1 g) was put to a beaker along with one hundred millilitres of distilled water. The solution was sonicated for around ten minutes in order to fully solubilize the substance. Next, a calibrated digital pH meter was used to measure the solution's pH [20].

3.4 Determination of Alcohol-soluble Extractive

5 g of the final product material were macerated with 100 ml of ethanol for 24 hours in a closed flask. The maceration was done with constant stirring for the first 6 hours and then let to stand for 18 hours. 25 ml of the filtrate was dried in a pot of hot water after being filtered for 24 hours. The filtrate was then moved to an evaporating dish with a flat bottom. After cooling, the material was weighed and dried at 105 °C [20]. To determine the percentage of extractives soluble in alcohol, the residue's weight was utilized, and the result was given in percentage terms.

$$\text{Alcohol Soluble Extractive\% (w/w)} = \frac{W_F \times V_S \times 100}{W_I \times V_F}$$

While,
W_I specifies the initial weight of the sample
V_F specifies the volume of filtrate taken
W_F specifies the final weight of the sample
V_S is the volume of the alcohol taken for soaking.

3.5 Determination of Water-soluble Extractive
Approximately 5 g of the product powder was submerged for 24 hours with 100 ml of distilled water), shaking consistently for the first 6 hours, and then being left to stand for the final 18 hours. Following a 24-hour filtering period, 25 ml of the filtrate was transferred to an evaporating plate with a flat bottom and dried in a pot of hot water. At 105 °C, the sample was dried, cooled, and weighed [20]. The weight of the residual was used to compute the percentage of water-soluble extractive, which was then defined as a percentage.

$$\text{Water Soluble Extractive\% (w/w)} = \frac{W_F \times V_S \times 100}{W_I \times V_S}$$

While
W_I specifies the initial weight of the sample
V_F specifies the volume of filtrate taken
W_F specifies the final weight of the sample
V_S is the volume of the alcohol taken for soaking.

4. Proximate analysis
4.1 Determination of Moisture content
First, 5 g of the tablets (W_I) was weighed and placed in a pre-weighed moisture box. The initial weight of the sample was recorded as W_I. Then, the moisture box with the sample was put in a preheated hot air oven for 3 hours at 105 ± 2°C. After this, the moisture box was allowed to cool by placing it in a desiccator. The final weight of the sample was then measured and recorded as W_F [21]. The moisture content was calculated using the following formula.

$$\text{Moisture (\%)} = [\{(WI - WF)/WI)\} * 100].$$

4.2 Determination of Ash content
First, 2 g of the crushed tablet powder (W_I) was weighed and placed in a pre-weighed crucible. The initial weight of the sample was recorded as W_I. Then, the crucible containing the sample was positioned in a muffle furnace for a period of 12 hours at 550±25 °C. After this, the sample was allowed to cool, and the final weight of the sample was recorded as W_F [21]. The ash content can be calculated using the following formula.

$$\text{Ash (\%)} = [\{(WI - WF)/WI)\} * 100].$$

4.3 Determination of Protein content
The protein was estimated using the Kjeldhal method using partially automated digestion and Kjeldhal distillation equipment. A total of 0.2 g of the crushed tablet powder is digested with 40 g of K_2SO_4, 4 g of $CuSO_4$, and 10 ml of concentrated H_2SO_4. The digestive process begins by keeping the temperature at about 250 °C. The protein digester (Pelican Equipment's, Model: Kelvac) was set to three temperatures (250 °C for 10 minutes, 350 °C for 10 minutes, and 410°C for 90 minutes). At the end of the digestion, the sample's color changes from blue to green. The distillation (Pelican Equipment's, Model: Classic-DX VA) begins with 30 ml of water added to the sample, and the solution is made alkali with 40% NaOH. The released ammonia gets absorbed in 4% boric acid solutions, and the nitrogen concentration is measured by titration with 0.1 N HCl solutions [22]. The percentage of protein (on a dry weight basis) is calculated using the following formulas.

$$\text{Protein, \%w/w} = \frac{14.01XNX(TS - TB)X6.25X100X100}{WSX1000XTS}$$

While,
TS specifies the volume (ml) of 0.1 N HCl used for sample titration
TB specifies the volume (ml) of 0.1 N HCl used for blank titration
N specifies the Normality of HCl
WS specifies the weight (g) of the sample 14.01 denotes the atomic weight of Nitrogen 6.25 denotes the Protein – Nitrogen conversion factor for food and feed
TS specifies the Total solids (100 -% Moisture content).

4.4 Determination of Fat content
Soxhlet extraction was used to determine the fat content using a semi-automated Soxhlet Apparatus (Pelican Equipments, Model: SCS-6). 2 g of tablet powder (WS) was weighed and placed in an extraction thimble. The thimble was placed in a cylindrical container with 80 ml of petroleum ether, and the setup was set up on a heating mantle. The sample extraction in the Soxhlet apparatus begins with a pre-programmed section (100 °C - 90 minutes and 160 °C - 20 minutes). The beaker containing the sample is dried at 80-90 °C until completely dry. The total weight of the sample in the beaker is recorded as W2 [23]. The percentage of fat (on a dry weight basis) is calculated using the following formulas

$$\text{Fat, \%} = \frac{w2 - w1}{Ws} \text{ x} \frac{100}{Ts} \text{x100}$$

While,
W1 specifies the initial weight of the beaker (g)
W2 specifies the final weight of the beaker (g)
WS specifies the weight of the sample (g)
TS specifies the Total solids (100 -% Moisture content).

4.5 Determination of Carbohydrate and Energy
The percentage of carbohydrate content was determined employing the "By difference" method, and the energy value in kilocalories (Kcal) was estimated through the following formulas [24].
Total Carbohydrate content (% w/w) = 100 − [% of (Moisture + Ash + Fat + Protein)] Total Carbohydrate content (% w/w) = 100 − [% of (Moisture + Ash + Fat + Protein)]
Energy (Kcal) = (4×% Carbohydrate) + (4×% Protein) + (9×% Fat) Energy (Kcal) = (4×% Carbohydrate) + (4×% Protein) + (9×% Fat)

In these equations, the numerical values 4, 4, and 9 represent the general factors corresponding to carbohydrates, protein, and fat in the sample, respectively.

4.6 Estimation of gallic acid
Estimation of the active compound (gallic acid) was conducted using a Shimadzu-Prominence HPLC system, which included a pump (LC-20AD), UV detector (SPD-20 A), and auto sampler (SIL-20AC), along with a Shim-pack Solar C18 column (250 × 4.6 mm ID, 5 µm). The system operated at a flow rate of 1.5 ml/min, with a 10 µL sample injection, and an oven temperature of 30 ºC for both the sample and standards. For gallic acid analysis, the mobile phase comprised a buffer solution created by dissolving 0.136

g of anhydrous potassium dihydrogen orthophosphate (KH_2PO_4) in 900 ml of HPLC-grade water, with the addition of 0.5 ml of orthophosphoric acid. The solution was then made up to 1000 mL with water, filtered through a 0.45 µm membrane, and degassed in a sonicator for 3 minutes. The mobile phase involved an acetonitrile gradient with specific proportions at different time points. The standard preparation involved accurately weighing 20 mg of gallic acid into a 10 ml volumetric flask, dissolving it in 6 ml of methanol through sonication, and adjusting the volume to 10 ml with methanol. For sample preparation, the sample was crushed into a fine powder, and 100 mg of the powder was placed into a 10 ml volumetric flask. Six milliliters of methanol were added, and the mixture was sonicated for 30 minutes, with the volume adjusted to 10 ml using the same diluent (methanol). The prepared sample was then filtered using a 0.45 µm syringe filter. The standard curve exhibited linearity within the range of 1.00 ppm to 100.00 ppm, and a regression analysis yielded a calibration equation with a correlation coefficient (R^2) greater than 0.98. Sample peak areas were plotted on the calibration graph to determine the sample concentration in mg/L [25, 26].

4.7 Microbial Load

The microbial load in the sample was assessed following the standard procedures as outlined in the US Pharmacopoeia [27]. This comprehensive evaluation involved determining the total bacterial plate count, yeast, and molds, as well as the detection of specific microorganisms such as *Staphylococcus aureus, Escherichia coli, and Salmonella spp.* Furthermore, the results were verified to ensure compliance with the regulations set forth by the Food Safety and Standards Authority of India (FSSAI) for Nutraceuticals and Food Supplements in 2022. This step is critical to confirm that the product meets the required standards for microbial safety and quality, thus ensuring its suitability for consumption.

4.8 Determination of Shelf Life

The evaluation of shelf life involved considering various parameters, including pH, water-soluble extract, alcohol-soluble extract, moisture, ash, and the active ingredient (gallic acid). Data from three batches, collected at the 0th, 2nd, 4th, and 6th months, were compiled, and the average values for these parameters were calculated. To assess shelf life, separate data graphs were plotted for each parameter, depicting the four-time points, to analyze the slope and intercept of the trends. Shelf life was determined by calculating the time it takes for a 10% degradation in these parameters to occur, employing a specific formula [28].

Month When 10% degradation occurs = [0 Month Assay value – {(0 Month Assay Value X 10) / 1000}]-Intercept)

Slope

Applying this formula, the shelf life of each individual parameter was calculated. Subsequently, the average shelf life of the product was determined by considering all these parameters collectively. To estimate the overall shelf life of the *Triphala* tablets in accelerated studies, an extrapolation was performed using a real-time aging factor of 3.3. This factor is specifically applicable to climate zones III and IV countries, such as India, and is employed [29].

5. Results and Discussion

In the realm of Ayurveda, the term "Saviryata Avadhi" defines the duration during which the "Virya," or potency, of a medicinal substance remains unaltered by environmental and microbial influences. This concept holds paramount importance in Ayurvedic medicine, symbolizing the period wherein the therapeutic effectiveness of a substance is maintained. In the case of *Triphala*, extensively utilized in Ayurvedic formulations as both churna (powder) and tablet forms, specific guidelines are established based on Saviryata Avadhi. As per these guidelines, the expected shelf life for *Triphala churna* is typically within the range of 2-3 months, while *Triphala* Vatti (tablet) is generally anticipated to endure for 12 months. These durations are rooted in the traditional understanding of how long the potency and quality of these preparations can be sustained under specific storage conditions in Ayurvedic practices. In contrast, within the pharmaceutical system, the term "shelf life" refers to the duration during which an Active Pharmaceutical Ingredient (API) or Finished Pharmaceutical Product (FPP) is expected to retain its quality and efficacy within approved stability specifications. This expectation is contingent on the product being stored under recommended conditions. The shelf life for churna (powder) and tablets, as stipulated in rules 161-B and 1945 of the Drug and Cosmetic Act 1940 and 1945, respectively, is set at 2 and 3 years. These regulations are documented in GSR 763(E) dated 15.10.2009, with amendments up to 31.12.2016. Nevertheless, the guidelines for stability studies, outlined in the Ayurvedic Pharmacopoeia of India, Part-I, Volume-VIII, are pertinent to all Ayurvedic medicines [30]. These guidelines are designed to establish scientific, data-driven shelf-life determinations through real-time and accelerated studies. (Agarwal *et al.,* 2018) [31] discovered that three different brands of *Triphala churna* shared similar parameter values, except for a noticeable distinction in the flow properties of the powder. This underscores the importance of conducting analytical evaluations for each batch to optimize the final product and establish quality control and assurance limits [31]. In a separate study, (Shivakumar *et al.* 2016) examined the physical parameters, such as description and loss on drying, finding them to be in accordance with ICH guidelines. No degradation was observed, supporting the safety and efficacy of the product [32]. (Huang HZ *et al.,* 2018) reported that the HPTLC chromatographic fingerprint of *Triphala* Taplets remained consistent throughout their study, which focused on the stability control strategy of a *Triphala* solution. They identified an equilibrium point based on the balance between physical and chemical stabilities [33]. Savarikar *et al.* utilized the direct compression method for preparing *Triphala* Guggul Kalpa tablets [34]. Despite numerous quality assessments of *Triphala* being published, there is insufficient evidence to support shelf-life research. Therefore, our investigation commenced to assess the stability and shelf-life of *Triphala* tablets. In this accelerated stability study, product batches were analysed at intervals of 0^{th}, 2^{nd}, 4^{th}, and 6^{th} months. Figure 1 illustrates the changes in *Triphala*'s colour and appearance up to the sixth month, indicating minimal alterations in organoleptic qualities, including appearance, color, taste, and odour (Table 1). Table 2 demonstrates insignificant changes in the physico-chemical profile at different intervals. The proximate analysis results for *Triphala* tablets, as presented in Table 3, indicate compliance with expected standards or specifications. Crucially, Table 4 confirms that the *Triphala* tablets were devoid of microbial contamination form 0 and 6 month.

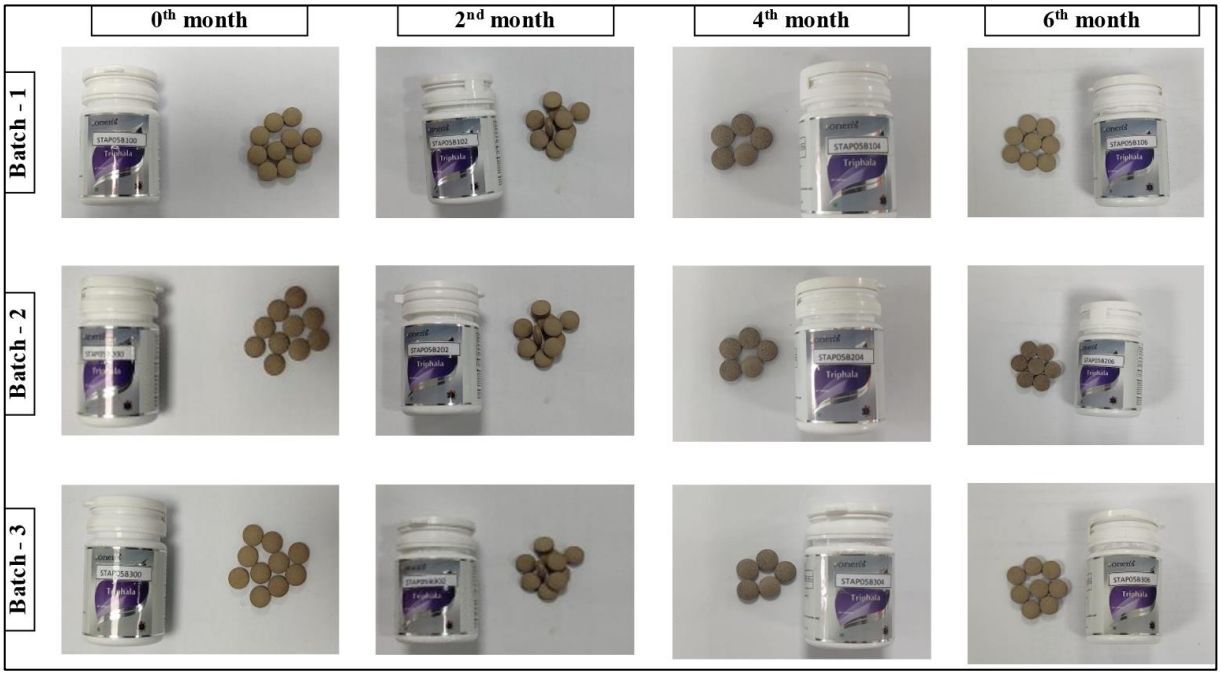

Fig 1: Visual Appearance of *Triphala* Tablets at Different Time Intervals

Table 1: Evaluation of organoleptic properties for *Triphala* Tablets

Test Parameters	Batch	0th Month	2nd Month	4th Month	6th Month	Criteria	Result
Organoleptic Properties							
Appearance	B-1	Round shaped tablet	Round shaped tablet	Round shaped tablet	Round shaped tablet	No significant change	No significant change
	B-2	Round shaped tablet	Round shaped tablet	Round shaped tablet	Round shaped tablet		
	B-3	Round shaped tablet	Round shaped tablet	Round shaped tablet	Round shaped tablet		
Colour	B-1	Light brown	Light brown	Light brown	Light brown	No significant change	No significant change
	B-2	Light brown	Light brown	Light brown	Light brown		
	B-3	Light brown	Light brown	Light brown	Light brown		
Taste	B-1	Characteristic	Characteristic	Characteristic	Characteristic	No significant change	No significant change
	B-2	Characteristic	Characteristic	Characteristic	Characteristic		
	B-3	Characteristic	Characteristic	Characteristic	Characteristic		
Odour	B-1	Characteristic	Characteristic	Characteristic	Characteristic	No significant change	No significant change
	B-2	Characteristic	Characteristic	Characteristic	Characteristic		
	B-3	Characteristic	Characteristic	Characteristic	Characteristic		

Table 2: Evaluation of organoleptic properties for *Triphala* Tablets

Test Parameters	Batch	0th Month	2nd Month	4th Month	6th Month	Criteria	Result
Disintegration Time (Min.)	B-1	24.30	24.17	19.20	19.25	Not more than 30.0 mins	Complies
	B-2	25.20	25.20	18.08	18.21		
	B-3	24.18	24.31	19.20	19.17		
Friability (%)	B-1	0.18	0.09	0.43	0.23	Not more than 1.0 %	Complies
	B-2	0.20	0.12	0.43	0.13		
	B-3	0.09	0.12	0.43	0.17		
Hardness (kg/sq.cm)	B-1	1.0	2.8	2.0	1.9	1.0 – 6.0	Complies
	B-2	3.8	3.9	5.8	5.0		
	B-3	4.2	3.9	3.1	5.2		
pH	B-1	4.25	4.17	3.12	4.21	3.0 – 5.0	Complies
	B-2	4.09	3.93	3.40	3.95		
	B-3	4.93	4.85	3.38	3.83		
Water Soluble Extractive (%)	B-1	56.41	50.41	55.63	52.40	± 25.0 %	Complies
	B-2	56.98	58.15	52.12	49.90		
	B-3	53.27	52.28	54.52	50.50		
Alcohol Soluble Extractive (%)	B-1	15.52	11.24	22.83	16.60	± 25.0 %	Complies
	B-2	9.74	7.99	18.96	15.64		
	B-3	13.26	12.05	19.62	15.30		

Table 3: Proximates and active ingredient of *Triphala* Tablet

Test Parameters	Batch	0th Month	2nd Month	4th Month	6th Month	Criteria	Result
Proximates							
Moisture (%)	B-1	1.89	3.92	3.42	3.81	Not more than 5.0 %	Complies
	B-2	3.29	2.90	5.90	5.98		
	B-3	1.10	4.23	3.66	3.78		
Ash (%)	B-1	22.57	22.57	22.72	25.23	± 25.0 %	Complies
	B-2	23.08	23.43	22.49	23.43		
	B-3	24.61	24.88	20.49	22.76		
Protein (%)	B-1	2.65	1.79	3.80	2.00	± 25.0 %	Complies
	B-2	3.15	2.69	2.93	2.40		
	B-3	2.64	2.24	3.41	3.08		
Fat (%)	B-1	0.09	0.19	0.03	0.24	± 25.0 %	Complies
	B-2	0.10	0.25	0.07	0.26		
	B-3	0.07	0.15	0.08	0.28		
Carbohydrate (%)	B-1	72.80	71.53	70.03	68.72	± 25.0 %	Complies
	B-2	70.38	70.73	68.61	67.93		
	B-3	71.58	68.50	72.36	70.10		
Energy (Kcal/100 g)	B-1	302.61	294.99	295.59	285.04	± 25.0 %	Complies
	B-2	295.02	295.93	286.79	283.66		
	B-3	297.51	284.31	303.80	295.24		
Active Compound (Gallic acid)							
Gallic acid (mg/Tablet)	B-1	17.30	16.30	15.40	14.81	± 15.0 %	Complies
	B-2	16.70	15.91	15.01	14.39		
	B-3	16.31	15.60	15.30	14.11		

Table 4: Microbial load of *Triphala*

Test Parameters	Batch	0th Month	2nd Month	4th Month	6th Month	Criteria	Result
Microbiological							
Total Plate Count (CFU/g)	B-1	< 10	-	-	< 10	1 X 10^5 / g	Complies
	B-2	< 10	-	-	< 10		
	B-3	< 10	-	-	< 10		
Yeast & Moulds (CFU/g)	B-1	< 10	-	-	< 10	1 X 10^3 / g	Complies
	B-2	< 10	-	-	< 10		
	B-3	< 10	-	-	< 10		
Staphylococcus (per g)	B-1	Absent	-	-	Absent	Absent	Complies
	B-2	Absent	-	-	Absent		
	B-3	Absent	-	-	Absent		
E. coli (per g)	B-1	Absent	-	-	Absent	Absent	Complies
	B-2	Absent	-	-	Absent		
	B-3	Absent	-	-	Absent		
Salmonella (per 25 g)	B-1	Absent	-	-	Absent	Absent	Complies
	B-2	Absent	-	-	Absent		
	B-3	Absent	-	-	Absent		

To determine the intercept and slope, many physicochemical parameter findings, as well as the active substance, were taken into account (Table 4). With 10% degradation under accelerated conditions of 40 °C 2 and 75% 5 relative humidity, the estimated shelf life of *Triphala* was computed (Table 5).

Table 5: The intercept and slope of different physicochemical parameters and active compound of *Triphala* Tablet

Intercept and slope of different physicochemical parameters						
Parameters	**0th month**	**2nd month**	**4th month**	**6th month**	**Intercept**	**Slope**
pH	4.42	4.16	3.3	4	4.3543	-0.1145
Water Soluble Extractive	55.55	53.61	35.6	50.93	55.556	-0.6697
Alcohol Soluble Extractive	12.84	10.74	5.49	15.81	10.764	1.9075
Moisture	2.09	3.68	4.33	4.53	2.4673	0.3962
Total Ash	23.42	23.63	21.9	23.81	23.273	-0.0278
Active Ingredient (Gallic acid)	16.77	15.94	15.24	14.44	16.749	-0.3845

Table 6: conclude shelf life of *Triphala* from different physico-chemical parameters and Active compound.

Triphala						
Stability data @ 40 °C± 2 and 75%±5 RH						
Parameters	**0th month**	**10% of 0th month**	**At 10% degradation**	**Intercept**	**Slope**	**Months at 10% degradation**
pH	4.42	0.442	3.978	4.3543	-0.11	3.29
Water Soluble Extractive	55.55	5.555	49.995	55.556	-0.67	8.30
Alcohol Soluble Extractive	12.84	1.284	11.556	10.764	1.908	0.42
Moisture	2.09	0.209	1.881	2.4673	0.396	-1.48

Total Ash	23.42	2.342	21.078	23.273	-0.03	78.96
Active Ingredient (Gallic acid)	16.77	1.677	15.093	16.749	-0.38	4.31
			Average mean (Months)			15.63
			Extrapolated value (Months)			51.58
			Shelf life (Years)			4.30

6. Conclusion

The extensive statistical analysis conducted on *Triphala* reveals a remarkable maximum shelf life of four years and three months. This noteworthy conclusion is drawn from an in-depth examination of accelerated stability data across various batches of the product. Significantly, this analysis indicates that there were no notable changes in the values of active ingredients, physicochemical properties, proximate components, microbiological parameters, or organoleptic characteristics over a six-month period. This duration of scrutiny involved subjecting the product to accelerated conditions, including elevated temperature (40 °C) and humidity (75%). The unexpected longevity of the shelf life, surpassing traditional expectations, is attributed to the integration of advanced packaging technology. This technological innovation plays a pivotal role in effectively controlling and regulating various aspects of the manufacturing process, thereby minimizing or eliminating potential drawbacks that could compromise the stability of the product. It's noteworthy that the tablets are prepared using the direct compression method, a manufacturing approach that not only meets but complies with stringent hardness and disintegration tests. This adherence to quality standards further substantiates the robustness and reliability of the product. The evaluation of the stability of herbal medicines, botanicals, and traditional medicines is inherently a complex and meticulous process. In this context, the regular analysis of bioactive markers emerges as an indispensable tool. Such analytical practices contribute significantly to understanding intricate situations and identifying potential solutions, ultimately leading to a more profound comprehension of the biological and biologically active compounds within the product. This thorough evaluation reinforces the product's efficacy and reliability, providing valuable insights into its sustained stability over an extended shelf life.

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8. Conflicts of Interest

The authors declare that they have no conflicts of interest.

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