Comparative quality evaluation on branded *Triphala* tablets in Ayurveda drug market of Sri Lanka

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Abstract

At present standardization is essential to guarantee the quality of products as the market of all commodities has become global. The objective of this study was to comparatively evaluate the quality of four different branded *Triphala* tablets and one capsule (sample A, B, C, D, and E) available in Ayurveda drug market of Sri Lanka. All the brands were purchased from Ayurveda drug market and assessed for organoleptic, physical, chemical and pharmaceutical parameters. According to the results, total ash values (5.4%, 5%, 3.3%, 5.7%, 4.9% respectively) were above the standard limit of 2%. Water-soluble ash (0.9%, 2.4%, 1.6%, 2.7%, 1.2%) and acid-insoluble ash (2.5%, 2%, 1.9%, 2%, 1%) values were <3%. Water-soluble extractive values (7.35%, 13.08%, 20.03%, 11.28%, 8.18%) were higher than alcohol-soluble extractive values (7.25%, 12.23%, 13.48%, 9.7%, 8.15%) in all brands. Loss on drying at 105^0C of all were below 12%. Ethanolic extracts of all were positive for tannins, flavonoids, phenols, steroids, glycosides and carbohydrates and negative for alkaloids, terpenoids and proteins. Only C was positive for saponins. TLC (Toluene: Ethyl-acetate: Formic acid/3:5:1) showed similar patterns for all brands. HPTLC fingerprints of all were alike in terms of number of peaks and their intensity, except tablet C with four additional peaks. A, C and E passed the weight variation test. Friability of A, B and C were below standard limit of 1%. Disintegration time of A was below the standard limit of 15minutes. Hardness ranged from 172N to 503N. As there is a considerable variation in physical and pharmaceutical parameters of all brands, it is urgent to maintain common standardization parameters in Ayurveda drug market.

Keywords: *Triphala,* Standardization, Physical parameters, Pharmaceutical parameters, HPTLC.

Introduction

In the current world, the market for various commodities has undergone a remarkable transformation, becoming increasingly interconnected on a global scale. This phenomenon holds true, particularly for health-related products, which are now being produced in various corners of the world with the aim of reaching markets across the globe. Amidst this global expansion, the importance of standardization holds a fundamental necessity. Standardization is the process of implementing and developing technical standards. It plays an important role in ensuring the uniformity of health-related products across diverse geographical regions, consequently guaranteeing consumers access to consistently high-quality products with well-defined constituents.

The leading organization in implementing global health standards is the World Health Organization (WHO). WHO, through its collaborative efforts and support, establish mechanisms for the integration of traditional plant medicines into primary healthcare programs. Since the global market for health-related products continues to grow day by day, the critical importance of standardization is a need of the world market. Proper standardization process must be continued from the initial point of raw materials and up to the final outcome of the finished products. The three main pillars of standardization are quality,

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safety and efficacy[1]. The assessment of safety and efficacy, ensuring the availability of an adequate supply of herbal medicines, while being mindful about adulteration and upholding standards for the quality control of both raw and processed materials is of vital necessity in the market of herbal products.

A conventional example of a traditional poly-herbal formula with a rich history of medicinal use is *Triphala*. This commonly used formula is composed of the pericarps of the fruits of *Terminalia chebula* Retz. and *Terminalia bellirica* (Gaertn.) Roxb. both of which belong to the Combretaceae family, along with *Phyllanthus emblica* Linn. from the Euphorbiaceae family in equal proportions, based on Ayurvedic Formulary of India (AFI). *Triphala* is honored for its numerous pharmacological actions, used in herbal medicinal practices. The pharmacological actions of *Triphala* span a diverse spectrum of health benefits, including its role as a potent laxative, capacity for rejuvenating ocular health[2], potential as an anti-diabetic agent[3], anti-inflammatory properties[4], function as an appetizer[5], anti-oxidant and anti-bacterial properties[6,7]. Each of these properties showcases the holistic nature of *Triphala*, reflecting its significance in preventive and curative aspects within the traditional medicine system.

Triphala, a prominent herbal drug widely employed in traditional medicinal practices within Sri Lanka, served as the focal point of this study. The primary aim of this study was to conduct a comparative evaluation of the quality attributes of five distinct commercial brands of *Triphala* formulations, denoted as A, B, C, D in tablet form, and E in capsule form, all of which are readily available within the Sri Lankan Ayurveda drug market. The selection of these five specific brands was based on their prevalence and common usage among Ayurveda medical practitioners in Sri Lanka. Subsequently, samples of all five brands were purchased from local Ayurveda drug market. The evaluation process consisted of a thorough analysis of the products, covering a range of parameters including organoleptic parameters, physical parameters, chemical parameters and pharmaceutical parameters[8].

Materials and methods

Three samples from each of the 5 brands of *Triphala* were purchased from local Ayurveda drug market to assess for their organoleptic parameters, physical parameters, chemical parameters and pharmaceutical parameters. Tablet forms were named as sample A, B, C & D and the capsule form was named as sample E. Basic information of all the 5 brands are shown in the Table no 1.

Organoleptic Evaluation

Color, odor, taste and texture were assed under organoleptic parameters. All the samples were examined under diffuse daylight to observe the color. A small portion of samples were placed on a dish and slowly and repeatedly inhaled the air of material to sense the odor. Pieces of samples were chewed and tasted for taste sensation. Samples were touched to detect the texture.

Physical Evaluation

Physical parameters such as, ash values (Total ash, Water-soluble ash & Acid-insoluble ash), extractive values (Water-soluble and Alcohol-soluble) and loss on drying at 105^0C were done in triplicate for each brand and the average was taken. Standard methods prescribed in WHO guidelines for quality control methods for medicinal plant materials were followed for each test[9].

Total ash

Crucibles with 4g of powdered samples were ignited in a muffle furnace at 550^0C for 5-6 hours till total white ash was obtained. The total ash values were calculated with reference to the air-dried powdered drug material.

Water-soluble and Acid-insoluble ash

To the crucibles containing residue after the determination of total ash, 25ml of 2M HCl was added and boiled gently for 5 minutes using bunsen burner. Then the solutions were filtered separately using Whatman filter paper no. 42 and the insoluble matter was collected on to it. Insoluble matter

retained on the filter papers was washed with hot water and then the filter papers were transferred to the same silica crucibles and ignited to constant weight in the muffle furnace at a temperature not exceeding 450^0C. The percentage of acid-insoluble ash values were calculated with reference to the air-dried powdered drug material. The above procedure was performed with 25 ml of distilled water to find the water-soluble ash value.

Water-soluble and Alcohol-soluble extractive values

Four grams of powdered samples were transferred to conical flasks with 100ml of water. The flasks were kept in the shaker for 6 hours and then they were allowed to stand still for 18 hours. The mixtures were filtered using Whatman filter paper no 1, 25ml of the filtrates were measured from each mixture and were transferred to porcelain dishes which the weights were previously measured. The dishes were placed on a water bath and the solvent was evaporated completely. After that they were dried in a hot air oven at 105^0C for 6 hours, cooled and finally weighed. The percentage of water-soluble extractive values were calculated with reference to the air-dried powdered drug material. The above procedure was performed with 100ml of ethanol to find the alcohol-soluble extractive value.

Loss on drying at 105^0C

Two grams of powdered samples were heated in a hot air oven at 105^0C till constant weight was obtained. The percentage moisture contents of the samples were calculated with reference to the air-dried powdered drug material.

Chemical Evaluation

Preparation of ethanolic extracts of the samples

Soxhlet extraction at 60^0C using 5g of sample powder from each brand and 250ml of 99% absolute ethanol was followed to obtain the ethanolic extracts of each sample. Ethanol in each extract was evaporated using rotary evaporator at 45^0C leaving a small yield of the concentrated extracts. The extracts were stored in air tight glass vials at 4^0C until taken for further analysis.

Phytochemical Screening[10]

Alkaloids, Tannins, Phenols, Saponins, Flavonoids, Terpenoids, Steroids, Cardiac Glycosides, Carbohydrates and Proteins were analyzed qualitatively in the five ethanolic extracts. The procedures followed for each phytochemical are shown in the Table no 2.

Thin Layer Chromatography and High-Performance Thin Layer Chromatography

Extracts were spotted on a pre-coated silica gel 60G F_{254} aluminum plate separately. Solvent system of Toluene: Ethyl acetate: Formic acid (3:5:1 v/v%) was used to obtain a clear separation of compounds. Developed TLC plate was visualized under UV radiation of 254 nm and 366 nm wave length. The plate was scanned with the HPTLC scanner using winCATS software.

Pharmaceutical Evaluation[11]

Weight variation

From each brand 20 tablets/capsules were weighed at random and average weight of the tablets/capsule were calculated. Then the individual weight of a tablet/capsule was compared with average weight.

Weight variation % = (Individual weight – Average weight)/ (Average weight) × 100%

(Acceptance criteria – Not more than 2 individual tablet weights deviate from the average weight by more than the deviation stated in the Indian Pharmacopeia/IP).

Friability

20 tablets from each brand were weighed and placed them in the rotating drum of the friability apparatus. The drum was rotated 100 times. The samples were reweighed and calculated the weight loss.

$$\text{Friability} = \frac{\text{Initial weight} - \text{Weight loss}}{\text{Initial weight}} \times 100\%$$

Table 1: Basic information of *Triphala* tablets and capsule

Brand	Manufacturing Date	Expiry Date	Batch No.	Dosage form
A	18.02.2023	18.02.2025	241	Tablet
B	05.06.2023	05.06.2024	039121	Tablet
C	04.04.2023	04.04.2024	252	Tablet
D	22.02.2023	21.02.2025	2517	Tablet
E	13.02.2023	12.02.2025	736A	Capsule

Table 2: Phytochemical analysis of ethanolic extracts of different brands of *Triphala* tablets

Phytochemical	Procedure	Observation
Alkaloid	Mayer's reagent test: 2 drops of the reagent was added to 2ml of each extract and mixed well. Wagner reagent test: 2 drops of the reagent was added to 2ml of each extract and mixed well.	Cream color precipitate Reddish color precipitate Reddish colour brown precipitate
Tannins	$FeCl_3$ Test: 5 drops of $Fecl_3$ were added to each extract and mixed well.	Black precipitate
Phenols	Lead acetate test: 3 drops of lead acetate solution was added to 5ml of each extract and mixed well.	Yellow precipitate
Saponins	Foam test: 5ml of each extract was mixed with 2.5ml of distilled water separately, shaken vigorously, and kept for 10 minutes.	Stable foam of honey comb appearance
Flavonoids	Ammonia test: 5ml of dil. Ammonia solution was added to 5ml of each extract followed by the addition of con. H_2SO_4.	Yellow color
Terpenoids	Salkowski test: 5ml of each extract was mixed with 2ml of Chloroform and 3ml of con. H_2SO_4 was added along the sides of the test tube.	Reddish brown color
Steroids	Lieberman Burchard test: 2ml of Acetic anhydride and 2ml of con.H_2SO_4 were added to 2ml of each extract and mixed well.	Dark bluish green color
Cardiac glycosides	Keller Kiliani's test: 1ml of Glacial acetic acid was added to 3ml of each extract and con.H_2SO_4 was introduced to the bottom of the tube.	Reddish brown ring at the interface of the two liquids
Carbohydrates	Benedict's test: 2ml of each extract was mixed with 3ml of Benedict's reagent and boiled for 2 minutes.	Brick red precipitate
Proteins	Biuret test: 2ml of each extract was mixed with 2ml of 1% NaOH and few drops of $CuSO_4$.	Purple color

Table 3: Weight variation limits of tablets as per Indian Pharmacopeia

Average weight of a tablet	% of weight variation acceptable
80mg or less	± 10%
80 – 250mg	± 7.5%
> 250mg	± 5%

Disintegration

One tablet was placed in each tube of the Disintegration apparatus and the basket of the apparatus was filled with distilled water at 37^0C. Then the time taken for all the tablets to disintegrate and pass through the mesh were observed. If any residue remains it must have a soft mass with no palpably firm core.

Hardness

Hardness of one tablet from each brand was tested using hardness tester.

Results

Organoleptic Evaluation

Brand A was having dark yellow color, brand B and C were having dark brownish green, brand D was having a dark yellow and brand E was having a light green color. Each brand was having a characteristic odor specific to them. Brands A, C and D were having sour taste and brands B and E were having a bitter taste. Brands A to E were having smooth texture.

Table 4: Results for the physical evaluation of different brands of *Triphala* tablets

Physical Parameters	Brand A M±SD	Brand B M±SD	Brand C M±SD	Brand D M±SD	Brand E M±SD
Total ash	5.4±0.10	5.0±0.10	3.3±0.10	5.7±0.10	4.9±0.10
Water-soluble ash	0.9±0.26	2.4±0.30	1.6±0.20	2.7±0.36	1.2±0.26
Acid-insoluble ash	2.5±0.20	2±0.20	1.9±0.10	2±0.20	1±0.20
Water-soluble extractive value	7.35±0.52	13.08±0.21	20.03±0.19	11.28±0.30	8.18±0.25
Alcohol-soluble extractive value	7.25±0.52	12.23±0.15	13.48±0.14	9.7±0.20	8.15±0.24
Loss on drying at 105^0C	8.6±0.10	5.15±0.20	7.75±0.13	7.1±0.30	9.1±0.10

Table 5: Results for the phytochemical analysis of ethanolic extracts of different brands of *Triphala* tablets

Phytochemical	Brand A	Brand B	Brand C	Brand D	Brand E
Alkaloid	-	-	-	-	-
Tannins	+	+	+	+	+
Phenols	+	+	+	+	+
Saponins	-	-	+	-	-
Flavonoids	+	+	+	+	+
Terpenoids	-	-	-	-	-
Steroids	+	+	+	+	+
Cardiac glycosides	+	+	+	+	+
Carbohydrates	+	+	+	+	+
Proteins	-	-	-	-	-

Physical Evaluation

The Table 4 shows the results for the physical evaluation of different brands of *Triphala* tablets.

Chemical Evaluation

The Table 5 shows the results for the phytochemical analysis of ethanolic extracts of different brands of *Triphala* tablets. The figure 1 show the Thin Layer Chromatogram of ethanolic extracts under 256nm and 366nm UV light while the figure 2 shows the HPTLC fingerprint profiles of the ethanolic extracts of *Triphala.*

Pharmaceutical Evaluation

Table no 6 shows results for the pharmaceutical evaluation of different brands of *Triphala* tablets.

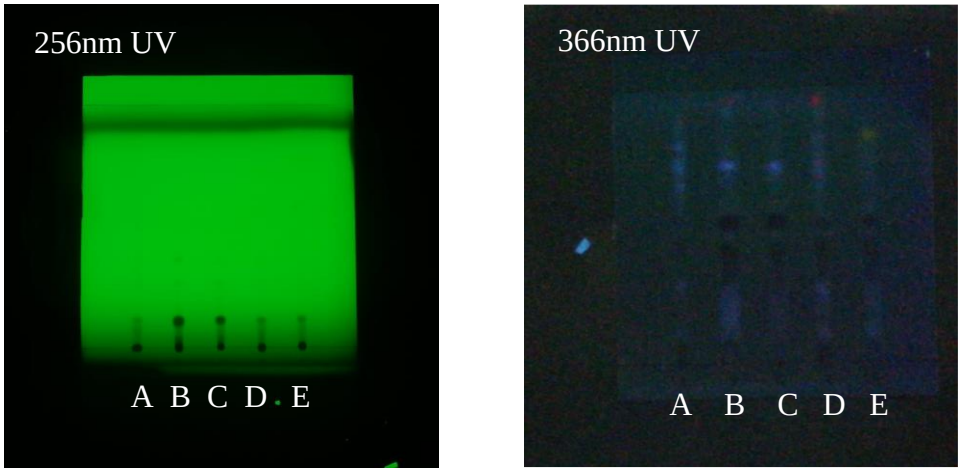

Fig. 1: TLC fingerprint profiles of the five ethanolic extracts of *Triphala* under 256nm and 366nm UV light

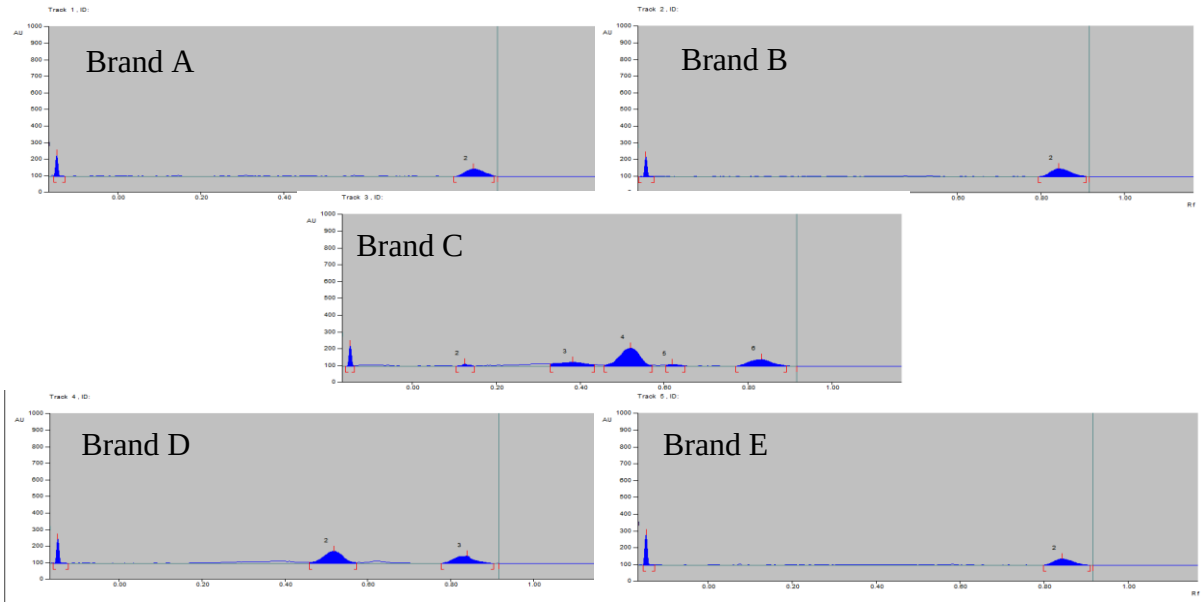

Fig. 2: HPTLC fingerprint profiles of the five ethanolic extracts of *Triphala*

Table 6: Results for the pharmaceutical evaluation of different brands of *Triphala* tablets

Pharmaceutical parameter	Brand A	Brand B	Brand C	Brand D	Brand E
Weight variation	Passed	Failed	Passed	Failed	Passed
Friability	0.03%	0.09%	00%	2.5%	--
Disintegration	12min	57min	30min	45min	--
Hardness	176N	205N	503N	172N	--

Discussion

Organoleptic studies showed more similarity in all the brands. Ash values are used to determine the quality and purity of a drug. Low ash values indicate more purity and quality while high ash values indicate contamination, substitution or adulteration of a drug. In this study, total ash values of all the brands were above the standard limit of 2%. These values were comparable with values obtained in a previous study on three different brands of *Triphala* tablets[12]. Acid-insoluble ash value indicates the presence of siliceous impurities while water-soluble ash value indicates the presence of inorganic contents. In this study those values for all the brand were below 3% which are within the standard limit[12]. These values were not comparable with the previous study[12]. Water-soluble extractive values are higher than alcohol-soluble extractive values in all brands in this study. The same result was obtained in the previous study[12]. Brand C was having the highest water-soluble and alcohol-soluble extractive values in this study. It indicates that most of the phytoconstituents in the samples were more extracted and soluble in water than alcohol. Loss on drying is used to determine the volatile components in a drug. Low moisture content prevent microbial growth and it is important for the stability of an herbal drug. In this study, loss on drying at 105^0C of all the brands were below the standard limit of 12% w/w% and these values were comparable with the previous study[12]. However, brand E was having a high loss on drying value when compared with the others.

In a previous study on *Triphala* tablets, the phytochemical screening of the aqueous extract of three different brands revealed the presence of tannins, flavonoids, phenols, steroids, carbohydrates, saponins while glycosides were present only in two brands[12]. In this study, ethanolic extracts of all the brands were positive for tannins, flavonoids, phenols, steroids, glycosides and carbohydrates and only extract C was positive for saponins. Ethanolic extracts of all the brands were negative for alkaloids, terpenoids and proteins. Difference in phytochemical screening may be due to collection of raw materials from different geographical locations, variations in quantity of each raw material, variations in excipients added in the production process, adulteration or substitution. Thin Layer Chromatogram showed similar patterns for all the brands. HPTLC fingerprints of brands A, B and E were similar in terms of number of peaks and their intensity. HPTLC fingerprint of tablet C showed four additional peaks and tablet D showed one additional peak.

In the pharmaceutical analysis, weight variation test determines uniformity in accordance with the formulation of each batch of tablets. In this study, tablets A, C and capsule E passed the weight variation test as per IP standards. Tablets B and D failed the weight variation test as per IP standards. Friability test determines the tendency of a tablet to chip or break upon compression. Friability of all the tablets in the study except tablet D were within the standard limit of 1%. Disintegration time determines when a tablet will disintegrate to reach dissolution. Tablet A had a disintegration time within the standard limit (<15min) while Tablets B, C and D exceeded the standard time for disintegration in this study. Hardness of a tablet determines the force required to break a tablet. Tablet requires a certain strength to withstand mechanical shocks on handling in manufacturing, packaging and transporting. In this study hardness of tablets of the different brands ranged from 172N to 503N.

Conclusion

Organoleptic and chemical parameters of all the brands of *Triphala* tablets had no considerable difference in their values. But physical and pharmaceutical parameters of all the brands of *Triphala* had considerable difference. The results of the study concludes that there is no uniformity in all the formulations. Therefore, there is an urgent need to make more rigid quality control parameters to maintain the standardization of *Triphala* tablets in the Ayurveda drug market.

Conflict of Interest

Not declared.

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