

Comparative Quality Assessment of Three Different Marketed Brands of Indian Polyherbal Formulation - Triphala Churna



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Abstract

Triphala Churna is a polyherbal formulation widely used in the traditional Indian system of medicine. It is an anti-oxidant rich formulation and possesses diverse beneficial properties.

Objective: The present study was designed to evaluate quality profile of Indian polyherbal formulation Triphala Churna. The study was proposed to assess the variation in quality specifications and comparing them with the standard values prescribed within the Ayurvedic and Indian Pharmacopoeia so that industry and regulatory agencies can be made aware about the defects if any, and recommendations may be proposed about the quality and consistency status of the products available in the market.

Methods: Three different marketed formulations of Triphala Churna were assessed comparatively for their organoleptic, physicochemical and phytochemical properties as per the methods prescribed in Pharmacopoeias.

Results: The data analysis revealed that all the parameters of three brands of Triphala Churna had approximately similar values with some significant variations in a few parameters and were compatible with the standard values mentioned in the Pharmacopoeias.

Conclusion: Therefore the present investigation reveals that there is a need to make more stringent quality control parameters in order to reduce variation among different Ayurvedic preparations.

Keywords: Quality Evaluation; Triphala Churna; Pharmaceutical Analysis; Physico-Chemical Analysis; Phytochemical Analysis; Heavy Metal Analysis

Abbreviations: API: Ayurvedic Pharmacopoeia of India; IP: Indian Pharmacopoeia; Pb: Lead; Cd: Cadmium

Introduction

Ayurveda is a system of herbal medicines accredited throughout the world and includes various Ayurvedic formulations such as Asava, Arishta, Ghruta, Taila, Churna, Vati, Gutika, Kwatha and much more. A variety of medicinal herbs has been used in the Ayurvedic medicine system since ancient times in both developed and developing countries [1]. Evaluation of the quality of herbal formulations is important to justify their acceptability and safety. One of the main problems faced by Ayurveda is the lack of unique quality control parameters for herbal medicines and their formulations. The standardization of herbal formulations is essential for assessing the quality of drugs. It is based on

the concentration of its active ingredients, physical, chemical, phytochemical and in vitro, in vivo parameters [2].

Triphala (Sanskrit; tri=three and phala=fruits) is a well-recognized and revered polyherbal medicine consisting of dried fruits of the three plant species *Embolia officinalis* (Family Euphorbiaceae), *Terminalia bellerica* (Family Combretaceae), and *Terminalia chebula* (Family Combretaceae) that are native to the Indian subcontinent. It is classified as a tridoshic rasayana in Ayurvedic medicine as it promotes longevity and rejuvenation in patients of all constitutions and ages. The formula consists of the fruits Amalaki or the Indian Gooseberry, Bibhitaki, and Haritaki of

the three plants generally in equal proportions (1:1:1) and has been used in traditional medicine in India for over 1000 years [3]. It has various applications in medical field like laxative, eye rejuvenator, antiinflammatory, antiviral and so on. It is also effective in headache, dyspepsia, ascites, and leucorrhea, also used as a blood purifier and possess anti- inflammatory, analgesic, antiarthritic, hypoglycemic and anti -aging properties. Triphala is claimed to have antiviral and antibacterial effect [4-13].

Materials and Methods

Procurement of Samples

The following marketed Triphala Churna preparations were used in the present study. Brand A (Batch No. AL 1700), Brand B (Batch No. E-1701), Brand C (Batch No. #A-TPC015). All brands of the Triphala Churna were procured from the local market from the registered Ayurvedic Pharmacy.

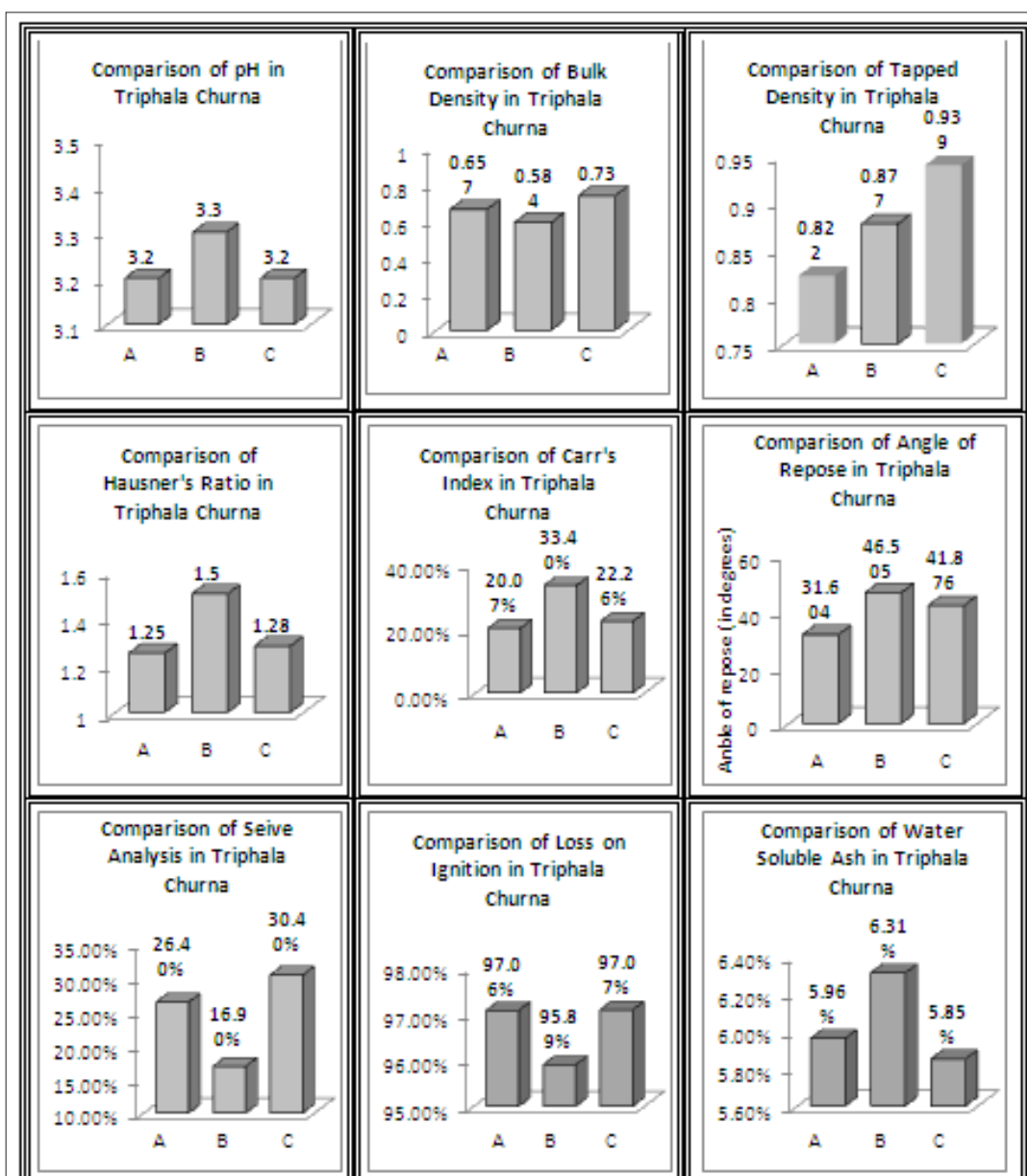
Organoleptic Evaluation

All the organoleptic properties viz. color, odor, taste, and texture of the drug to touch were performed as per standard procedure and noted down.

Pharmaceutical Evaluation

Pharmaceutical parameters like Bulk density, Tapped density, Carr’s Index, Hausner’s Ratio and Angle of repose were determined as per standard protocols.

Determination of Bulk Density and Tapped Density: Bulk density is defined as the mass of many particles of the material divided by the total volume they occupy. The total volume includes particle volume, inter-particle void volume and internal pore volume. Tapped density is the term used to describe the bulk density of a powder (or granular solid) after consolidation/compression prescribed in terms of “tapping” the container of powder a measured number of times, usually from a predetermined height.



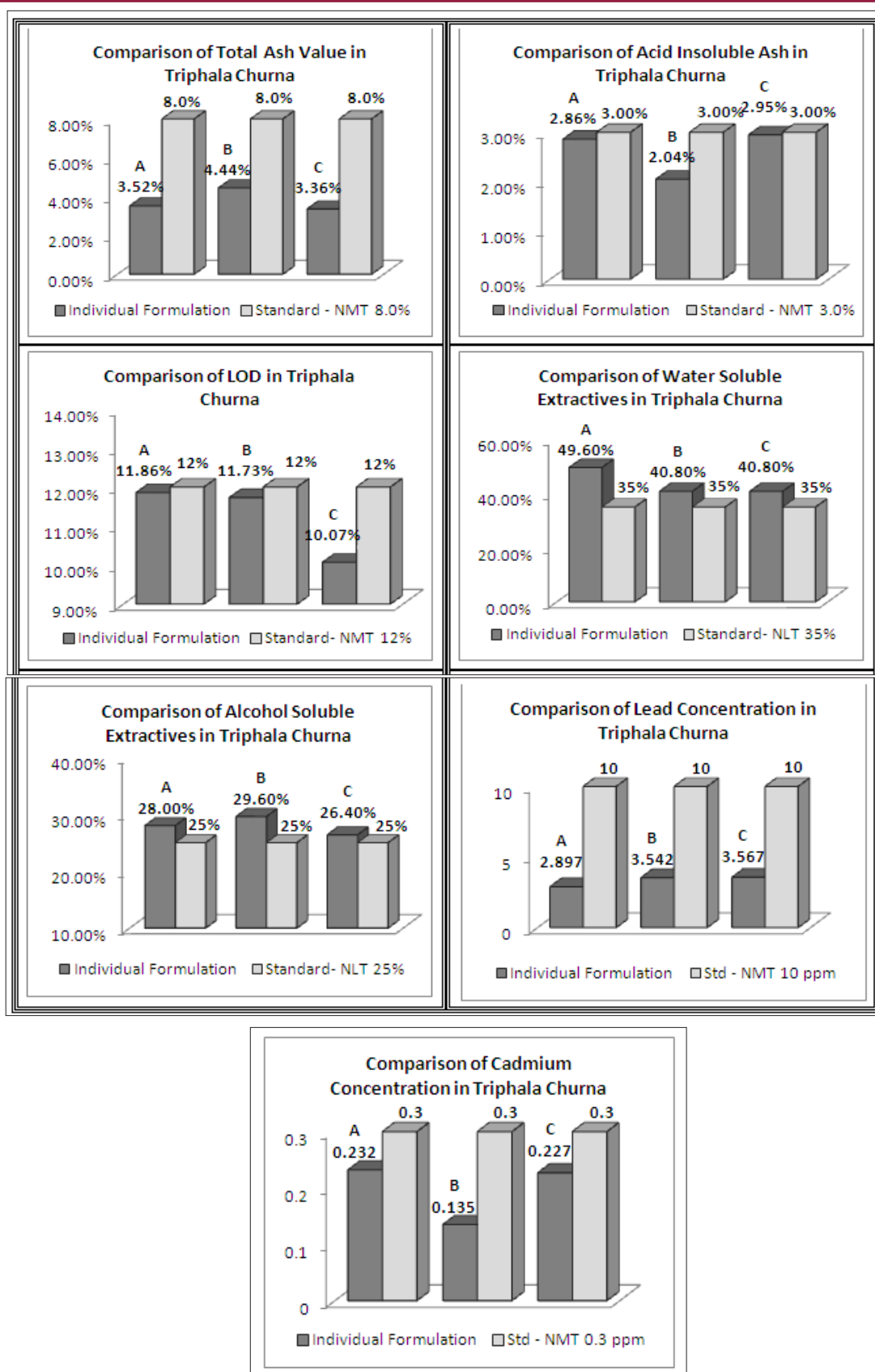


Figure1: Graphs for various Pharmaceutical and Physico-chemical parameters of different brands of Triphala Churna

The term bulk density refers to a measure used to describe a packing of particles or granules and the term Tapped density refers to the true density of the particles or granules (Figure 1).

Formula for calculation:

$$Bulk\ Density = \frac{Weight\ of\ powder\ taken}{Bulk\ Volume\ of\ powder} = \frac{10}{\pi r^2 h}$$

$$\text{Tapped Density} = \frac{\text{Weight of powder taken}}{\text{Tapped Volume of powder}} = \frac{10}{\pi r^2 h_t}$$

Where,

$\pi r^2 h =$ Volume of Graduated Cylinder

$h_b =$ Bulk height of powder

$h_t =$ Tapped height of powder

Determination of Carr's Compressibility Index: The Carr index is an indication of the compressibility of a powder. It is another indirect method of measuring the powder flow from bulk and tapped density.

Formula for calculation:

$$\text{Carr's Index (\%)} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

Determination of Hausner's Ratio: Hausner's ratio is related to inter-particle friction and as such can be used to predict the powder flow properties.

Formula for calculation:

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

Determination of Angle of Repose: The angle of repose is a parameter used to estimate the flowability of a powder. It is defined as the maximum angle possible between the surface of the pile of powder and the horizontal plane. Powders with low angles of repose will flow freely and powders with high angles of repose will flow poorly.

Formula for calculation:

$$\tan \theta = \frac{h}{r}$$

Where,

$\theta =$ Angle of repose

$h =$ Height of pile

$r =$ radius of the base of pile $\tan \theta$

Physico-Chemical Evaluation

Physicochemical parameters like foreign matter, moisture content (Loss on Drying), pH, total ash, acid Insoluble ash, water-soluble extractive, alcohol soluble extractive values of all three samples were determined as per standard protocols. All the procedures are described as follows:

Determination of Foreign Matter: 100g of sample was taken and spread in a thin layer on a suitable platform and was examined in daylight with unaided eye (or using 6x or 10x magnifying glass) and the foreign matter was separated and weighed. The percentage of foreign matter was calculated with reference to the drug sample.

Standard: The sample should not contain more than 2% of foreign matter, unless otherwise specified in individual monograph.

Determination of Moisture Content/ Loss on Drying (LOD):

An accurately weighed 5g of polyherbal formulation powder was taken in a tarred evaporating dish. The crude drug was then heated at 105 °C in an oven for 3 hours. The drying and weighing was continued at half an hour interval until difference between two successive weighing corresponded to, not more than 0.25 per cent. Percentage moisture content of the sample was calculated with reference to the air dried powdered drug material.

Formula for calculation:

$$\% \text{LOD} = \frac{w_2 - w_3}{w_3 - w_1} \times 100\%$$

Where,

$W_1 =$ weight of container (g)

$W_2 =$ weight of container + wet sample (g)

$W_3 =$ weight of container + dried sample (g)

$W_2 - W_3 =$ weight of moisture

$W_3 - W_1 =$ weight of dried sample

Determination of Loss on Ignition (LOI)

An accurately weighed 5g of polyherbal formulation powder was taken in a previously ignited and tared silica crucible and was heated in the oven at 105 °C overnight (or the previously dried sample can also be used). The crucible was cooled and reweighed. The crucible was then placed into the furnace tray and was ignited in the Muffle Furnace at 500 °C for about 4hrs. The sample was then cooled in a dessicator for 30min and reweighed with the ash in it (W_A). The observations were noted.

Formula for calculation:

$$\% \text{LOI} = \frac{w_s - w_a}{w_s - w_c} \times 100\%$$

Where,

$W_c =$ weight of crucible (g)

$W_s =$ weight of sample (g)

$W_A =$ weight of ash (g)

Determination of Total Ash: An accurately weighed 3g of the sample was taken in a previously ignited and tared silica dish/ crucible. The material was evenly spread and ignited in a Muffle Furnace by gradually increasing the temperature to not more than 450 °C – 600 °C till the carbon free ash was not obtained. The total ash value was calculated with reference to the air-dried powdered drug material.

Formula for calculation:

$$\% \text{ Total Ash} = \frac{\text{Weight of Ash}}{\text{Weight of sample taken}} \times 100\%$$

Determination of Acid Insoluble Ash: Ash above obtained, was boiled for 5min with 25ml of 1M Hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water and filter paper was

burnt to a constant weight in a muffle furnace. The percentage of acid insoluble ash was calculated with reference to the air-dried powdered drug material.

Formula for calculation:

$$\% \text{ of acid-Insoluble Ash} = \frac{\text{Weight of acid insoluble residue}}{\text{Weight of sample taken}} \times 100\%$$

Determination of Water Soluble Ash: 1g of ash obtained in total ash experiment was boiled for 5min with 25ml water and insoluble matter collected on an ashless filter paper which was then washed with hot water and ignited for 15min at a temperature not exceeding 450 °C in a muffle furnace. Difference in weight of ash and weight of insoluble matter was determined as difference represents the value. The percentage of water insoluble ash was calculated with reference to the air-dried powdered drug material.

Formula for calculation:

$$\% \text{ of water soluble Ash} = \frac{\text{Weight of water soluble residue}}{\text{Weight of sample taken}} \times 100\%$$

Determination of Extractive Values

a. **Determination of Alcohol Soluble Extractives:** 5gm of churna was accurately weighed and placed inside a glass stoppered conical flask. It was then macerated with 100ml of ethanol. The flask was shaken frequently during the first 6 hours and was kept aside without disturbing for 18 hours. It was then filtered and about 25ml of filtrate was transferred into a tared flat-bottomed shallow dish and was evaporated to dryness on a water bath. It was then dried to 105 °C for 6 hours, cooled and finally weighed. The percentage of Alcohol Soluble extractives was calculated with reference to the air-dried powdered drug material.

Formula for calculation:

$$\% \text{ of alcohol soluble Extractive} = \frac{\text{Weight of residue} \times 100 \times 100}{25 \times \text{Weight of sample taken}} \%$$

b. **Determination of Water Soluble Extractives:** Proceed as directed for determination of Alcohol-Soluble Extractive, using chloroform water (2.5ml chloroform in purified water to produce 1000ml) instead of ethanol.

Determination of pH Value: The powder sample of triphala churna was weighed to about 5g and immersed in 100 ml of water in a beaker. The beaker was closed with aluminum foil and left behind for 24 hours in room temperature. Later the supernatant solution was decanted into another beaker and the pH of the formulation was determined using a calibrated digital pH meter.

Phytochemical Evaluation

The aqueous and alcoholic extracts of the respective formulations were prepared and were subjected to preliminary phytochemical screening. These tests reveal the presence of various bioactive secondary metabolites which might be responsible for their medicinal attributes. Methods for preliminary qualitative phytochemical tests of the plant extracts are given below in the Tables 1 & 2.

Table 1: Relationship of Angle of Repose, Carr's Index & Hausner's Ratio with Flow Properties of Powder.

Angle of Repose	Carr's Index	Hausner's Ratio	Flow Properties
25-30	<10	1.00-1.11	Excellent
31-35	11-15	1.12-1.18	Good
36-40	16-20	1.19-1.25	Fair
41-45	21-25	1.26-1.34	Passable
46-55	26-31	1.35-1.45	Poor
56-65	32-37	1.46-1.59	Very Poor
>66	>38	>1.60	Very Very Poor

Table 2: Preliminary Phytochemical Tests for Plant Extracts

S.No.	Phyto-Constituents	Name of Tests	Procedure	Observation
1.	Alkaloids	Mayer's test	2ml extract + few drops of HCl + Mayer's reagent	Cream Precipitation
		Hager's test	2ml extract + few drops of HCl + Hager's reagent	Yellow Precipitation
		Wagner's test	2ml extract + few drops of HCl + Wagner's reagent	Reddish brown color
2.	Carbohydrates	Molish test	2ml extract + 2 Drops of Molish reagent + few drops of Conc. H ₂ SO ₄	Violet or Reddish color
3.	Reducing sugars	Fehling's test	1ml extract + 1ml Fehling Solution (A and B)	First a Yellow and then Brick Red Precipitation
4.	Flavonoids	Alkaline reagent test	2ml extract + few drops of 40% NaOH solution	Intense yellow color forms which becomes colorless on addition of dil. acid
		Lead acetate test	2ml extract + few drops of Lead Acetate solution	Yellow precipitation
5.	Saponins	Foam test	2ml extract + 4ml distilled H ₂ O Mix well and shake vigorously	Foam formation
6.	Tannins	Braymer's test	2ml extract + 2ml H ₂ O + 2-3 drops of 5% FeCl ₃	Black green or bluish color

7.	Steroids	Salkowski's test	2ml extract + 2ml Chloroform + 2ml Conc. H ₂ SO ₄	Chloroform layer appears red and acid layer shows greenish-yellow fluorescence
8.	Proteins	Millon's test	3ml extract + 5ml Millon's reagent	White precipitate which turns brick red on warming
9.	Glycosides	Keller Killiani's test	2ml extract + Glacial acetic Acid + 1 drop of 5% FeCl ₃ + Conc. H ₂ SO ₄	Reddish brown color appears at the junction of 2 layers and upper layer appears bluish green
10.	Phenols	-	2-3ml of extract + few drops of 5% FeCl ₃ solution	Deep blue-black color
			2-3ml of extract + few drops of Lead Acetate solution	White precipitate
11.	Amino acids	Ninhydrin test	3ml of extract + 3 drops of 5% Ninhydrin solution Keep in boiling water bath for 10min.	Purple or bluish color appears
12.	Terpenoids	Copper Acetate test	2ml extract dissolved in water + 3-4 drops of Copper Acetate solution	Emerald green color

Determination of Heavy Metals (Lead and Cadmium)

Method (Direct Calibration Method): Three reference solutions of the element being examined having different concentrations were prepared covering the range recommended by the instrument manufacturer. Separately the corresponding reagents were added for the test solution and the blank solution was prepared with the corresponding reagents. The absorbance of the blank solution and each reference solution were measured separately, and the readings were recorded. A calibration curve was prepared with the average value of 3 readings of each concentration on the ordinate and the corresponding concentration on the abscissa. A test solution of the substance being examined was prepared as specified in the monograph. The concentration was adjusted such that it falls within the concentration range of the reference solution. The absorbance was measured 3 times, and the readings were recorded and the average value was calculated. The mean value was interpolated on the calibration curve to determine the concentration of the element.

Preparation of Lead standard solution: Lead standard solutions were prepared from Stock solution (1000ppm Sisco Research Laboratories Pvt. Ltd. stock solution). Standard solutions of concentrations, 2, 4, 6, 8 and 10ppm were prepared. The absorption of standard solution measured at 217nm using hollow cathode lamp as a light source & air acetylene blue flame on Atomic absorption Spectrophotometer.

Preparation of Cadmium standard solution: Cadmium standard solutions were prepared from Stock solution (1000ppm Sisco Research Laboratories Pvt. Ltd. stock solution). Standard solutions of concentrations 0.2, 0.4, 0.6, 0.8 and 1.0ppm was prepared. The absorption of standard solution measured at 228.8nm using hollow cathode lamp as a light source & air acetylene blue flame on Atomic absorption Spectrophotometer.

Preparation of Test solution: Weigh accurately about 0.5g of the coarse powder of the substance being examined, transfer into a casparian flask, add 5-10ml of the mixture of nitric acid (HNO₃) and perchloric acid (HClO₄) (4 : 1), add a small hopper on the flask-

top, macerate overnight, heat to slake on the electric hot plate, keep somewhat-boiling, if brownish-black in color, add again a quantity of the above mixture, continuously heat till the solution becomes clear and transparent, then raise temperature, heat continuously to thick smoke, till white smoke disperse, the slaked solution becomes colorless and transparent or a little yellow, cool, transfer it into a 50ml volumetric flask, wash the container with 2% nitric acid solution (HNO₃), add the washing solution into the same volumetric flask and dilute with the same solvent to the volume, shake well. Prepare synchronously the reagent blank solution according to the above procedure.

Determination: Measure accurately 1ml of the test solution and its corresponding reagent blank solution respectively, add 1 ml of solution containing 1% NH₄H₂PO₄ and 0.2% Mg(NO₃)₂, shake well, pipette accurately 10-20μl to determine the absorbance.

Sample analysis: The analysis of the digested samples were carried out using an Atomic Absorption Spectrophotometer (EC Electronics Corporation of India limited AAS Element AS AAS4141) for Lead and Cadmium. The instrumental conditions for Lead analysis are depicted in Table 3.

Table 3: Instrumental Conditions for Analysis of Lead and Cadmium.

Parameters	Pb	Cd
Wavelength (nm)	217	228.8
Slit width (nm)	1.0	0.5
Light Source	Hollow Cathode Lamp	Hollow Cathode Lamp
Flame type	Air/C ₂ H ₂	Air/C ₂ H ₂
Current	10	3.5
AAS Technique	Flame	Flame

Results

Organoleptic Evaluation

The observations for the organoleptic evaluation of three brands of Triphala Churna are reported in Table 4.

Table 4: IResults for Organoleptic Evaluation of different brands of Triphala churna

S.No.	PROPERTIES	BRAND A	BRAND B	BRAND C
1.	Appearance	Powder	Powder	Powder
2.	Color	Brown	Light Brown	Yellowish Brown
3.	Odor	Characteristic	Characteristic	Characteristic
4.	Taste	Salty and sour	Salty and sour	Bitter
5.	Texture	Fine Powder	Moderately Fine Powder	Moderately Fine Powder

Pharmaceutical Evaluation

The observations for the pharmaceutical evaluation of three brands of Triphala Churna are reported in Table 5.

Table 5: Results for Pharmaceutical Evaluation of different brands of Triphala churna.

S.No.	PROPERTIES	BRAND A	BRAND B	BRAND C
1.	Bulk Density	0.657	0.584	0.730
2.	Tapped Density	0.822	0.877	0.939
3.	Hausner's Ratio	1.25	1.50	1.28
4.	Carr's Index	20.07%	33.40%	22.26%
5.	Angle of Repose	31.604 ^o	46.505 ^o	41.876 ^o

Table 7: Phytochemical Screening of Triphala Churna.

S. No.	PHYTO-CONSTITUENT	NAME OF TESTS	BRAND A		BRAND B		BRAND C	
			Aq.	Alco.	Aq.	Alco.	Aq.	Alco.
1.	Alkaloids	Hager's test	-	-	-	-	-	-
		Wagner's test	-	-	-	-	-	-
		Mayer's test	-	-	-	-	-	-
2.	Glycosides	Keller Killani's test	-	-	+	+	-	-
3.	Carbohydrates	Molisch's test	+	+	+	+	+	+
4.	Proteins	Biuret's test	-	-	-	-	-	-
		Millon's test	-	-	-	-	-	-
5.	Amino Acids	Ninhydrin's test	-	-	-	-	-	-
6.	Steroids	Salkowski's test	+	+	+	+	+	+
7.	Flavonoids	Alkaline Reagent test	+	+	+	+	+	+
		Lead acetate test	+	+	+	+	+	+
8.	Terpenoids	Copper Acetate test	-	-	-	-	-	-
9.	Tannins	Ferric Chloride test	+	+	+	+	+	+
10.	Saponins	Foam test	+	-	+	-	+	-
11.	Phenols	Ferric Chloride test	+	+	+	+	+	+
		Lead Acetate test	+	+	+	+	+	+
12.	Ascorbic Acid	-	+	+	+	+	+	

Physico-Chemical Evaluation

The observations for the physico-chemical evaluation of three brands of Triphala Churna are reported in Table 6.

Table 6: Results for Physico-chemical Evaluation of different brands of Triphala churna.

S.No.	PROPERTIES	BRAND A	BRAND B	BRAND C	STANDARD (IP)
1.	Foreign Matter	Nil	Nil	Nil	NMT 3.0%
2.	pH	3.2	3.3	3.2	-
3.	Loss on Drying/ Moisture Content	11.86%	11.73%	10.07%	NMT 12.0%
4.	Water Soluble Extractive	49.6%	40.8%	40.8%	NLT 35.0%
5.	Alcohol Soluble Extractive	28.0%	29.6%	26.4%	NLT 25.0%
6.	Loss on Ignition	97.06%	95.89%	97.07%	-
7.	Total Ash Value	3.52%	4.44%	3.36%	NMT 8.0%
8.	Acid Insoluble Ash	2.86%	2.04%	2.95%	NMT 3.0%
9.	Water Soluble Ash	5.96%	6.31%	5.85%	-

Phytochemical Evaluation

The observations for the phytochemical evaluation of three brands of Triphala Churna are reported in Table 7.

Determination of Heavy Metals (Lead and Cadmium)

The observations for the heavy metal determination of three brands of Triphala Churna are reported in Table 8.

Table 8: Heavy metal analysis of Triphala Churna.

S.No.	PROPERTIES	BRAND A	BRAND B	BRAND C	STANDARD (API)
a.	Lead	2.897	3.542	3.567	10ppm
b.	Cadmium	0.232	0.135	0.227	0.3ppm

Discussion

Triphala churna of Brand A was of powder form of Brown color with a characteristic odor and salty-sour taste. This preparation had pH value of 3.2, and Loss on drying value of 11.86% w/w. Preparation had Alcohol soluble extractives and Water soluble extractives values of 28.0%w/w and 49.6%w/w respectively. The bulk density and tapped density of the powder were 0.657 and 0.822 respectively. The powder flow was fair-good as it had the Carr's Index of 20.07% (Fair), Hausner's ratio of 1.25 (Fair) and Angle of repose of 31.604° (Good). It had Total Ash value of 3.52% w/w, and Acid insoluble ash and Water soluble ash value of 2.86% w/w and 5.96%w/w respectively. Loss on ignition was found 97.06%w/w. The concentrations for heavy metals Lead and Cadmium were found to be 2.897 and 0.232 respectively which were within the prescribed limits. Phytochemical screening revealed the presence of Carbohydrates, Steroids, Flavonoids, Tannins, Phenols and Ascorbic acid in both the extracts and of Saponins in aqueous extract only.

Triphala churna of Brand B was of powder form of Light brown color with a characteristic odor and salty-sour taste. This preparation had pH value of 3.3, and Loss on drying value of 11.73%w/w. Preparation had Alcohol soluble extractives and Water soluble extractives values of 29.6%w/w and 40.8%w/w respectively. The bulk density and tapped density of the powder were 0.584 and 0.877 respectively. The powder flow was poor-very poor as it had the Carr's Index of 33.40% (Very poor), Hausner's ratio of 1.50 (Very poor) and Angle of repose of 46.505° (Poor). It had Total Ash value of 4.44%w/w, and Acid insoluble ash and Water soluble ash value of 2.04%w/w and 6.31%w/w respectively. Loss on ignition was found 95.89%w/w. The concentrations for heavy metals Lead and Cadmium were found to be 3.542 and 0.135 respectively which were within the prescribed limits. Phytochemical screening revealed the presence of Glycosides, Carbohydrates, Steroids, Flavonoids, Tannins, Phenols and Ascorbic acid in both the extracts and of Saponins in aqueous extract only.

Triphala churna of Brand C was of powder form of Yellowish brown color with a characteristic odor and bitter taste. This preparation had pH value of 3.2, and Loss on drying value of 10.07%w/w. Preparation had Alcohol soluble extractives and Water soluble extractives values of 26.4%w/w and 40.8%w/w respectively. The bulk density and tapped density of the powder were 0.730 and 0.939 respectively. The powder flow was passable as it had the Carr's Index of 22.26% (Passable), Hausner's ratio of 1.28 (Passable) and Angle of repose of 41.876° (Passable). It had

Total Ash value of 3.36% w/w, and Acid insoluble ash and Water soluble ash value of 2.95%w/w and 5.85%w/w respectively. Loss on ignition was found 97.07%w/w. The concentrations for heavy metals Lead and Cadmium were found to be 3.567 and 0.227 respectively which were within the prescribed limits. Phytochemical screening revealed the presence of Carbohydrates, Steroids, Flavonoids, Tannins, Phenols and Ascorbic acid in both the extracts and of Saponins in aqueous extract only.

Conclusion

Thus, all the parameters of three brands of Triphala Churna had approximately similar values and were compatible with the standard values mentioned in the Pharmacopoeias except that there was a considerable difference between the flow properties of the powder of all three brands. Hence, from the overall results it can be concluded that phytochemical and analytical evaluation of all the formulations should be done analytically on every batch so as to optimize the final product according to the Pharmacopoeial standards which probably has an impact on the therapeutic activity of the product. The results obtained from the study could be utilized as a reference for setting limits for the reference standards for the quality control and quality assurance of these drugs.

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