ORIGINAL ARTICLE

Comparative analysis to report quality parameters of Triphala Churna: Laboratory preparation and marketed formulation

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Abstract

Aim: The current research revealed the quality analysis of two polyherbal formulations (PHF), that is, Triphala churna by comparative analysis and standardization of laboratory prepared and Marketed Triphala churna. Triphala Churna is a PHF, rich in antioxidant having great remedial efficacy and it is extensively-used in the traditional Indian medicinal system, for over 1000 years. **Materials and Methods:** The churna was prepared from the raw accoutrement deduced from the plant origin –Amalaki, Bibhitaki, and Haritaki in equal proportion (1:1:1) as per *ayurveda*. Here, different quality tests have been done to assess the quality of the herbs as well as safety and efficacy of the both formulations. **Results:** The result is given on the bases of different types of evaluation tests such as organoleptictest, foreign matter test, phytochemical screening, and physicochemical properties. **Conclusion:** Hence, in the final analysis, it was found that both of the formulations have similar values and found under limits as per the WHO and ayurvedic formulary.

Key words: Antioxidant, physicochemical, quality evaluation, standardization

INTRODUCTION

Polyherbal formulations (PHF) are medicinal preparations which consist of more than one herb. The concept of polyherbs has been there for over 1000 years, it is primarily found in *ayurveda* and also in other traditional medicinal systems, where two or more than two herbs are used in a particular ratio for the treatment of the illness. In the *Ayurveda,* single or multiple herbs in the form of extract or in the particular dosages form are used therapeutically. The notion of "PHFs or polyherbalism" was enlightened by the Ayurvedic literature "Sharangdhar Samhita," which helps to attain increased medicinal efficacy.[1] Individual plant active phytochemical constituents are insufficient to deliver the desired therapeutic effect. When numerous herbs are mixed in a predetermined ratio, they provide a stronger medicinal impact and assist to decrease toxicity.[2]

PHF evaluation is important to justify their quality, acceptance, adequacy, operation, and safe for use. The standardization of polyherbal expression is prominent to analyze the quality of the drugs active constituent. It is grounded on assessment of its medicinal ingredients, physical and chemical properties, phytochemical properties, and *in vitro* and *in vivo* criteria.[3]

Churna are defined as collected, dried, and powdered drugs in Ayurvedic system of medicines. PHF according to the components of a specific churna is gathered, cleansed, dried, and crushed, and then sieved to produce a fine powder. They are blended in the right proportions and kept in the right containers.

Types of Churna Based on Nature of Ingredients

1. Single herb powder – example – Ashwagandha powder
2. Poly herbal powder – example – Triphala churna (a combinations of Haritaki, Bibhitaki, and Amalaki).

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3. Metallic powder – example – Loha bhasma (iron calx, zinc calx, etc.).

Dosage and Shelf Life

1. Traditional dosage amount: One karsha (12 g).
2. Practical dosage amount: 3 – 6 g in single or divided dose.

Shelf life is 2 months, as per Sharangdhar Samhita.

If the drug is stored in air tight containers, it can be stored up to 5–6 months.

Marketed churna have about 2 years of shelf life, as per Drug and Cosmetic Act.[4]

Triphala is a well-recognized and reverse polyherbal remedial drug native to the Indian subcontinent, constructed from three distinct plant species' dried fruits Emblica officinalis (*F. Euphorbiaceae*), *Terminalia bellerica* (*F. Combretaceae*), and *Terminalia chebula* (*F. Combretaceae*). Triphala is recognized as a tridoshic rasayana in *Ayurveda,* since it enhances life cycle and revives patients of all ages. The formulation consists of dried herbal fruits, that is, Amalaki, Bibhitaki, and Haritaki in similar proportions of 1/3 each, reported in "The Ayurvedic Pharmacopoeia of India" has been used in Indian medicinal system over millenniums.[5] There are wide range of applications of Triphala in medicinal field such as laxatives, eyes rejuvenator, anti-inflammatory, anti-viral, analgesic, antiarthritic, liver disorder, edema, hypoglycemic, and so on.[6-8] Analysis of maker compounds is essential to maintain the qualitative value and identification of the formulation. Procured medications were subjected to different quality control procedures to determine the quality of in-house formulations.[9]

Significance of PHF

Polyherbal remedy has implemented a crucial role in care of both significant and insignificant types of medical conditions. In the present scenario, the consumers in India rely mostly on herbal medicines. In fact, physicians still uses and recommends numerous drugs that retains botanical origins. The therapeutic capabilities of polyherbal drugs cannot be ignored and have highlighted in the following content.

- They have a huge customer base.
- They are more patient-friendly.
- Advancement of knowledge and technology, herbal pharmaceuticals' standards, attribute, potency, and safety have improved.
- They are economical.
- They do not show any harmful/dangerous effects or toxicity.
- Long-term usage of polyherbal medication may attest to their safety and efficacy.
- The medicinal plants are renewable source of medicines.[10]

MATERIALSAND METHODS

Procurement of Samples

The retailed Triphala Churna preparations and laboratory formulated preparations were used in the present study. Marketed Triphala Churna was obtained from a licensed Ayurvedic Pharmacy store located in Muzaffarnagar, Uttar Pradesh Figure 1 and Other, laboratory formulation was prepared using crude drugs- Haritaki, Bibhitaki and Amalaki Figure 2 at laboratory scale as per standard pharmacopoeial norms and then it was subordinated to various quality controls tests.

Methods to Prepare Triphala Churna

The ingredients for Triphala churna - Haritaki or Harad, Bibhitaki or Baheda, Amalaki or Amla are collected from the local market's registered Ayurveda shop Figure 3. Then, fine powder of crude drugs is made by grinding and filtering them through sieves.

Laboratory Triphala Churna is formulated using the prepared powdered, they are mixed thoroughly in ratio of 1:1:1 as per

Figure 1: Sample 1 marketed Triphala Churna

Figure 2: Sample 2 laboratory formulated Triphala Churna

Figure 3: Amalaki (a), Haritaki (b) and Bibhitaki (c)

the standard pharmacopoeial norms and then stored in well air tight container Table 1.

Development of Standardization and Quality Assessment Parameters for Triphala Churna[11]

Organoleptic evaluation

Both marketed herbal drug and laboratory formulated drug were studies for their preliminary organoleptic evaluation such as color, odor, texture, and taste.

Foreign matter evaluation

The parts of the organ or organs aside from those parts of drug mentioned within the definition and description of the drugs are referred to as foreign organic matter. They can be insects, earthly material, animal excreta, etc.

Determination of Physicochemical Parameters

Total ash determination

In a tared silica crucible, 3g of sample was obtained. After that, the materials were placed inside the Muffle Furnace and was ignited to the temperature not exceeding 450°C–600°Ctill all carbon was burnt off. Then, it was left to be cooled in a desiccator before being weighed. The amount of total ash in air-dried medicine was calculated.

Formula: $$\%\text{ of Total Ash} = \frac{weight\ of\ Ash}{\text{weight of sample}\ taken} x100\%$$

Acid insoluble ash determination

The ash produced by the total ash method, using 25 ml of dilute hydrochloride acid was heated for 5 min before being filtered using ash-less filter paper. Using hot water, the obtained insoluble matter debris was washed and ignited with the filter paper in muffle furnace to a consistent weight. The proportion of insoluble ash in the air-dried medication was determined.

Formula:

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

Determination of water-soluble ash

Similarly as acid insoluble ash determination, the ash produced by the total ash method was heated with water for 5 min. Using hot water, the obtained insoluble matter debris was washed and ignited with the filter paper in muffle furnace to a consistent weight at temperature not exceeding 450°C. The proportion of soluble ash in the air-dried medication was determined.

Table 1: Formulation composition of laboratory formulated Triphala Churna

S. No.	Ingredients	Botanical/English name	Quantity
1.	Amalaki	*Emblica officinalis*	1 part
2.	Haritaki	*Terminalia chebula*	1 part
3.	Bibhitaki	*Terminalia bellerica*	1 part

Formula:

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

Determination of moisture content

Accurately weighed 2 g of polyherbal sample powder was deposited in a tared china dish. The crude medicine was then heated for 5 h at 105°C in a hot air oven. Every hour, the drying and weighing were repeated until the difference of the two subsequent-the amount was <0.25%.

Formula: $$\%\,LOD = \frac{w2 - w3}{w3 - w1} \times 100$$

Determination of alcohol-soluble extractive

Accurately weighed 5 g of churna was transfer to a 250 ml Borosilicate Glass Conical Flask with Glass Stopper. Then, it was soddened with 100 ml ethanol. For the first 6 h, the flask was regularly shaken, and then it was set aside for 18 h. On a water bath, the filtrate was transferred to a tared flat-bottomed shallow dish and evaporated to dryness. After that, it was dried for 6 h at 105°C, cooled, and weighed. The proportion of alcohol-soluble extractives in the air-dried pulverized powdered medication material was determined.

Formula:

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

Determination of water-soluble extractive

Similarly as the alcohol-soluble extractive, instead of ethanol, chloroform water (2.5 ml chloroform in 1000 ml purified water) was used.

Determination of swelling index

Accurately weighed 1 g of churna was placed in 25 ml stoppered cylinder, followed by the addition of water up to 25 ml marking. It was shaken occasionally during 23 h and was set aside for 1 h without disturbing. Calculate the volume occupied by swollen powder.

Determination of foaming index

Accurately weighed 1 g of churna was placed in 500 ml conical flask, 100 ml boiling water was added and keep the water boiling for 30 min. Then, it was left to be cooled and filtered, filtrate/decoction was transferred in 100 ml volumetric flask and adjust the volume to 100 ml by adding sufficient water.

Pour the decoction into 10 stoppered test tube as 1 ml, 2 ml, 3 ml, up to 5 ml. Then volume make-up to 10 ml of each test tube by adding sufficient quantity of water and stopper the tubes. Shake the test tube for 15 sec in length-wise motion (2 shakes per second) and allow the test tube to stand for 15 min before determining the foam height.

- If the measure of foam height appears to be <1 cm, then foaming index is 100.
- If the measure of foam height appears to be more than 1 cm, then foaming index is over 1000.

Table 2: Result for organoleptic evaluation for marketed and laboratory formulated Triphala Churna

S. No.	Properties	Marketed	Lab formulated
1.	Color	Yellowish-Brown	Brown
2.	Odor	Characteristic	Characteristic
3.	Taste	Not specific	Not specific
4.	Texture	Fine Powder	Moderately Fine Powder

- Volume of the decoction of plant material in that tube (a) is utilized to get the foaming index using the given formula if the height of foam in any tube is 1 cm:

Formula: $$\text{Foaming index} = \frac{1000}{a}$$

Pharmaceutical Evaluation of Churna[12]

Bulk density

The mass of sample of a substance divided by the total volume they occupy is known as Bulk density. It is estimated by sending a precisely weighed quantity of powder sample to a graduated cylinder through a tube. The initial reading was noted.

Formula: $$Bulk\ Density = \frac{w}{vo}\ g/ml$$

Where,
w = powder's mass
v_o = untapped volume.

Tapped density

Tapped density is a phrase used to characterize the bulk density of a powder after compression, as measured by "tapping" the sample powder vessel a certain times, usually from a certain height. Tapped density also known as the true density of the powder's particle.

Formula: $$Tapped\ density = \frac{w}{vf}\ g/ml$$

Where,
w = mass of the powder
v_f = tapped volume.

Carr's compressibility index

The Carr index measures a powder's tendency to be compressed. It is another indirect method to measure the flow of powder using the bulk and tapped density.

Table 3: Result for organoleptic evaluation for marketed and labortory formulated Triphala Churna

S. No.	Properties	Marketed	Labortory Formulated	Standard (IP)
1.	Foreign Matter	Nil	Nil	NMT 3.0%
2.	Moisture Content	2.0%	13.6%	NMT 12.0%
3.	Water Soluble Extractive	40.8%	46.9%	NMT 35.0%
4.	Alcohol Soluble Extractive	19.2%	24.0%	NMT 25.0%
5.	Total Ash Value	9.3%	9.1%	NMT 8.0%
6.	Acid Insoluble Ash	2.36%	2.96%	NMT 3.0%
7.	Water Soluble Ash	5.89%	6.42%	-
8.	Swelling Index			-
9.	Foaming Index	100	< 100	-

Formula:

$$Carr's\ Index = \frac{Tapped\ density - Bulk\ density}{Tapped\ density} \times 100\,\%$$

Hausner ratio

It denotes the powder's flow characteristics. Hausner ratio is the ratio of the tapped density to its fluffy density.

Formula: $$Hausner's\ ratio = \frac{Tapped\ density}{Bulk\ density}$$

Angle of repose

The internal angle produced by the powder pile surface and the horizontal surface is known as the angle of repose. It is a metric for determining a pulverized powder's flowability. The angle of repose can be calculated using formula:

Formula: $$Angle\ of\ Repose = \tan^{-1}(2h / D)$$

Where,
h= height of powder pile
r= radius of powder pile

Table 4: Result for pharmaceutical evaluation for marketed and laboratory formulated Triphala Churna

S. No.	Properties	Marketed	Laboratory Formulated
1.	Bulk Density	0.434	0.370
2.	Tapped Density	0.606	0.476
3.	Carr's Index	27.88	22.26
4.	Hausner's Ratio	1.38	1.28
5.	Angle of Repose	46.93 °C	41.98 °C
6.	pH	3.2	3.3

Determination of pH value

Accurately weighed 5 g powder of both Marketed and Laboratory formulated Triphala Churna was taken and placed in a beaker and 100 ml of water was added. For 24 h, the beaker was wrapped with aluminum foil and kept at room temperature. A calibrated digital pH meter was utilized to estimate the pH of both the marketed and laboratory formulations.

Phytochemical Evaluation[13]

The alcoholic and aqueous extracts of both Marketed and Laboratory formulated Triphala Churna were prepared and following that preliminary phytochemical testing was performed on the material. Phytochemical evaluation tests demonstrate the existence of a number of potent chemical component that may be responsible for their therapeutic properties.

- Detection of Alkaloids
- Detection of Carbohydrates
- Detection of Tannins
- Detection of Saponins
- Detection of Steroids
- Detection of Proteins
- Detection of Amino acid
- Detection of Phenol
- Detection of Flavonoids.

RESULTS AND DISCUSSION

Organoleptic Evaluation

The results of the organoleptic evaluation of laboratory prepared and Marketed Triphala Churna are reported in Table 2.

Table 5: Result for phytochemical evaluation for marketed and laboratory formulated Triphala Churna

S. No.	Phytoconstituent	Name of test	Marketed		Laboratory Formulated	
			Aqueous	Alcohol	Aqueous	Alcohol
1.	Alkaloids	Hager's Test	-	-	-	-
		Wagner's Test	-	-	-	-
		Mayer's Test	-	-	-	-
2.	Carbohydrate	Molisch's Test	+	+	+	+
3.	Tannins	Braymer's Test	+	+	+	+
4.	Saponins	Foam Test	+	-	+	-
5.	Steroids	Salkowski's Test	+	+	+	+
6.	Proteins	Millon's Test	-	-	-	-
7.	Amino acid	Ninhydrin's Test	-	-	-	-
8.	Phenol	Ferric chloride Test	+	+	+	+
9.	Flavonoids	Alkaline Reagent Test	+	+	+	+

Present (+); Absent (-)

Physico-Chemical Parameters

The results of the physicochemical examination of laboratory prepared and Marketed Triphala Churna are reported in Table 3.

Pharmaceutical Evaluation

The results of the pharmaceutical analysis of laboratory prepared and Marketed Triphala Churna are reported in Table 4.

Phytochemical Evaluation

The phytochemical examination of laboratory prepared and Marketed Triphala Churna are reported in Table 5.

CONCLUSION

The present investigation examines, comparative analysis and numerous characteristics for standardization such as organoleptic evaluation, pharmaceutical evaluation, and physicochemical standards. It can be concluded that both marketed and laboratory formulated Triphala Churna had almost same values and were comparable against the standards pharmacopoeial norms except considerable difference in the moisture content of powders.

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