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Research Article

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Comparative standardization of a polyherbal ayurvedic formulation trikatu churna

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ABSTRACT

In the few decades, there has been exponential growth in the field of herbal medicines. Most of the traditional system of medicine is effective but they lack standardization. So there is a need to develop a standardization technique. Standardization of herbal formulation is essential in order to assess the quality, purity, safety and efficacy of the drug. The present paper reports the investigation and standardization of trikatu churna, an Ayurvedic formulation. Two marketed formulation samples and in-house preparation were subjected to organoleptic study, physical characteristics and physicochemical screening. Trikatu is a compound churna as it consists of more than one ingredient. It consists of coarse powder (sieve 40 size) of fruits of Piper longum, Piper nigrum and rhizomes of Zingiber officinale. The principle of using churnas is due to the fact that therapeutic value of most of the substances greatly increases when they are reduced to a very fine state of subdivision. They are also easily administrable especially in the cases of children where they cannot swallow pills, tablets or capsules. The results of various parameters obtained from the study showed that marketed formulation 2 & In-house have comparable physical values. The flowability of formulation was found to be poor in all formulation. There is no uniformity in preparation of formulations, and these results could be utilized as a reference for setting limits for the reference standards for the quality control and quality assurance of these drugs.

Keywords: Trikatu Churna, Standardization, Formulation

INTRODUCTION

India is having a rich heritage of traditional medicine constituting with its different components like *Ayurveda, Siddha* and *Unani.* Botanical constituents are the major part of these traditional medicines. The development of these traditional systems of medicine with the perspectives of safety, efficacy, and quality will help not only to preserve the traditional heritage but also to rationalize the use of natural products in healthcare [1-2]. Along with this, the growing need for a safer drug, where attention has been drawn to the quality, efficacy, and standard of Ayurvedic formulations [3]. Churna is one such ayurvedic formulation that is defined as a fine powder of drug or drugs in ayurvedic system of medicine. The churna is free flowing and retains its potency for one year, if preserved in an air tight container. They are similar to powder formulations in Allopathic system of medicine. In recent days churna is formulated into tablets in order to fix the dose easily. These forms of medicament are prescribed generally because of their particle size. Smaller the particle size greater is the absorption rate from G.I.T and hence the greater is the bioavailability [4]. Due to lack of modern pharmacopoeial standards laid down and followed for processing of trikatu churna using traditional methods, the medicine may not have the desired quality and batch to batch consistency. Thus WHO has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable standards and parameters [5]. Standardization and quality control depends upon the nature of crude drug and compound drugs, it's source i.e. factors associated with raw materials which are beyond of human control like seasonal, geographical, age of the plant, time of collection, type of drying etc. due to these natural conditions. The percentage of chemical constituents of the drug does no remain uniform as

our expectation. The need of quality control for ayurvedic drug is due to the fact that the preparation of drug according to the ancient method has been reduced due to the commercialization of ayurvedic pharmacy [6].

In the present research work, an attempt was made to standardize various formulations of "Trikatu churna" an ayurvedic polyherbal formulation made up of three herbs possessing strong antibacterial, rejuvenator and stimulant activity, it is also used as digestive tonic for the assimilation of the other food in the body [7], also helps in minimizing gas formation in the abdomen [8], also shows analgesic and antibacterial activity [9]. The aqueous extract of churna is also reported to have anthelmintic activity [10]. This is also reported to have anthelmintic activity.

EXPERIMENTAL SECTION

1. Procurement of Churna

The two marketed formulations were purchased from the pharmacy of ankur medical store, Satna. Third or In-House preparation was made based on the Ayurvedic parameters such as (colour), gandha (odour), ruchi (taste), aakruti varna (shape) and parimana (size).

Preparation of Polyherbal Formulation

Formulation was made by taking equal proportion of each powdered drugs. All the procured and authenticated individual drugs were dried in shade and cleaned by hand sorting. The individual drugs were then crushed using willing grinder and passed through mesh no. 40. The individual drugs were then weighed as per the quantity required. The drugs were mixed geometrically using a double cone blender (Kshitij innovations, ambala). The mixed formulation was unloaded, weighed, and packed in labeled glass bottles [11].

Table 1. Trikatu Churna Formulation

S. No.	Herbs	Other Common Name	Botanical Name	Family	Parts
1.	Pimpli	Peeper	*Piper longum* L.	Piperaceae	One Part
2.	Black Pepper	Maricha	*Piper nigrum* L.	Piperaceae	One Part
3.	Dried Ginger	Sunthi	*Zingiber officinale Roscoe*	Zingiberaceae	One Part

2. Evaluation of Physical Parameters

2.1. Organoleptic Characteristics [12]

Color: Churna was taken into watch glasses and placed against white background in white tube light. It was observed for their color by naked eye.

Odour: Two gram Churna was smelled.

Taste: A pinch of Churna was taken and examined for its taste on taste buds of the tongue.

Table 2. Organoleptic Characters

S. No.	Trikatu Formulation	Appearance	Color	Odour	Taste
1.	Marketed 1 Churna	Fine powder with smooth texture	Light brown	Pungent	Characteristic
2.	Marketed 2 Churna	Fine powder with smooth texture	Buff brown	Pungent	Astringent and Sour
3.	In-House Churna	Fine powder with smooth texture	Slight brown	Pungent	Bitter after taste

2.2. Determination of pH [12]

Placed accurately weighed 1 gm of churna in a 100 ml volumetric flask and made up the volume up to 100 ml with distilled water. The solution was sonicated for about 10 minutes. pH was measured with the help of digital pH meter.

2.3. Determination of loss on drying [12]

Loss on drying was determined by weighing about 2 gm of the powdered material in previously weighed dried petridish (tarred evaporating dish) and dried in an oven at 105-110 ºC, till two consecutive weights, which do not differ by more than 5mg. The weight after drying was noted and loss on drying was calculated. The percentage was expressed as % w/w with reference to air dried Sample.

2.4. Determination of Ash Values [13]

i. Total Ash Value

2 gm of churna was weighed accurately in a previously ignited and tarred silica crucible. The material was then ignited by gradually increasing the heat to 500-600°C until it appeared white indicating absence of carbon. It is then cooled in a dessicator and total ash in mg per gm of air dried material is calculated.

ii.Acid Insoluble Ash Value

To the crucible containing total ash, 25 ml of HCl was added and boiled gently for 5minutes, and then about 5 ml of hot water was added and transferred into crucible. The insoluble matter was collected on an ashless filter paper. This was then washed with hot water until filtrate is neutral and the filter paper along with the insoluble matter was transferred into crucible and ignited to constant weight. The residue was then allowed to cool and then weighed.

iii. Water Soluble Ash Value

2.5. Determination of Extractive Values [13]

i. Water Soluble Extractive Value

5 gm of churna was accurately weighed and placed inside a glass stoppered conical flask. It is then macerated with 100ml of chloroform water for 18 hours. It was then filtered and about 25ml of filtrate was transferred into a china dish and was evaporated to dryness on a water bath. It was then dried to 105° C for 6 hours, cooled and finally weighed.

ii. Alcohol Soluble Extractive Values

Ethanol was used as solvent in place of chloroform water and remaining procedure was the same as that of water soluble extractive value.

Table 3. Physico-Chemical Parameters

S. No.	Physico-Chemical Parameters	Marketed 1 Churna	Marketed 2 Churna	In-House Churna
1.	pH	6.0	5.9	6.2
1.	Total ash	3.9	3.8	3.5
2.	Acid insoluble ash	2.2	1.9	1.5
3.	Water soluble ash	2.5	2.1	2.2
4.	Water soluble extractive	2.32 gm	0.15 gm	0.80 gm
5.	Alcohol soluble extractive	1.48 gm	0.56 gm	1.30 gm
5.	LOD	0.5231 gm/cm^3	2.6070 gm/cm^3	0.6118 cm^3

3. Determination of Physical Characteristics

Table 4. Physical characteristics

S. No.	Physical Parameters	Marketed 1 Churna	Marketed 2 Churna	In-House Churna
1.	Tapped density	0.666 gm/cm^3	0.645 gm/cm^3	1.111 gm/cm^3
2.	Bulk density	0.476 gm/cm^3	0.434 gm/cm^3	0.769 gm/cm^3
3.	Angle of repose	45^o	45^o	45^o
4.	Houser's ratio	1.39 gm/cm^3	0.673 gm/cm^3	0.692 gm/cm^3
5.	Carr's Index	39.91	48.61	44.47

3.1. Bulk Density [5]

Bulk or fluff density is the ratio of given mass of powder and its bulk volume. It is determined by transferring an accurately weighed amount of powder sample to the graduated cylinder with the aid of a funnel. The initial volume was noted as untapped or poured volume. The ratio of weight of the volume it occupied was calculated.

Bulk Density = (W/V0) gm/ml
Where,
W = mass of the powder
V0 = untapped volume

3.2. Tapped Density [5]

It is measured by transferring a known quantity (25 gm) of powder into a graduated cylinder and tapping it for a specific number of times. The initial volume was noted. The graduated cylinder was tapped continuously for a period of 10-15 min. The density can be determined as the ratio of mass of the powder to the tapped volume.

Tapped Volume = (w/vf) gm/ml

Where,
W = mass of the powder
Vf = tapped volume.

3.3. Angle of Repose [5]

Angle of Repose has been used as indirect methods of quantifying powder flowability because of its relationship with inter particle cohesion [6]. The internal angle between the surface of the pile of powder and the horizontal surface is known as the angle of repose. The powder is passed through funnel fixed to a burette at a height of 4 cm. A graph paper is placed below the funnel on the table. The height and the radius of the pile were measured. Angle of repose of the powder was calculated using the formula

Angle of Repose= tan-1(h/r)
Where,
h=height of the pile
r = radius of the pile

Table 5 Angle of Repose I.P limits [14]

S.no.	Angle of Repose	Powder flow
1.	<25	Excellent
2.	25-30	Good
3.	30-40	Passable
4.	>40	Very Poor

3.4. *Hausner Ratio* [6]

It is related to inter particle friction and as such can be used to predict the powder flow properties. Powders with low interparticle friction such as coarse spheres have a ratio of approximately 1.2, whereas more cohesive, less flowable powders such as flakes have a Hausner ratio greater than 1.6.

Hausner ratio is = Df / Do,
Where Df = Tapped density &
Do = Bulk density.

Table. 6 Hausner's Ratio I.P Limits [14]

S.No	Hausner's Ratio	I.P Limits value
1	Excellent	1.00 – 1.11
2	Good	1.1 – 1.18
3	Fair	1.19 – 1.25
4	Possible	1.26 -1.34
5	Very poor	1.35 -1.45
6	Very very poor	>1.60

Carr's Index [3]

Another indirect method of measuring the powder flow from bulk density is Carr's index. Carr's index = % compressibility = (Df-Do/Do) × 100

Where Df = Tapped density &
Do = Bulk density.

Table 7 Carr's Index I.P limits [14]

S. No.	Carr's Index	IP Limits value
1	Excellent	<10
2	Good	11 – 15
3	Fair	16 – 20
4	Possible	21 – 25
5	Poor	26 – 31
6	Very poor	32 – 37

RESULTS AND DISCUSSION

The churna consisting of fine powder of herbs in appropriate ratio was subjected to standardization by means of various physical and chemical methods. The organoleptic characters were comparable, however, adversity in taste was observed, as marketed formulation 2 was strongly astringent. The pH value obtained was found to be within the

standards. Both the ash values, acid insoluble and water soluble, obtained were found to be within the standard limits. In the present study, both the water soluble and alcohol soluble extractive values were found to be more than the standard values. On physical characterization, the results of the market formulations and in house formulation were found to be comparable. The marketed formulation 2 had appropriable physicochemical characteristics however; it had a greater LOD values and lower extractive values which is not acceptable. The flowability of the formulation was found to be poor in both marketed formulation and in house formulation, which was further confirmed by high values of Hausner ratio. All the formulations had their different physical characteristics vales but all were over the acceptable range, which could not be practically considered as per standards.

The physical parameters such as pH was determined to avoid gastric irritation and the moisture content was determined to find out any increase in weight caused by moisture absorption. Since ashing process involves oxidation of components of product, an increase in ash value indicates contamination, substitution and adulteration. The total ash value is an indicative of total amount of inorganic material after complete incineration and the acid insoluble ash value obtained is an indicative of silicate impurities, which might have aroused due to improper washing of crude drugs. The extractive values namely water-soluble and alcohol soluble indicates the amount of active constituent in given amount of plant material when extracted with respective solvents, a lower value compared to standard value indicates presence of exhausted material [4]. The water-soluble extractive value indicated the presence of sugar, acids and inorganic compounds. Less or more extractive value indicates addition of exhausted material, adulteration or incorrect processing during drying, or storage or formulating. Other physical characteristics like tapped density gives information on consolidation of a powder [15]. The Hausner ratio and Carr's index are both measures of the flow properties of powders. The smaller the Carr's Index the better the flow properties [16].

Quality assurance of herbal products may be ensured by proper quality control of the herbal ingredients and by means of good manufacturing practice. Some of herbal products have many herbal ingredients with small amount of individual herb being present [17]. Thus maintaining the quality of Ayurvedic medicine becomes the sole responsibility of the manufacturer.

CONLCUSION

This evaluation study was intended to determine quality, purity, integrity of trikatu churna with due aid of comparative analysis of laboratory and marketed product. It is concluded that there is no uniformity in preparation of formulations which is may be due to varied geographical locations where these plants grow, coupled with the problem of different vernacular names these plants are known by, a great deal of adulteration or substitution is encountered in commercial market and physicochemical parameters such as the water-soluble, alcohol-soluble, and, moisture content, bulk density, tapped density, Carr's index, Hausner's ratio, pH, water-soluble ash, acid-insoluble ash, and organoleptic characteristics can be efficiently used for standardization of polyherbal formulation. 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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