Current Pharma Research
ISSN-2230-7842
CODEN-CPRUE6
www.jcpronline.in/

Research Article

Comparative Standardization Study of Two Marketed Triphala Churna Formulations

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Received July 07, 2016; received in revised form August 16, 2016; accepted August 18, 2016
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ABSTRACT
In the few decades, there has been exponentionally growth in the field of herbal medicines. Most of the traditional systems of medicine are 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. Triphala Churna is used for immune system stimulation, improvement of digestion, relief of constipation, gastrointestinal tract cleansing, relief of gas, treatment of diabetes and treatment of eye disease. In the present study two marketed triphala churna formulations of Dabur and Patanjali were thoroughly evaluated for their organoleptic characteristics and physicochemical parameters such as moisture content, ash values, extractive values were carried out. Heavy metal content studies were also carried out to ascertain the quality, purity and safety of this herbal formulation.

KEYWORDS
Dabur Triphala churna, Patanjali Triphala churna, organoleptic parameters, physicochemical parameters, extractive values

1. INTRODUCTION

Herbal drugs have been used since ancient times as medicines for the treatment of a range of diseases. Medicinal plants have played a key role in world health. In spite of the great advances observed in modern medicine in recent decades, plants still make an important contribution to health care. Medicinal plants are distributed worldwide, but they are most abundant in tropical countries. Plants contain several hundred constituents and some of them are present at very low concentrations. In spite of the modern chemical analytical procedures available, only rarely do phytochemical investigations succeed in isolating and characterizing all secondary metabolites present in the plant extract. Apart from this, plant constituents vary considerably depending on several factors (see below) that impair the quality control of phytotherapeutic agents. Quality control and standardization of herbal medicines involve several steps. However, the source and quality of raw materials play a pivotal role in guaranteeing the quality and stability of herbal preparations.

1.1. Advantages of Herbal Medicine

1. They have large amount of use.
2. They have better patient tolerance as well as acceptance.
3. The medicinal plants have renewable source of cheaper medicines.
4. Improvements in the quality, efficacy and safety of herbal medicines with the development of science and technology.
5. Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.
6. They are cheap in cost.
7. They are not harmful.
8. They are more effective than any synthetic drug.

1.2. Need of Standardization

The quality control of herbal crude drug & formulation is important in justifying their acceptability in modern system of medicines. WHO has emphasized the need to ensure quality control of medicinal plants products by using modern techniques and by applying suitable standards and parameters. Standardized products and services are valuable. User confidence builder's being perceived as: Safe, Healthy, Secure, High quality, Flexible. Standardization brings important benefits to business including a solid foundation upon which to develop new technologies and an opportunity to share and enhance existing practices. Triphala is among the most common formulations used in Ayurvedic medicine, comprised of the fruits of three medicinally important plants, Indian gooseberry (Amalaki, Emblica officinalis), Belleric myrobalan (Vibhitaka, Terminalia balerica) and Chebulic myrobalan (Haritaki, Terminalia chebula). Triphala is mentioned throughout the ancient literature of Ayurvedic medicine as a tonifying blood cleanser and gentle laxative, highly prized for its ability to regulate the process.

Present work reports the study of two marketed triphala churna formulations of Dabur and Patanjali and evaluation for their organoleptic characteristics and physicochemical parameters such as moisture content, ash values, extractive values and heavy metal content.

2. MATERIALS AND METHODS

2.1. Introduction of Sample

2.1.1. Sample Name

Triphala Churna

2.1.2. Main Constituents

Senna leaves, Haritaki and Liquorice

2.2. Uses

Constipation, acidity, headache

Fig. 1. Dabur Triphala Churna

Fig. 2. Patanjali Triphala Churna

2.3. Plan of Work

Comparative standardization of Triphala churna formulated by Dabur & Patanjali was planned to carry out development of quality standards for the finished marketed formulation. The method used for the comparative standardization was planned to be carried out as follows:

2.4. Development of Standardization Parameters for Triphala Churna

2.4.1. Study of organoleptic characters

1. Colour
2. Odour
3. Taste

2.4.2. Determination of Physico-chemical Parameters

1. Loss on drying
2. Total ash value
3. Phytochemical tests
4. Acid insoluble ash value
5. Water soluble ash value
6. Alcoholic extract value
7. Water soluble extract value
8. Thin plate chromatography

2.4.3. Evaluation of Churna

1. Bulk density

2. Tap density
3. Compressibility
4. Hauser ratio
5. Angle of repose
6. Carr's index

2.4.4. Determination of pH

2.4.5. Establishing the safety pertaining to Heavy metals

Procedures[2]

2.4.5. 1. Study of Organoleptic Characters

The polyherbal formulation is studied for organoleptic characters like color, odour and taste using the sensory organs of our body.

2.4.5. 2. Determination of Physico-chemical Parameters

2.4.5. 2. 1. Determination of Loss on Drying

Weigh about 1.5gm of the powdered drug into a weighed flat and thin porcelain dish. Dry in the oven at 100 c, until two consecutive weighing does not differ by more than 0.5gm. Cool in a desiccator and weigh. The loss in weigh is weight is usually recorded as moisture.

2.4.5. 2. 2. Determination of Total ash value

Weigh and ignite flat, thin, porcelain dish or a tared silica crucible. Weigh about 2gm of the powdered drug into the dish/crucible. Support the dish on a pipe-clay triangle placed on a ring of retort stand. Heat with a burner, using a flame about 2cm high and supporting through dish about 7cm above the flame, heat till vapours almost cease to be evolved; then lower the dish and heat more strongly until all the carbon is burn off. Cool in a desiccator. Weigh the ash and calculate the percentage of total ash with reference to the air dried sample of the crude drug. If a carbon free ash cannot be obtained in this way then any one of the following method can be used. Exhaust the charred mass with hot water, collect the residue on an ashless filter paper incinerate the residue and filter paper, add the filter , evaporate to dryness and ignite at a temp. not exceeding 450c.Cool the crucible; add 15ml of alcohol break up the ash with glass-rod burn off the alcohol and again heat the whole to a dull red heat. Cool, weigh the ash.

2.4.5. 2. 3. Phytochemical tests

Different phytochemical tests were performed such as test for glycosides, carbohydrates, proteins, steroids, flavonoids, amino acids etc.

2.4.5. 2. 4. Determination of acid insoluble ash

The total ash obtained was boiled for 5 minutes with 25 ml of dilute hydrochloric acid; the insoluble matter obtained was collected on an ash less filter paper, washed with hot water and ignited to constant weight. The percentage of acid insoluble ash was calculated with reference to the air dried drug.

2.4.5. 2. 5. Determination of Water-soluble Ash

The ash obtained in the determination of total ash was boiled for 5 minutes with 25 ml of water. The insoluble matter was collected on an ash less filter paper and washed with hot water. The insoluble ash was transferred into a tarred silica crucible and ignited for 15 minutes at a temperature not exceeding 450˚C. The weight of the insoluble matter was subtracted from the weight of the total ash. The difference in weight was considered as the water- soluble ash was calculated with reference to the air dried drug.

2.4.5. 2. 6. Determination of Alcohol-soluble extractives

Weigh about 4gm of the coarsely powdered drug in a weighing bottle and transfer it to dry 250ml conical flask. Fill a 100ml graduated flask to the delivery mark with the solvent (90% alcohol). Wash out the weighing bottle and pour the washing, together with the remainder of the solvent into the conical flask. Cork the flask and set aside for 24 hours, shaking frequently. Filter into a 50 ml cylinder. When sufficient filtrate has collected, transfer 25ml of the filtrate to a weighed, thin porcelain dish, as used for the ash value determinations. Evaporate to dryness on a water bath and complete the drying in an oven at 105^0c for 6 hrs. Cool in desiccators for 30min and weigh immediately. Calculate the percentage w/w of extractive with reference to the air dried drug.

2.4.5. 2. 7. Determination of water soluble extractive

Procedure for alcohol soluble extractive was followed for the determination of water soluble extractive but chloroform water was used instead of 90% alcohol.

2.4.5. 2. 8. Thin plate chromatography[3]

Mobile phase: Toluene: Ethyl acetate: Acetic acid (5:4:1)

2.4.5. 2. 8.1. Procedure

1. Prepare mobile phase and saturate the chamber.
2. Prepare TLC plate with silica gel which acts as an adsorbent.
3. Activate TLC plate by keeping it in hot air oven at 110^0c for 30 min.
4. Prepare solution of a sample.
5. Remove TLC plate from oven.
6. Dip the capillary tube into the solution and then gently touch the end of it onto the proper location on the TLC plate.
7. Place the prepared TLC plate in the developing beaker, cover the beaker with the Petri plate, and leave it undisturbed. The solvent will rise up the TLC plate by capillary action.
8. Allow the plate to develop until the solvent is about half a centimeter below the top of the plate. Remove the plate from the beaker and immediately mark the solvent front with a pencil. Allow the plate to dry.
9. Prepare iodine chamber for visualization of the spot. Keep TLC plate in iodine chamber for visualization of the spot.

10. If there are any colored spots, circle them lightly with a pencil.
11. Most samples are not colored and need to be visualized with a UV lamp. Hold a UV lamp over the plate and circle any spots you see.
12. Calculate and report R_f value of a compound.

2.5. Evaluation of Churna[1]

2.5.1. Bulk density

It 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. The ratio of weight of the volume it occupied was calculated.
Bulk Density= W/V_0 g/ml
Where,

W = mass of the powder,
V_0 = untapped volume

2.5.2. Tapped density

It is measured by transferring a known quantity (25g) of powder into a bulk density apparatus and tapping it for 100 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/V_f g/ml
Where,

W = mass of the powder,
V_f = tapped volume

2.5.3. Compressibility index

It is the propensity of the powder to be compressed. Based on the apparent bulk density and tapped density the percentage compressibility of the powder can be determined using the following formula:
Compressibility index = $[(v_0-v_f)/v_0] \times 100$
% compressibility index= [(tapped density – bulk density)] / tapped density] x 100 --- (1)

2.5.4. Hausner ratio

It indicates the flow properties of the powder. The ratio of tapped density to the bulk density of the powder is called Hausner ratio.
Hausner ratio= Tapped density/bulk density

2.5.5. Angle of repose

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 s 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) --- (2)
Where, h=height of the pile, r = radius

2.5.6. Determination of pH range

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 pH meter.

2.5.7. Heavy metal tests

Table 1. Cadmium test

Test	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	p/o cadmium
Potassium ferrocyanide is added	White ppt is absent	p/o cadmium

Table 2. Bismuth test

Test	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	p/o bismuth

Table 3. Lead test

Test	Observation	Result
Dil HCL add in a sample solution	White ppt of $CaCl_2$ is absent	p/o lead
KI is added	Yellow ppt is absent	p/o lead

3. RESULTS AND DISCUSSION

Table 4. Determination of Organoleptic Characters

Sample	Dabur Triphala Churna	Patanjali Triphala Churna
Color	Yellowish	Brownish
Odour	characteristic	Characteristic
Taste	salty	Salty

Table 5. Ash value – Sample-Dabur Triphala Churna

Sr. No.	Type of ash value	% of ash value(w/w)
1.	Total ash value	7%
2.	Acid insoluble ash value	3.5%
3.	Water soluble ash value	6%

Table 6. – Sample-Patanjali Triphala Churna

Sr. No.	Type of ash value	% of ash value(w/w)
1.	Total ash value	10%
2.	Acid insoluble ash value	8%
3.	Water soluble ash value	5%

Table 7. Moisture content/Loss on drying – Sample-Dabur Triphala Churna

Sr. No.	Loss on drying
1.	94.6%

Table 8. Sample-Patanjali Triphala Churna

Sr. No.	Loss on drying
1.	93.3%

Table 9. Extractive value- Sample: Dabur Triphala Churna

Sr. No.	Types of solvent	%extractive value (w/w)
1.	Water	5%
2.	Alcohol	16%

Table 10. Sample-Patanjali Triphala Churna

Sr. No.	Types of solvent	%extractive value (w/w)
1.	Water	6%
2.	Alcohol	16%

Table 11. Qualitative analysis- Sample: Dabur Triphala Churna

Sr. No.	Chemical constituent	Alcohol extract
1.	Reducing sugar	++
2.	Amino acid	++
3.	Cardiac glycosides	++
4.	Saponin glycosides	++
5.	Alkaloids	++
6.	Phenolic compound	++

Table 12. Sample-Patanjali Triphala Churna

Sr. No.	Chemical constituents	Alcohol extract
1.	Reducing sugar	++
2.	Amino acid	++
3.	Cardiac glycosides	++
4.	Saponin glycosides	++
5.	Alkaloids	++
6.	Phenolic compound	++

Table 13. Determination of physical characteristics of powder-Sample-Dabur Triphala Churna

Sr. No.	Parameter	Reading
1.	Bulk density	0.6097
2.	Tap density	0.8333
3.	Carr's index	0.7316

4.	% compressibility	26.83%
5.	Hausner ratio	1.3667
6.	Angle of repose	38.01829

Table 14. Sample-Patanjali Triphala Churna

Sr. No.	Parameter	Reading
1.	Bulk density	0.6097
2.	Tap density	0.8333
3.	Carr's index	0.7316
4.	% compressibility	26.83%
5.	Hausner ratio	1.3667
6.	Angle of repose	38.01829

Table 15. Determination of pH-Sample- Dabur Triphala Churna

Sr. No.	pH (in 1%)
1.	3.65

Table 16. Sample-Patanjali Triphala Churna

Sr. No.	pH (in1%)
1.	3.41 to 3.5

Table 17. Heavy metal tests-Sample: Dabur Triphala Churna -Cadmium test.

Test	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	Absence of cadmium
Potassium ferrocyanide is added	White ppt is absent	Absence of cadmium

Table 18. Bismuth test

Test	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	Absence of bismuth

Table 19. Lead test

Test	Observation	Result
Dil HCl add in a sample solution	White ppt of $CaCl_2$ is absent	Absence of lead
KI is added	Yellow ppt is absent	Absence of lead

Table 20. Sample: Patanjali Triphala Churna-Cadmium test

Test	Observation	Result
NH_4OH add in a sample solution	White ppt is absent	Absence of cadmium
Potassium ferrocyanide is added	White ppt is absent	Absence of cadmium

Table 21. Bismuth test.

Test	Observation	Result
NH4OH add in a sample solution	White ppt is absent	Absence of bismuth

Table 22. Lead test.

Test	Observation	Result
Dil HCl add in a sample solution	White ppt of $CaCl_2$ is absent	Absence of lead
KI is added	Yellow ppt is absent	Absence of lead

Table 23. TLC Values

Sample	Rf value
Dabur triphala	0.5476

churna		
Patajali churna	**triphala**	0.5263

4. CONCLUSION

From the present investigation various standardization parameters such as physicochemical standards like total ash, acid insoluble ash, water & alcohol soluble extractive values, loss on drying, phytochemical analysis, flow properties and safety evaluation were carried out, it can be concluded that the formulation of Dabur Triphala Churna and Patanjali churna contains all good characters of an ideal Churna and it was found to be harmless, more effective, and economic. The sample shows satisfactory results, but the efficacy of the products can only be judged by doing the pharmacology of which is suggested as future scope of R & D. The study shows that the contents of formulation presents within the permissible limits as per WHO, all these investigations are not specified in the standard literature such as in pharmacopoeia, which could helpful in authentication of Dabur Triphala Churna and Patanjali churna. The result of present study will also serve as reference monograph in the preparation of drug formulation.

5. REFERENCES

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