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A REVIEW ON STANDARDIZATION OF PATNANJALI TRIPHALA CHURNA

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ABSTRACT

The development in these traditional systems of medicine leads to maintain proper quality of the product. India is rich in its flora and fauna. These plants are being used for curing many diseases as such in raw condition rather the being prepared as formulation.

Churana is defined as a fine powder of drug or drugs in Ayurvedic system of medicine. Drugs mentioned in patha, are cleaned properly, dried thoroughly, pulverised and then sieved. The churana is free flowing and retains its potency for one year, if preserved in air tight containers.

Churna formulations 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. The churana was evaluated depending on various evaluation parameters and from the results obtained it was found to be within the standards.

These preliminary tests can be prescribed as standards to fix the quality control test the churana and can be used in routine analysis of the same. The can also be used to perform quality control and quality assurance in the laboratory.

In a few decades, there has been exponential growing 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 to assess the quality, purity, safety, and efficacy of the drug based on the concentration of their principles.

This articles reports on standardization of Triphala churna. Polyherbal ayurvedic medicines used to treat constipation, gastric disorder. The present research study deal the Standardization.

The standardization of this formulation, organoleptic characteristics, physical properties such as moisture content (LOD), ash value, extractive values, crude fiber content was carried out. The heavy metal content, tannin test, and alkaloid test study also carried out to ascertain the quality, purity, and safety of these herbal formulations.

INTRODUCTION

Nature always stands as a golden mark to exemplify the outstanding phenomena of symbiosis. Today about 80% of people in developing countries still rely on traditional medicine based largely on the different species of plants for their primary health care.

About 500% of plants with medicinal uses are mentioned in ancient literature, and 800 plants have been used in the indigenous system of medicine. The various indigenous system such as Ayurveda, Siddha, Unani use several plant species to treat different ailments.

Herbal medicines make up an essential component of the trend toward alternative medicine.

A Harvard study recently found that one in three respondents acknowledged the use of at least one alternative therapy within the past year. Extrapolated, these findings suggest that up to $13.7 billion were spent in 1990 alone for these treatments. Tyler defines herbal medicines as "crude drugs of vegetable origin utilized for the treatment of disease states, often of a chronic nature, or to attain or maintain a condition of improved health." 5 current demands for herbal medicines have resulted in an annual market of $1.5 billion and increasingly widespread availability6.

Triphala Churna and its composition

Emblicaofficinalisis effective in the treatment of hepatotoxicity, amlapitta (peptic ulcer) and in dyspepsia.[9] The fruits exhibit hypolizpiadaemic and anti-atherosclerotic effects in rabbits and rats. The fruit extract has antimutagenic activity on certain directly acting mutagens in some strains of Salmonella typhimurium. The extract of alma also has antimicrobial

properties. Amlaki is an antioxidant with free radical scavenging properties which may be due to the presence of high levels of super oxide dismutase.

Lignin isolated form Terminalia belliricawere shown to possess anti-HIV, antimalarial, protective effect on liver and anti-fungal activities. The fruit pericarp of Terminalia chebula showed Cytoprotective activity, cardio tonic activity, anti-mutagenic activity and antifungal properties.

Potential Benefits of Herbal Drugs

Historically, herbal medicines have played a significant role in the management of both minor and major medical illnesses. One example is foxglove, which contains cardiac glycosides, and serves as a classic treatment for congestive heart failure. Even now, physicians still use many drugs that possess botanical origins. Huxtable notes that one-quarter of the prescriptions currently written in the United States are for plant products, while one quarter is for agents based on botanical compounds. The therapeutic potential of herbal medicines cannot be ignored and is highlighted in the three examples provided next.

Advantages of Herbal Medicine

1. They have a large amount of use.
2. They have better patient tolerance as well as acceptance.
3. The medicinal plants have a 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 uneventful use of herbal medicines may testify to their safety and efficacy.
6. They are cheap.
7. They are not harmful.
8. They are more effective than any synthetic drug throughout the world herbal medicines have provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form as well as a pure chemical upon which modern medicines are constructed.

Fig. 1: Advantages of triphala.

The Need for Standardization – Producers and Consumers Perspective

In the global perspective, there is a shift towards the use of the medicine of herbal origin, as the dangers and the shortcoming of modern medicine are getting more apparent. It is the cardinal responsibility of the regulatory authorities to ensure that consumers get the medication, which guarantees purity, safety, potency and efficacy. The regulatory authorities rigidly follow various standards of quality prescribed for raw materials and finished products in pharmacopeias, formularies and manufacturing operation through statutory imposed good manufacturing practices. These procedures logically would apply to all types of medication whether included in the modern system of medicine or one of the traditional systems.

The quality control of herbal crude drug and formulation in important in justify there acceptability in modern system of medicine the batch to batch variation start form the collection of raw material itself in absence of any reference standard for identification.

Standardization of synthesis drugs offer no. problems with very when defind parameters of analysis it is not uncommon to have as many as five more different herbal ingredient in one singal formulation WHO as a emphasize the need to ensure quality medicinal plant product by using modern techniques and by applying suitable standards and parameters. Standardization of products and service are valueable.

Users comfidence builders being perceived as:

- Healthy
- Safe
- Secure
- Flexible

- High quality

Standardization brings important benefits to business including a solid foundation upon which to develop new technologies and and opportunity and an opportunity to share and enhance existing practices. Standardization also plays a pivotal role in assisting governments, Administration, Regulation and the legal profession as legislation, regulation and policy initiatives are all supported by standardization.

Plan of Work

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

Development of standardization parameters for Patanjali Triphal churna

Study of Organoleptic Characters

- Colour
- Odor
- Taste

Determination of Physicochemical Parameters

- Total ash
- Acid-insoluble ash
- Water soluble ash
- Moisture content/ Loss on drying
- Water-soluble extractive
- Alcohol soluble extractive
- Crude fiber contents

Evaluation of Churna

1. Powder fineness
2. Bulk density
3. Tap density
4. Angle fo repose
5. Hausner’s ratio
6. Compressibility index/ Carr’s index

Determination of pH

Establishing the Safety about Heavy Metals & Microbial Load

Fluorescence Analyses

MATERIALS AND METHODS

Samples Preparation

Triphala churn contains mainly three ingredients as Harad or Haritaki (*Chebulic Myrobalans* or *Terminalia chebula*), Baheda or Bibhitaki (*Terminalia Bellirica*) and Amla or Amalaki (Indian gooseberry or *Emblica officinalis*).

Fig 2: Ingradients of chrna.

- **Baheda or Bibhitaki(Terminalia Bellirica)**
- **Amal or Amalaki(Indian gooseberry or Emblica officinalis)**
- **Harad or Haritaki (Chebulic Myrobalans or Terminalia chebula)**

Sample: PATANJLI TRIPHALA CHURNA

Fig 3. Sample: Patanjli triphala churna.

Method to Prepare the Triphala Churna

Fig 4: Patanjali Triphala Powder.

Harad or Haritaki (Chebulic Myrobalans or *Terminalia chebula*), Baheda or Bibhitaki (*Terminalia Bellirica*) and Amla or Amalaki (Indian gooseberry or *Emblica officinalis*) collected from the local market. The fine powder was made both by grinding and filtering them. All the powders were mixed properly in a ratio 1:2:4. The Triphala Churna is prepared and ready to use. For future use, it can keep into a plastic box.

Developments of Standardization Parameters for Patanjali Triphala Churna

Study of Organoleptic Characters

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

Physicochemical Analysis

A) Ash Value

Determination of Total Ash

About 2 to 3 g of sample was accurately weighed in a tarred silica dish at a temperature not exceeding 45 °C until it was free from carbon. Then it was cooled and weighed. The percentage of total ash was calculated concerning the air-dried drug.

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 ashless filter paper, washed with hot water and

ignited to constant weight. The percentage of acid insoluble ash was calculated concerning the air-dried drug.

Determination of Water-soluble Ash

The ash obtained in the determination of total ash was boiled for 5 min with 25 ml of water. The insoluble matter was collected on an ashless filter paper and washed with hot water. The insoluble ash was transferred into a tarred silica crucible and ignited for 15 min at a temperature not exceeding 45 °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 concerning the air-dried drug.

B) Determination of Loss and Drying

10 g of the sample (without preliminary drying) was weighed and placed in a tared evaporating dish. It was dried at 105 °C for 5 h, and at 1-h interval until difference two successive weighing corresponded to not more than 0.25%.

C) Determination of Extractive Values

Determination of Water-Soluble Extractive

5 g of the test sample was weighed and macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, frequently shaking during six hours and allowing standing for eighteen hours. It was filtered rapidly, taking precautions against the loss of solvent. 25 ml of the filtrate was taken and evaporated to dryness in a tarred flat bottomed shallow dish at 105 °C, to constant weight and weighed the percentage of water-soluble extractive was calculated concerning the air-dried sample.

Determination of Alcohol-Soluble Extractive

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

D) Determination of Crude Fiber Content

Mix about 2g of the powdered drug in no.60 with 50 ml of 10% nitric acid. Bring to boil and maintain at the boiling point for 30 sec. Dilute with water and strain through a fine filter cloth held over the mouth of filter funnel. Transfer the washed residue to the beaker and boil further 30 seconds with 50 ml of a 2.5% solution of sodium hydroxide. Collect and wash residue as before, mount and examine.

Qualitative Phytochemical Screening

A) Detection of Tannins

2-3 ml of aqueous or alcoholic extract of powders were tested carefully with various tannins test reagents as:

- **5% FeCl3 Solution:** A deep blue-black color indicates the test is positive.
- **Lead Acetate Solution:** A white precipitate indicates the test is positive.
- **Bromine Water:** Deceleration of bromine water indicates the test is positive.
- **Dilute Iodine Solution:** Transient red color indicates the test is positive.

B) Detection of Alkaloids

50 mg of solvent-free extract was hydrolyzed with dil. HCl and filtered. The filtrates were tested carefully with various alkaloid test reagents as follows

- **Dragendroff's Test:** To a few ml of filtrates, 1 to 2 ml of Dragendroff's reagent was added. A prominent yellow precipitate indicates the test is positive.
- **Wagner's Test:** To a few ml of filtrates, few drops of Wagner's reagent were added by the side of the test tube. A reddish-brown precipitate confirms the test as positive.
- **Test:** To a few ml of filtrates, few drops of Mayer's reagent were added by the side of the test tube. A white or creamy precipitate if obtained indicates the presence of alkaloids.

Determination of Physical Characteristics

A) Bulk Density

It is the ratio of the 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 the weight of the volume it occupied was calculated.

Bulk density= w / v0 g/ml

Where, w = mass of the powder, v0 = untapped volume.

B) Tapped Density

It is measured by transferring a known quantity (25g) 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 10-15 min. The density can be determined as the ratio of the mass of the powder to the tapped volume.

Tapped volume = w/vf g/ml

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

C) Compressibility Index/ Carr's 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/ Carr's index = [(V0-Vf)/V0] × 100

Or

% Compressibility/ Carr's Index = [(Tapped density – Bulk density)]/ Tapped density] × 100

D) Hausner's Ratio

It indicates the flow properties of the powder. The ratio of tapped density to the bulk density of the powder is called Hausner's ratio.

Hausner's ratio= Tapped density/bulk density

E) 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 radius of the pile were measured. The 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.

Determination fo 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 aluminium foil and left behind for 24-h s 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.

Table No. 1: Heavy Metal Test.

- **FOR CADMIUM**

TEST	OBSERVATION	INFERENCE
NH4OH added in the sample solution	White ppt. of cadmium hydroxide soluble in excess NH4OH	Presence of cadmium
Potassium ferrocyanide added	White ppt. of cadmium ferrocyanide	Presence of cadmium

- **Table No. 2: For Bismuth.**

TEST	OBSERVATION	INFERENCE
H2S gas added in the sample solution NH4OH	Dark brown ppt. soluble in hot dil. HNO3 but insoluble in NH4S White ppt. insoluble in excess NH4OH dissolved in dil. HCl	Presence of Bismuth Presence of Bismuth

- **Table No. 3 For Lead.**

TEST	OBSERVATION	INFERENCE
Dil. HCl added in the sample solution KI is added in the sample solution	White ppt. of CaCl2 soluble in boiled water & conc. HCl Yellow ppt. soluble in boiling water	Presence of Lead Presence of Lead

Fluorescence Analysis

A little amount of churna was macerated with a small quantity of solvents like 1N sulphuric acid, 1N nitric acid, 1N hydrochloric acid, iodine, potassium hydroxide, ammonia, 1N sodium hydroxide for an hour and then filtered. The filtrate was then analyzed under daylight and UV light for color and fluorescence.

DISCUSSION AND RESULT

- **Table No. 4:- Determination of Organoleptic Character.**

CHARACTERISTICE	SAMPLE
Colour	Light yellow
Odour	Characteristic
Taste	Very bitter
Flow property	Excellent

PHYSICOCHEMICAL PARAMETERS ANALYSIS

- **Table No. 5:- ASH Value.**

TYPE OF ASH	SAMPLE
Total ash	6.65
Acid in soluble ash	2.25
Water soluble ash	2.21

- **Table No. 6:- Moisture Contain / Loss on Drying.**

CHARACTERISTIC	SAMPLE
Moisture contain/ loss on drying	0.778

- **Table No. 7:- Extractive Value.**

CHARACTERISTIC	SAMPLE
Water	3.2
Alcohol	1.24

- **Table No. 8:- Quantitative Estimation (Qulatative Phytotenical Screeing).**

TEST	SAMPLE
Test of Tannin 5% of Fecl3 solution	Positive
Led acetat solution	Positive
Bromine water	Positive
Dilute Iodine solution Test for Alkaloids Dragendroff's test Wagner'stest Mayer's test	 Positive Positive Positive

DETERMINATION OF PHYSICAL CHARACTERISTICS

- **Table No. 9:- Bulk Density and Tapped Density.**

CHARACTRISTICS	SAMPLE
BULK DENSITY	0.666
TAPPED DENSITY	0.97

- **Table No. 10:- Carr's Index and Hausner's Ratio.**

CHARECTERISTICS	SAMPLE
Carr's index	26.74
Hausner's ratio	1.35

- **Table No. 11:- Angle of Repose.**

CHARECTERISTICS	SAMPLE
Angle of repose	36.50

- **Table No. 12:- Determination of PH Sample.**

CHARACTERISTICS	SAMPLE
p^H	6(acidic)

- **Table No. 13:- Estimation FO PH Sample.**

CHARACTRISTICS	SAMPLE
Crude Fiber	4.7

Heavy Metal Test: Triphala Churna of Patanjali.

- **Table No. 14:- Test for Cadmium.**

TEST	OBSERVATION	RESULT
NH4OH added in the sample solution	White ppt. is absent	Absence of cadmium
Potassium ferrocyanide added	White ppt. is absent	Absence of cadmium

- **Table No. 15:- Test for Bismuth.**

TEST	OBSERVATION	RESULT
H2S gas added in the sample solution	Dark brown ppt. is absent	Absence fo bismuth
NH4OH	White ppt. is absent	Absence of bismuth

- **Tabel No. 16:- Test for Lead.**

TEST	OBSERVATION	RESULT
Dil HCl added in the sample solution	White ppt. of CaCl2 is absent	Absence fo lead
KI is added added in the sample solution	Yellow ppt. is absent	Absence of lead

- **Table No. 17:- Fluoresnece Analysis for Sample.**

Solvent added	Colour observed under		
	Daylight	Short wavelength (256nm)	Long wavelength (356nm)
1N Sulpuric acid	Light brown	Light green	Dark green
1N Nitric acid	Light brown	Light green	Dark green
1N Hydrochloric acid	Light brown	Light green	Dark blue
Iodine	Greenish brown	Dark green	Dark blue
Potassium hydroxide	Brown	Green	Dark blue
Ammonia	Brown	Green	Dark blue
1N Sodium hydroxide	Dark brown	Dark green	Dark blue

DISCUSSION

From the heavy metal test it is concluded that Triphala Churna of Patanjali formulation are free from heavy metals.

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 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 Patanjali Triphala Churna. The result of present study will also serve as reference monograph in the preparation of drug formulation.

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 *Triphala* churna contains all good characters of an ideal churna and it was found to be harmless, more effective, and economic.

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