"STANDARDIZATION OF HERBAL MARKETED FORMULATION OF AMLAKI CHURNA "

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Abstract:

In the few decades, there has been essential growth found in the field of herbal drugs, preparation, and field of herbal medicines. Most of the traditional system of medicine is effective from the ancient times but they lack of standardization. So for that purpose there is a need to develop a standardization of herbal medicine and its technique. Standardization of herbal formulation is essential in order to assess the quality, purity, safety and efficacy of the drug. Amlaki Churna is helps in boosting immunity naturally, Aamlaki churna is power house of nutrients, reduces the risk of heart disease by regulating the buildup of bad cholesterol, gastrointestinal tract cleansing, Aamlaki churna having antioxidant activity that helps in fighting free radicals in the body this reduces cell damage and also risk of cancer and inflammation. The present research study deals with standardization of Amlaki churna (Amla), Terminalia bellirica (Gaertn.) The standardization of this formulation, the organoleptic characters, physical properties, the various physico-chemical properties 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- Aamlaki Churna

1. Introduction

Amla helps in maintaining proper health of hair. It makes them thick and soft. Amla is a source of Vitamin-C whose deficiency can lead to hair loss and hair breakage. Antioxidants prevent hair from premature aging and graying. Amla Powder contains essential fatty acids that help in promoting hair growth.[1]

Nature always stands as a golden mark to exemplify the outstanding phenomena of symbiosis. Today about 80% of people in developing countries still relay 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 indigenous system of medicine. The various indigenous system such as Ayurveda, Siddha, Unani use several plant species to treat different ailments. [2]

1.1 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. [3]

1.2 Advantages of Herbal Drugs

 high Low/Minimum cost

 complete accessibility

 enhanced tolerance

 More protection

 fewer side-effects

 Potency and efficiency is very high.

1.3 Disadvantages of Herbal Drugs

 Not able to cure rapid sickness and accidents

 Risk with self-dosing

 Complexity in standardizations.[4]

2. Plant Profile

2.1 *Aamla:*

Fig – Amla Fruit and churna

2.2 Scientific classification-

Kingdom	**Plantae**
Clade: Clade:	Angiosperms Eudicots
Order:	Malpighiales
Family:	Phyllanthaceae
Genus:	Phyllanthus
Species:	P. emblica

2.3 Plant morphology –

The tree is small to medium in size, reaching 1–8 m (3 ft 3 in–26 ft 3 in) in height. The branchlets are not glabrous or finely pubescent, 10–20 cm (3.9–7.9 in) long, usually deciduous; the leaves are simple, subsessile and closely set along branchlets, light green, resembling pinnate leaves. The flowers are greenish-yellow. The fruit is nearly spherical, light greenish-yellow, quite smooth and hard on appearance, with six vertical stripes or furrows.

2.4 Chemical constituents -

These fruits are reputed to contain high amounts of ascorbic acid (vitamin C) and have bitter taste that may derive from a high density of ellagitannins, such as emblicanin A (37%), emblicanin B (33%), punigluconin (12%), and pedunculagin (14%). Amla also contains punicafolin and phyllanemblinin A, phyllanemblin other polyphenols, such as flavonoids, kaempferol, ellagic acid, and gallic acid.[5,6]

3. Need of Standardization

The quality control of herbal crude drug & formulation is important in justifying their acceptability in modern system of medicines. Standardization of synthetic drugs offers no problem with very well defined parameters of analysis. It is not uncommon to have as many as five or more different herbal ingredients in one single formulation. The batch to batch variation starts from the collection of the raw materials itself in absence of any reference standard for identification. 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. Standardization also plays a pivotal role in assisting Governments, Administrations, Regulators and the legal profession as legislation, regulation and policy initiatives are all supported by standardization.[7,8,9]

4. MATERIALS AND METHODS.

Introduction of Sample:

Sample Name-

Aamlaki Churna

Main Constituents

Aamla

Uses –

It is rich herbal source of vitamin c and iron helps enhance immunity it is said to have antioxidant properties. It is said to have anti-inflammatory properties. Many have beneficial effect on hair and skin.

4.1 Development of Standardization Parameters for Aamlaki Churna:

4.1.1 Study of organoleptic characters-

- Colour
- Odour
- Taste

4.2 Determination of physico-chemical Parameters-

- Moister content
- Total ash
- Acid insoluble ash

- Water soluble ash
- Water soluble extractive
- Alcohol soluble extractive

4.3 Evaluation of Churna

- Powder fineness
- Bulk density
- Tap density
- Angle of repose
- Compressibility
- Hausner ratio

Determination of pH.

Establishing the safety pertaining to Heavy metals.

5. Procedures:

5.1 Study of Organoleptic Characters

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

5.2 Physico-Chemical Analysis

5.2.1 Determination of Loss on Drying

10 g of the sample (without preliminary drying) was weighed and placed in a tarred evaporating dish. It was dried 105˚C for 5 hours and at 1 hour interval until difference between two successive weighing not more than 0.25%.

5.2.2 Determination of Total ash

About 2 to 3 g of sample was accurately weighed in tarred silica dish at a temperature not exceeding 450˚C until it was free from carbon. Then it was cooled and weighed. The percentage of total ash was calculated with reference to air dried drug.

5.2.3 Determination of Acid insoluble ash

The total ash was obtained boiled for 5 minutes with 25 ml of dilute hydrochloric acid; the insoluble matter obtained was collected on 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.

5.2.4 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.

5.2.5 Determination of Water-soluble extractive

5 g of test sample was weighed and macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently 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 with reference to the air dried sample.

5.2.6 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.[10,11,12]

5.3 Determination of Physical Characteristics

5.3.1 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/V0 g/ml

Where, W = mass of the powder, V0 = untapped volume

5.3.2 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 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 g/ml

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

5.3.3 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 = [(v0-vf)/v0] x 100,

Or

% Compressibility = [(tapped density – bulk density)] / tapped density] x 100

5.3.4 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

5.3.5 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)

Where, h=height of the pile, r = radius of the pile.

5.4 Determination of pH range

The powder sample of Aamlaki 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.[13,14,15,16]

6. Result -

6.1 Heavy metals test

For Cadmium

Experiment	Observation	Inference
NH4OH add in a sample solution	White ppt is absent	Cadmium is absent

Table No. 01

For Bismuth

Experiment	Observation	Inference
NH4OH add in a sample solution	White ppt is absent	Bismuth is absent

Table No. 02

For Lead

Experiment	Observation	Inference
Dilute Hcl is added in sample solution	White ppt of CaCl2	Lead is absent

Table No. 03

6.2 Determination of Organoleptic Characters

Colour	Slightly Yellowish
Odour	Charecteristic
Taste	Bitter, Salt like

Table No. 04

6.3 Physico Chemical Standards

6.3.1 Ash Values

Serial No.	Type of ash	% of Ash Value (w/w)(S.E.M.)
1	Total Ash	9.64 ± 1.6
2	Acid Insoluble Ash	3.61 ± 4.37

Table No. 05

6.3.2Moisture Content/ Loss on Drying

Serial no.	% Loss on Drying (S.E.M.)
1	0.12 ± 10.29

Table No. 06

6.3.3 Extractive Values

Serial no.	Type of solvent	% Extractive Value (w/w) (S.E.M.)
1	Water	2.41 ± 5.38
2	Alcohol	1.48 ± 8.19

Table No. 07

6.3.4 Qualitative Analysis

Serial no.	Chemical Constituents	Alcohol Extracts
1	Glycosides	++
2	Alkaloids	++
3	Tannin	++

Table No. 08

6.4 Determination of Physical Characteristics of Powder

6.4.1 Bulk Density & Tap Density

Serial no.	Bulk Density (S.E.M)	Tapped Density (S.E.M)
1	0.49 ± 3.42	0.54 ± 2.29

Table No. 09

6.4.2 Carr's Index & Hausner Ratio

Serial no.	Carr's Index (S.E.M)	Hausner Ratio (S.E.M)
1	29.2 ± 0.58	1.53 ± 1.13

Table No. 10

6.4.3 Angle of Repose

Serial. No.	Angle Of Repose
1	36.4 ± 1.92

Table No. 11

6.4.4 Determination of pH

Serial. No.	pH
1	5.8

Table No. 12

7. DISCUSSIONS

The total ash value is indicating total amount of inorganic material after complete incineration and the acid insoluble ash value is an indication of silicate impurities, which might have been arise due to improper washing of the drug. The loss on drying obtained is an indicative amount of moisture will be present in drug.the extractive values mainly water and alcohol soluble extractive indicating the amount of active constituent in given amount of plant material extracted with respective solvent, values obtained supports that drug is unexhausted which is contrary to lower extractive values. The results of Phytochemical screening indicate the presence of glycosides, alkaloids, and tannins.from the heavy metal test it was concluded that Aamlaki churna of yogesh pharmacy is free from heavy metals. From the all above values, it can be concluded that the quality of Aamlaki churna "GOOD".

8. CONCLUSION

From the present study various standardization parameters such as physicochemical standards like total ash, acid insoluble ash, water and 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 Aamlaki churna of yogesh pharmacy contains all good characters of an ideal churna and it was found to harmless, more effective and economic.

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