

**Research Article****Evaluation of standardization parameter of polyherbal digestive “churna”**

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Keywords:Polyherbal,
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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 than 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.

Introduction

Ayurvedic science has got its rich heritage in India. People in India believe that natural products are safe compared to synthetic drugs. 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 than being prepared as formulation; Standardisation is an essential parameter to be done. It is a vital step in formulation since it determines the quality of the product and is essential to develop a protocol on standardisation of every product available in the market to avoid variation arising between batch to batch. Plant materials are not like synthetic drugs, they vary in many conditions even in their chemical content depending on the time and season of collection of plant material, the geographical location of the plant being grown etc[1]. The CCRAS and WHO has introduced certain standards and guidelines to maintain uniformity between the production batches. Good manufacturing practices and quality control of the ingredients and products can result in ensuring quality assurance of the formulation. The present study is to standardise a polyherbal formulation available in the market called as Churna used to treat many ailments of the body. The churna is evaluated for organoleptic properties, physical properties, physiochemical parameters and phytochemical screening to standardise the same[2]. Churna 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 churna 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[3]. 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 bioavailability. It is prescribed by the Ayurvedic physician for treating conditions such as diabetes, indigestion, constipation etc. Indigestion is a common ailment affecting the general population and in allopathic system antacids are commonly prescribed. Since the usage of such aluminium containing antacids cause deleterious effects like Alzheimer's disease upon long term usage, we explored an alternative and safe remedy for indigestion. Hence we prepared a churna with natural ingredients commonly used by mankind for culinary purposes. Thus the present study examined the favourable influence of four spices formulated into churna said to have digestive property[4].

Methodology

Preparation of Polyherbal Churana: The churana solution was prepared by means of diluting 1gm of churana to 100ml using distilled water. This is used to carry out limit test for iron and lead and also to perform qualitative test for mercury. 10ml of churna solution was pipette out into a flask and about 10ml of concentrated nitric acid was added and evaporated to

dryness on a water bath. The residue was then dried at 130° C for 30minutes then about 10ml of hydrazine molybdate reagent was added and refluxed for 20minutes. The solution was then cooled and absorbance of both standard & test solution was measured at 800nm using Perkin Elmer UV

spectrophotometer. Churna is a powdered dosage form which has a specific therapeutic effect. Generally we used churna for the treatment of digested problems but it has many other pharmaceutical uses in our daily life.



Fig 1: Ayurvedic churna is prepared by using different process in which we firstly grind the crude material in fine powder by using electrical grinder. These materials grind in to fine powder individually, after that dries these powdered drugs in sun light for few hours. After the proper drying mixed the all powdered drug according to required amount or according to given formula

Evaluation of Physical Parameters

Determination of pH

The pH of 1% solution of formulated churna was determined using pH meter (Elico pH meter). For the evaluation of pH we use buffer tablets of different pH and measure the pH of churna at a specific concentration. pH value of churna was determined with the help of buffer tablet which have pH 7 and pH 11. For the determination of pH value we use distilled water.

Determination of Moisture content

The moisture content of churna was found using the hot air oven. For the evaluation of moisture content we weight accurately 10 gm of powder and put the sample in the hot air oven for at least 4 hrs and check the weight after a particular time period. Finally we calculate the % moisture content present in the churna. Moisture content was determined with the help of hot air oven in which we kept the sample for 4 hours and check the sample after the 15 minutes interval.

$$\% \text{ Loss of Drying} = \frac{\text{Loss in weight in sample}}{\text{Weight of the Sample}} \times 100$$

Determination of Ash Values

Total Ash Value

2gms 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 desiccators and total ash in mg per gm of air dried material is calculated. For the determination of ash value present in the powdered sample by using the muffle furnace apparatus which have a very high temperature. At this high temperature all the organic material was burned and we calculate the ash value of our powdered drug.

$$\text{Total Ash value} = \frac{\text{Weight of total ash}}{\text{Weight of crude drug taken}} \times 100$$

Acid Insoluble Ash Value

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

Determination of Extractive Values

Water Soluble Extractive Value

5gms of churna was accurately weighed and placed inside a glass stopper conical flask. It is then macerated with 100ml of chloroform water for 18hours. 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 6hrs, cooled and finally weighed.

$$\text{Acid insoluble ash value} = \frac{\text{Weight of acid insoluble ash}}{\text{Weight of crude drug taken}} \times 100$$

$$\% \text{ Yield} = \frac{\text{Weight of water extract}}{\text{Amount of drug taken}} \times 100$$

Alcohol Soluble Extractive Values

Water and remaining procedure was the same as that of water soluble extractive value. Alcohol soluble extractive value was

calculated for the determination of alcohol soluble content present in the churna preparation.

Alcohol soluble extractive value was determined with the help of following formula:-

$$\% \text{ Yield} = \frac{\text{Weight of alcohol extract}}{\text{Amount of drug taken}} \times 100$$

Determination of Crude Fibre Content

2gms of accurately weighed churna was placed in a round Bottom flask and then 100ml of 0.128 M sulphuric acid was Added and refluxed for 1 hour then filtered through ash less Filter paper and the residue was washed with water until

Bulk Density

10g of churna was taken in a graduated measuring cylinder and tapped on a wooden surface. Bulk density is calculated by using the formula. For the determination of bulk density we use tap density volumetric flask in which we fell the 10g powder sample and calculate the bulk density by using following formula.

Physical characteristics of churna

$$\text{Bulk Density} = \frac{\text{Weight taken}}{\text{Bulk volume}}$$

Tap Density

Tap density of churna was determined after 50 tapping with the help of tap density apparatus. For the determination of tap density we check the tap volume of churna and determine the

ratio of weight taken and tap volume of churna sample. The following formula can be used for the determination of tap density:

$$\text{Tap Density} = \frac{\text{Weight taken}}{\text{Tapped volume}}$$

Angle of Repose

Angle of repose was determined by using funnel method. The powder was allowed to flow through a funnel fixed on a stand

to form a heap. The height and the radius give the angle of repose.

$$\text{Angle of Repose } (\theta) = \tan^{-1} \left(\frac{h}{r} \right)$$

$$\theta = \text{Tan}^{-1} (h/r)$$

Where, h = height of heap
r =radius of heap

Compressibility / Carr's Index

This is calculated using the formula:

$$\text{Carr' Index} = \frac{\text{Bulk density (Tapped)} - \text{Bulk density (Untapped)}}{\text{Bulk density (Tapped)}} \times 100$$

Hausner's Ratio

The formula used to determine Hausner's ratio we use bulk density and tap density ratio. For the determination of Hausner's ratio following formula:-

$$\text{Hausner's Ratio} = \frac{\text{Bulk density (Tapped)}}{\text{Bulk density (untapped)}}$$

Particle Size Distributions

This was done by sieve method. Sieves were arranged in an ascending order. Churna was weighed and added to the top sieve and the assembly was shaken for 15mins. Then the sieves were removed and the weight of churna retained over each sieve was measured.

Determination of Heavy Metal Contamination**Arsenic Content****Preparation of Standard Solution (10PPM)**

0.33gms of arsenic trioxide was dissolved in 5ml of 2M Sodium hydroxide solution and then diluted to 250ml with water. One volume of this was then diluted to 100ml volume with water.

Preparation of Sample

The churna solution was prepared by means of diluting 1gm of churna to 100ml using distilled water. This is used to carry out limit test for iron and lead and also to perform qualitative test for mercury. 10ml of churna solution was pipette out into a flask and about 10ml of concentrated nitric acid was added and evaporated to dryness on a water bath. The residue was then dried at 130° C for 30minutes then about 10ml of hydrazine molybdate reagent was added and refluxed for 20minutes.

Limit test for Iron**Preparation of Standard Solution (20 PPM)**

One volume of 0.1726% w/v solution of ferric ammonium sulphate solution was diluted in 0.05 M sulphuric acid to 10ml volume using distilled water.

Preparation of Sample

Limit test was performed in Nessler's cylinder. 2ml of test and standard solutions were taken in separate cylinders and then 2ml of 20% solution of citric acid and 0.1 ml thioglycolic acid were added. The solution was then mixed and made alkaline with iron free ammonia, diluted to 50ml with distilled water. It was then allowed to stand for 5minutes and colour obtained in sample was compared with that of standard colour.

Limit Test for Lead**Preparation of Standard (20 PPM)**

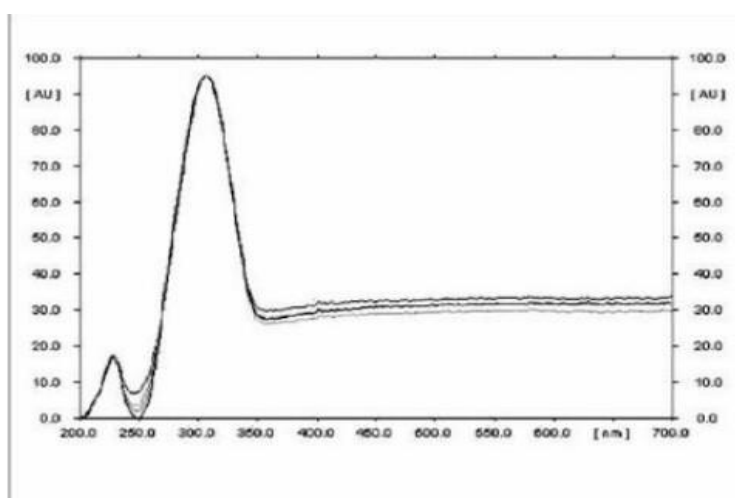
0.4 gm of lead nitrate was dissolved in water containing 2ml of nitric acid and sufficient water to produce 250ml. About 1volume of above solution was diluted to 10 volumes using distilled water.

Tests for Mercury

To 10 drops of test solution 6M Hcl was added to geta white precipitate. The precipitate was then treated with 6M ammonia solution. If the colour of precipitate changesto grey or black colour then it indicates the presence of mercury.

UV Spectroscopy Test

Absorbance of churna can be calculated by using the UV Spectroscopy. For the evaluation of churna different dilution of churna was prepared with the help of distilled water. The absorbance of churna can be show in following figure:



Result Physicochemical Parameter

Loss on drying, ash values, extracting values, pH and crude fibre content⁷ was determined for the physicochemical parameters [Table: 2].

Table 2: Physicochemical Evaluation

S.No.	Parameters	Observation
2.1	pH 1% & 10% w/w	6.7±0.07 & 6.2±0.03 respectively
2.2	Loss of Drying (%)	3.7±0.14
2.3	Total ash Value	0.1616.9±
2.3.1	Acid Insoluble ash Value	3.7±0.09
2.3.1	Water Soluble ash value	13±0.21
2.5	. Alcohol soluble extractive value (% w/w)	2.78±0.23
2.4.1	Water soluble extractive value (% w/w)	0.91
2.4.2	Crude fibre content (g)	8.91±0.05

Results of Physical Parameters:

Bulk density, Angle of repose, Hausner's ratio, Carr's index, and particle size distribution was determined for evaluating the physical characteristics of the churana [Table 3].

Table 3: Physical evaluation

S.No.	Parameters	Observation
3.1	Bulk density (g/ml)	0.478±0.013
3.2	Tapped density (g/ml)	0.659±0.017
3.3	Angle of Repose (θ°)	33°92'±0.11
3.4	Compressibility index (%)z	27.46±0.024
3.5	Hausner's ratio	1.37±0.012
3.6	Particle size distribution (µm)	21.67±0.21

Detection of Heavy Metals in Churana

S. No.	Heavy Metals	Values
1	Arsenic (Spectrophotometer)	0.205 ppm
2	Iron (Limit Test)	Within Limit
3	Lead (Limit Test)	Within Limit
4	Mercury (Qualitative Analysis)	Absent

Conclusion

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 of pharmaceutical of Teerthankar Mahaveer College of pharmacy (Moradabad).

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