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Formulation and Evaluation of Panchaudara Polyherbal Tablets

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Abstract:

Herbal preparations are advantageous than the allopathic medicines. They have multidimensional usage i.e. a single herbal formulation can be used for variety of ailments. They have low toxicity when compared to allopathic medications and can be prepared at low cost. But herbal formulations have their own limitations. There is need of standardization. This work involves the preparation and standardization of a new herbal formulation panchaudara churna. The standardization of churna include microscopy, determination of physico-chemical properties like extractive values, ash values, micromeritic properties, total viable aerobic count, preliminary phytochemical screening, The Poly herbal tablets can be prepared from Poly herbal churna for better long shelf life, mask the bitter taste of churna and easily swallow able compared to churna. Panchaudara tablets are prepared by the wet granulation and compression of the churna. The preformulation studies on the granules show that granules have required moisture content, good compression properties and they are free flowing. Thus they can be compressed to a tablet. The tablets are evaluated as per Indian Pharmacopoeia. The evaluation of panchaudara tablets included weight variation test, friability test, and disintegration test, the dissolution test is not needed because it is cumbersome. The tablets can be used for the same diseases which are treated by churna.

Keywords: Poly herbal, Churna, Pancha udara, Tablet, Cyperus rotundus, Dental analgesic

1. INTRODUCTION

1.1 Herbal Formulations

Herbal formulation shall mean a dosage form consisting of one or more herbs or processed herb(s) in specified quantities to provide specific nutritional, cosmetic benefits, and/or other benefits meant for use to diagnose treat, mitigate diseases of human beings or animals and/or to alter the structure or physiology of human beings or animals.[1]

Dosage forms commonly employed for food or cosmetic or pharmaceuticals may be employed to formulate one or more herb or processed herbs. Dosage forms known in traditional medicines may also be adopted for preparing herbal formulations, either for external use or for internal administration. Adequate consideration for uniform distribution of herb or processed herbs as well as stability of the same in the dosage form shall be provided during formulation

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development.

Herbal formulation shall be labeled to comply with relevant labeling requirements under food or drug or cosmetics laws as applicable. Additionally, adequate information shall be provided on label of such formulations to include the name of the herb, parts used, nature and type of extract or processed herb used, extraction ratios, quantity per unit dose or per serving, name (s) of inert excipients used and any preservatives added shall be provided on the label.

Advantages of Herbal Medicine

- 1. Medicinal plants have a renewable source, which is our only hope for sustainable supplies of cheaper medicines for the world growing population.[2]
- 2. Availability of medicinal plants is not a problem especially in developing countries like India having rich agro-climatic, cultural and ethnic biodiversity.
- 3. The cultivation and processing of medicinal herbs and herbal products is environmental friendly.
- 4. Prolong and apparently uneventful use of herbal medicines may offer testimony of their safety

and efficacy.

5. Herbal medicine has provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form and as a pure chemical upon which modern medicines are structured.

Limitations of Herbal Medicines

- 1. Ineffective in acute medical care.[2]
- 2. Inadequate standardization and lack of quality specifications.
- 3. Lack of scientific data.

Need of Standardizations

- Authentication is needed during the collection of the herbs.[3]
- There may be occurrence of batch to batch variations in preparation.
- To check the safety and efficacy of the herbal formulations.
- Lack of the quality control during manufacturing.

Current Regulations for Standardization of Crude Drugs are provided by [4]

- Pharmacopoeia Committee
- Chinese Herbal Pharmacopoeia
- United States Herbal Pharmacopoeia
- British Herbal Pharmacopoeia
- British Herbal Compendium
- Japanese Standards for Herbal Medicine

Guidelines for Quality Standardized Herbal Formulations

In the modern herbal ayurvedic monographs the standardization parameters are discussed in a comprehensive way[5, 6]. According to the modern ayurvedic monograph the quality control protocols include the following:

Title, synonyms, publications related to that plant, constituents present and analytical methods.

Descriptive evaluation

Description of the drug, phytomorphological, microscopical, organoleptic evaluations, foreign matter and foreign minerals etc.

Physicochemical parameters

Identity: Physical and chemical identity, chromatographic finger prints, ash values, extractive values, moisture content.

Strength: Ethanol and water extractive values, volatile oil and alkaloidal assays, quantitative estimation protocols, etc.

Biological Activity Evaluation: Bitterness values, astringency, swelling factor, foam index, Hemolytic index, etc.

1.2 Churna

Ayurvedic formulations can be classified into three categories broadly. They are

Solid preparations	Churna, Bhasma, Pisti etc.
Semisolid preparations	Lepa, Lehya etc.
Liquid preparations	Taila, Asava, Arishta etc.

Churna is a coarse powder made by grinding of certain drugs or combination of drugs.[7] Ayurvedic medicines derived from plants are prepared either in form of powder or decoctions. Before these plants are subjected to processing they are thoroughly examined by the specialists and proper identification is made. Each of the ingredients is pulverized separately as the different ingredients when pulverized together do not pass through the sieve equally which affects the composition. The churna is free flowing and retains potency for one year, if protected in air tight container.

Advantages of churna

- Churna is usually used in variety of ailments.
- Churna can be stored for longer duration.
- It can be easily dispensed.

The current churna preparation- Panchaudara churna contain

- Terminalia chebula
- Terminalia belerica
- Piper longum
- Eugenia caryophyllus
- Cyperus rotundus

1.3 Polyherbal tablets

A tablet is a pharmaceutical dosage form. [8, 9] It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted from a powder into a solid dose. The excipients can include diluents, binders or granulating agents, glidants (flow aids) and lubricants to ensure efficient tabletting disintegrants to promote tablet break-up in the digestive tract, sweeteners or flavors to enhance taste, and pigments to make the tablets visually attractive. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or to enhance the tablet's appearance.

Polyherbal tablets are the new approach in the herbal remedies. These are prepared by the compression of powders from herbal sources along with suitable excipients.

Advantages of Polyherbal tablets

- 1. We can enhance the shelf-life of the herbal preparations.
- 2. The bitterness of the herbal preparations can be decreased.
- 3. They can be prepared at less cost when compared to allopathic tablets.

Herbal preparations are advantageous than the allopathic medicines. They have multidimensional usage i.e. a single herbal formulation can be used for variety of ailments. They have low toxicity when compared to allopathic medications. They can be prepared at low cost. But herbal formulations have their own limitations. There is need of standardization. The work involves the preparation and standardization of a new herbal formulation - panchaudara churna.

The standardization of churna include the microscopy, determination of physicochemical properties like extractive values, ash values, micromeritic properties, total viable aerobic count, preliminary phytochemical screening, thin layer chromatography. The churna can be converted into tablets. The tablets have long shelf-life when compared to churna. The tablets are evaluated as per Indian Pharmacopoeia. The evaluation of panchaudara tablets included weight variation test, friability test, and disintegration test. The dissolution test is not needed because it is cumbersome. The tablets can be used for the same diseases which are treated by churna. These polyherbal tablets have long shelf-life when compared to churna. The current preparations Panchaudara churna and Panchaudara tablets contain Piper longum, Terminalia chebula, Terminalia belerica, Eugenia caryophyllus and Cyperus rotundus.

These preparations are used to treatment of variety of ailments. These preparations can be indicated in:

- GI disturbances
- Respiratory tract infections
- Cough
- Helminthic infections
- Purgative
- Dyspepsia
- Antiseptic
- Dental analgesic
- Piles
- Ulcers
- Appetite
- Demulcent

Dose

5-10g of churna powder daily twice or each

tablet twice daily.

2. MATERIALS AND METHODS

2.1 Preparation of Panchaudara churna

Formula:

Piper longum	1part
Terminalia chebula	1 part
Terminalia belerica	1 part
Eugenia caryophyllus	1 part
Cyperus rotundus	1 part

Procedure

- 1. Different herbs used in the churna were purchased from the local market in anantapur of Andhra Pradesh.
- 2. They are identified on the basis of macroscopical and microscopical characters and compared it with standard Pharamacopoeial monographs.
- 3. The foreign matter is removed from the plant parts.
- 4. Churna is prepared by the grinding of the ingredients separately using a mortar and pestle. The powders obtained above are mixed thoroughly using motor and pestle. The prepared churna is stored in a well closed container.

Procedure

Macroscopy

The macroscopic characters like taste and odour were observed. Pale brown, moderately fine powder,pungent odour, slightly pungent taste with tingling sensation.

Microscopy- preparation

A few mg of churna was washed with distilled water, treated with iodine and potassium iodide, drop of glycerin was added and mounted on a microscopic slide. It is observed under compound microscope.

Physico-chemical parameters

Extractive values

Churna (5g) was extracted in Chloroform, Water, Ethanol 50ml each separately by cold maceration method and their extractive values are determined as per the method given in Ayurvedic pharmacopoeia of India. [11, 12]

Ethanol soluble extractive

Churna was dispersed in 50ml of ethanol and allowed to stand for 24 hours and occasional shaking and filtered and solvent was evaporated. The product obtained was dried and weighed.

Water soluble extractive

Churna was dispersed in 50ml of water and allowed to stand for 24 hours and occasional shaking

and filtered and solvent was evaporated. The product obtained was dried and weighed.

Chloroform soluble extractive

Churna was dispersed in 50ml of chloroform and allowed to stand for 24 hours and occasional shaking and filtered and solvent was evaporated. The product obtained was dried and weighed. Loss on drying

A weighing bottle was weighed accurately; 2g churna powder placed into the weighing bottle, spread the sample so that the layer is not thicker than 5 mm, and weighed it accurately. The weighing bottle is dried in hot air oven at 105°C. Cooled it in the dessicator and weigh it again. The percentage of loss on drying was calculated.

Determination of total ash

Churna (2gm) was weighed and taken in the separate crucible and are intended to burn in the Muffle furnace at temperature 475°C in the absence of atmospheric air. The total ash collected and weighed after one hour, weighed and the ash value is determined. Determination of Acid Insoluble Ash

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

Determination of Water Soluble Ash

The ash obtained in above step is boiled for 5 minutes with 25 ml of water; the insoluble matter is collected in an ash less filter paper, washed with hot water and ignited to constant weight temperature not exceeding 475°C. Subtract the weight of the insoluble matter from the weight of the ash; the difference in weight represents the water soluble ash. The percentage of water-soluble ash with reference to the air dried drug was calculated

Micromeritic parameters

The physical characteristics of the formulation were determined in terms of the true density, bulk density and angle of repose. [13, 14]

Angle of Repose

50 gm of the powder was placed in a plugged glass funnel which had a distance of 10 cm from the flat surface. The powder was then allowed to flow through the 8 mm funnel orifice by removing the cotton plug from the funnel orifice. The height of the heap (h) formed as well as the radius of the heap (r) was noted. The angle of repose (θ) was calculated as

 $\theta = \tan - 1 h/r$

Bulk and Tapped Densities

Exactly 50 gm of powder was weighed on chemical balance and transferred into a 100 ml measuring cylinder. The cylinder was dropped on a wooden platform from a height of 2.5 cm three times at 2 seconds interval. The volume occupied by the powder was recorded as the bulk volume. The cylinder was then tapped on the wooden platform until the volume occupied by the powder remained constant.

Microbial limit test

Method: Spread plate method Medium: Nutrient agar medium

Preparation of nutrient agar medium (see Table 6):

- 1. The ingredients were dissolved in water with the aid of heat.
- 2. pH is adjusted to 8.0 with 5M sodium hydroxide and boiled for 10 minutes.
- 3. It is sterilized by maintaining at 115°C 15 lb pressure for 30 minutes and adjusted the pH to 7.3

2.2 Methodology

Prepare the dilutions of given sample with the help of sterile pipettes. Add 0.1ml of any prepared dilution on sterile nutrient agar plate. Spread the dilution with the help of glass spreader, sterilized by 95% alcohol. Glass spreaders are sterilized by flaming after dipping in alcohol and are allowed to become cool between two burners. Incubate petriplates at 35°C to 37°C for 24 hours.

Observe all Petri plates and count total number of colonies using Quebec colony counter or mechanical hand counter. The number of microorganisms per ml of sample is calculated by multiplying the number of colonies by dilution factor.

Preliminary phytochemical screening

Plants possess a wide variety of chemical compounds and are classified as primary metabolites. Primary metabolites and secondary metabolites are substances widely distributed in nature and most of them are occurring in the form or other virtually in all organisms and perform the basic cell metabolism; starch, cellulose, carbohydrates etc. secondary metabolites perform no apparent function in plants, primary metabolism but often have an ecological role; example includes alkaloids, steroids, Terpenoids, Flavonoids, quinoids, iroids, coumarins, tannins, phenols and their other glycoside. Secondary metabolites tend to be synthesized in specialized cell type and distinct developmental stages making their extraction purification is difficult. As a result, secondary metabolite s after isolation and structural elucidation are screened for activity are used as commercially as biologically

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active compounds known as phytopharmaceuticals. Chemical evaluation comprises of different chemical tests and chemical assays.[15] The isolation, purification, and identification of active constituents are chemical method of evaluation. The qualitative, chemical tests are useful in detection of adulteration. The systematic investigations of plant material for its phytochemical behavior involve four stages.

- The procurement of raw material and quality control.
- Extraction, purification and characterization of the constituents of pharmaceutical interest inprocess quality control.
- Investigation of biosynthetic pathways to particular compounds.
- Quantitative evaluation.

Phytochemical analysis:

The chemical tests for various phytoconstituents in the Ethanolic extract, Water extract and Chloroform extract were carried out as described below.

D. Test for alkaloids

i. Dragendroffs test

In a test tube containing 1 ml of extract, few drops of Dragendroffs reagent was added and the colour developed was noticed. Appearance of orange colour indicates the presence of alkaloids.

ii. Wagner's test

To the powder, 2ml of Wagner's reagent was added the formation of a reddish brown precipitate indicated the presence of alkaloids.

iii. Mayer's test

To the powder, 2ml of Mayer's reagent was added, a dull yellow precipitate is revealed the presence of alkaloids.

iv. Hager's test

To the powder 2ml of Hager's reagent was added, a dull yellow precipitate revealed the presence of alkaloids.

B. Tests for Terpenoids (Noller's test)

To 1 ml of extract, tin (one bit) and thionyl chloride (1 ml) were added. Appearance of pink colour indicates the presence of Terpenoids.

C. Test for steroids

i. Liebermann – Burchard's test

The powder was dissolved in 2ml of chloroform in a dry test tube. 10 drops of acetic anhydride and 2 drops of concentrated sulfuric acid were added. The solution become red, then blue and finally bluish green indicates the presence of steroids.

ii. Salkowski test

The powder was dissolved in chloroform and equal volume to cherry red colour in chloroform layer

and green fluorescence in the sulphuric acid layer represented the steroid components in the test samples

D. Test for tannin

- i. To a few mg of powder, ferric chloride was added, formation of a precipitate showed the presence of tannins.
- ii. To a few mg of powder, potassium dichromate solution was added, formation of a precipitate showed the presence of tannins and phenolics
- iii. The sample powder was mixed with basic lead acetate solution. Formation of white precipitate indicated the presence of tannins.

E. Test for Saponins

About 1g of powder is mixed with distilled water to 20ml and shaken in a graduated cylinder for 15 min. Layer of foam was not formed which indicates the absence of Saponins.

F. Test for Flavonoids

- i. Shinoda's test: To few mg of the powder, magnesium turnings and 1- 2 drops of concentrated HCl were added. Formation of red colour shows the presence of Flavonoids.
- ii. Zinc hydrochloric acid reduction test: To few mg of the powder zinc dust and concentrated hydrochloric acid was added. Formation of magneta colour shows the presence of flavonoid.
- iii. Ferric chloride test: To few mg of the powder, a small quantity of Ethanolic solution and few drops of neutral ferric chloride were added. Blackish red colour indicates the presence of Flavonoids.
- iv. Alkaline reagent test : To few mg of the powder, a few drops of dilute sodium hydroxide was added. An intense yellow colour, which becomes colourless on addition of a few drops of dilute acid, indicates the presence of Flavonoids.

G. Tests for quinones

To the 1ml of extract of concentrated sulphuric acid were added. Formation of red colour shows the presence of quinones.

H. Test for anthraquinones (borntrager's test)

The powder extract was macerated with ether and after filtration, aqueous ammonia or caustic soda was added. Pink or violet colour in the aqueous layer after shaking indicates the presence of anthraquinones.

I. Test for Phenols

To the 1ml of extract, 2ml of distilled water was added followed by few drops of 10% aqueous fer-

ric chloride. Appearance of blue or green colour indicates the presence of phenols

J. Test for proteins

- i. Biurette test: To the few mg of powder, 1ml of 40% sodium hydroxide solution and two drops of 1% copper sulphate solution were added. Formation of violet colour indicates the presence of proteins.
- ii. Xantho protein test: To the few mg of powder, 1ml of concentrated nitric acid was added. As a white precipitate was formed, it is boiled and cooled. Orange colour indicates the presence of aromatic amino acids.
- iii. Tannic acid test: To the powder, 10% tannic acid was added. Formation of white precipitate indicates the presence of proteins.

K. Test for carbohydrates (sugar)

- i. Molisch's test: To the powder 1ml of α -napthol solution and concentrated sulfuric acid through the sides of test tube were added. Purple or reddish violet colour at junction of the two liquids revealed the presence of carbohydrates.
- ii. Fehling's test: To the powder, equal quantities of Fehling's solution A and B were added and on heating, formation of a brick red precipitate indicated the presence of carbohydrates.

L. Test for glycosides

The extract was mixed with a little anthrone on a watch glass. One drop of concentrated sulfuric acid was added into a paste, warmed gently over water bath. The presence of glycosides was identified by dark green colouration.

M. Test for gum

The extract mixed with water leads to the thickening of the substance, indicates the presence of gum.

N. Test for starch

The extract mixed with water leads to the thickening with 1% iodine solution. Formation of blue colour indicates the presence of starch.

O. Test for fixed oil (spot test)

A small quantity of powder extract was pressed between the filter paper. Formation of grease spot indicates the presence of fixed oils and fats.

P. Test for catechin

A test solution of drug and Ehrlich reagent followed concentrated hydrochloric acid gives pink colour indicating the presence of catechin.

Q. Volatile oil

Substance is treated with Sudan red III (in al-

2.5 Thin-Layer Chromatography (TLC)

Thin-layer chromatography is a technique in which a solute undergoes distribution between two phases, stationary phase acting through adsorption and a mobile phase in the form of a liquid. [16] The adsorbent is a relatively thin, uniform layer of dry finely powdered material applied to a glass, plastic or metal sheet or plate. Glass plates are most commonly used. Separation may also be achieved on the basis of partition or a combination of partition and adsorption, depending on the particular type of support, its preparation and its use with different solvent. Identification can be effected by observation of spots of identical Rf value and about equal magnitude obtained respectively, with an unknown and a reference sample chromatographed on the same plate. A visual comparison of the size and intensity of the spots usually serves for semi-quantitative estimation.

TLC profile

Solvent system

Toluene: Ethyl acetate : formic acid in a ratio of 5.0 : 3.0 : 1.5

Detecting reagent	:	Iodine chamber
TLC adsorbent	:	Silica gel G plates

Preparation of plates

- i. Slurry of the silica gel G is prepared and spread on a flat glass plate (20X10 cm) to form a uniform layer of the suspension, 0.25 to 0.30 mm thick.
- ii. The coated plates are allowed to dry in air.
- iii. Heated at 100°C to 105°Cfor at least 1 hour and allowed to cool, protected from moisture.

Method

- 1. Ethanolic extract of the churna is spotted on the prepared TLC plate.
- 2. The TLC plates are placed in the TLC chamber having the mobile phase Toluene: Ethyl acetate: formic acid in ratio of 5.0: 3.0: 1.5.
- 3. The plates are allowed till the mobile phase moves 3/4th of TLC plate.
- 4. The plates are dried in hot air oven at 105°C for few min.
- 5. Then the plates are kept in Iodine chamber to visualize the spots.
- 6. Rf values are calculated by using the formula.

Formulation of tablets

Formula

Churna powder	50 g
Acacia powder	5% solution

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Starch	2.5 g
Talc	0.5g

Method: Wet granulation method

Procedure:

- 1. Ingredients are weighed and passed through sieve no. 80.
- 2. Acacia 5% solution was prepared.
- 3. A wet mass of churna powder was prepared by triturating with acacia solution in small quantities.
- 4. Pass the above mass into sieve no. 10 to form granules.
- 5. Then the granules are dried at 50°C.
- 6. Add the talc (as lubricant) to granules and passed through sieve no. 10.
- 7. The granules are compressed using Dolphin single punch hand machine.
- 8. The tablets are collected and stored.

Evaluation Procedures:

A. Evaluation of granules:

Evaluation of granules is done prior to the compression. ("Table 4" on page 243)

1. Angle of Repose

50 gm of the granules was placed in a plugged glass funnel which had a distance of 10 cm from the flat surface. The granules were then allowed to flow through the 8 mm funnel orifice by removing the cotton plug from the funnel orifice. The height of the heap (h) formed as well as the radius of the heap (r) was noted. The angle of repose (θ) was calculated as

$\theta = tan - 1 h/r$

2. Bulk and Tapped Densities

Exactly 50 gm of granules was weighed on chemical balance and transferred into a 100 ml measuring cylinder. The cylinder was dropped on a wooden platform from a height of 2.5 cm three times at 2 seconds interval. The volume occupied by the granules was recorded as the bulk volume. The cylinder was then tapped on the wooden platform until the volume occupied by the granules remained constant. This was repeated three times for granules. The data generated was used in calculating the Carr's compressibility index (CI) and Hausner's ratio (HR) for the granules.

CI = 100(TD-BD)/TD

HR = TD/BD

3. Moisture Content

1 gm of the granules was put into a crucible and dried to constant weight in a hot air oven at 105°C. The moisture content (MC) was deduced as difference between the initial (Wo) and final weight (Wf) of the granules expressed as a percentage and calculated as

MC = 100 (Wo - Wf)/Wo

B. Evaluation of tablets [15]:

1. Organoleptic characters

- The tablets are pale brown in colour.
- They are slightly bitter in taste.

2. Tablet thickness

The thickness of 10 tablets each selected at random from the formulated tablets was determined using a vernier calipers and the mean of these readings was taken as the mean tablets thickness.

3. Weight variation ("See Table 1" on page 240)

- i. 20 tablets were collected randomly.
- ii. They are weighed and average weight is calculated.
- iii. Tablets are weighed individually.
- iv. Compare the individual weights with the average.
- v. The tablets meet the IP if no more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.
- vi. The weight variation tolerance for uncoated tablets differ depending on average tablet weight.

4. Friability

The friability test is carried out in an instrument called a friabilator. A friability testing apparatus should stimulate the conditions that the product will be exposed to during the process of production. This test is a method to determine physical strength of uncoated tablets upon exposure to mechanical shock and attrition.

The commonly used friabilator in laboratories is the Roche friabilator.

Apparatus

This instrument consists of a plastic chamber for placing the tablets which is attached to a horizontal axis. The drum has an inside diameter of 287mm and is about 38mm in depth, made of a transparent synthetic polymer with polished internal surface. A set of pre weighed tablets are placed in the plastic chamber revolving at 24-25rpm for 4 min. The tablets are subjected to combined effects of abrasion and shock. The tablets are dropped at a distance of six inches on each revolution.

Procedure

1.20 tablets are weighed.

2. They are placed in the drum of friabilator.

- 3. The friabilator is set to rotate for 100 revolutions i.e. 4 min.
- 4. The tablets are collected, removed from dust and reweighed.
- 5. The loss of weight in calculated.
- 6. Conventional tablets that lose less than 0.5 to 1.0% of their weight are generally acceptable.

$F = (1 - Wo / W) \ge 100$

5. Disintegration

Apparatus: Electrolab disintegration apparatus.

The USP disintegration apparatus uses 6 glass tubes that are 3 inches long, open at the top, and held against a 10-mesh screen at the bottom end of the basket rack assembly. To test for disintegration time, one tablet is placed in each tube, and the basket rack is positioned in a 1 lt beaker of water at $37^{\circ}C \pm 2^{\circ}C$, such that the tablets remain 2.5 cm below the surface of liquid on their upward movement and discard not closer than 2.5 cm from the bottom of beaker. A standard motor-driven device is used to move the basket assembly containing the tablets up and down through a distance of 5 to 6cm at a frequency of 28 to 32 cycles per minute.

Procedure

- 1.6 tablets are placed in the tubes. (One tablet in each tube).
- 2. Water is used as the fluid in the beaker.
- 3. The disintegration apparatus is set to up and down motions till all the 6 tablets are disintegrated completely.
- 4. The time required to disintegrate is noted down.

3. RESULTS

Standardization of Churna

Microscopy of churna ("Fig 1" on page 245)

It showed the characters like orange coloured Parenchymatous cells, stone cells, aril tissue, perisperm cells, vessels with spiral thickening, rosette and prismatic crystals of calcium oxalate, biseriate and multiseriate medullary ray, lignified sclereids and orange coloured particles.

Physico-chemical properties of churna: ("Table 2" on page 243)

Total viable aerobic count: ("Fig 2" on page 245) The total viable aerobic count is found to be nil.

Preliminary phytochemical screening: ("Table 3" on page 241)

Thin layer chromatography: ("Fig 3" on page 246) The TLC plate was observed with two spots with Rf

Evaluation of tablets

Thickness of tablet: 2.25 mm

Friability: The percentage weight loss on friability is 0.8%. Thus they pass the friability test.

Disintegration: The disintegration time of the prepared polyherbal tablets is 8 min.

Weight Variation: The prepared polyherbal tablets pass the weight variation test. Not more than 2 tablets are outside the percentage limit and no tablet differs by more than 2 times the percentage limit. ("Table 5" on page 244)

4. DISCUSSION ON RESULTS

Panchaudara churna was prepared using five different types of herbs. This preparation is standardized using the protocols for the testing ayurvedic formulations. The standardization of the churna is needed for the manufacturing on large scale. The churna can be used for the various diseases.

The standardization of churna included the macroscopic and microscopic determination which showed the presence of Aril tissue, Spiral vessels, Pit-ted vessels, rosette calcium oxalate crystals etc.

Determination of micromeritic properties, physicochemical properties like extractive values, ash values, micromeritic properties etc. was done. The total viable aerobic count of the churna preparation was found to be nil. So that it is free from the microbial growth.

On preliminary phytochemical screening it was found that the preparation contains alkaloids, terpenoids, tannins, volatile oils, protein and carbohydrates.

The thin layer chromatography showed two spots. But further research is required for the identification of compounds.

The Polyherbal tablets can be prepared from Polyherbal churna for better long shelf life, mask the bitter taste of churna and easily swallowable compared to churna.

Panchaudara tablets are prepared by the wet granulation and compression of the churna. The preformulation studies on the granules show that granules have required moisture content, good compression properties and they are free flowing. Thus they can be compressed to a tablet. The tablets are evaluated as per Indian Pharmacopoeia.

The evaluation of panchaudara tablets included weight variation test, friability test and Disintegration test. The dissolution test is not needed because it is cumbersome. These preparations are used to treat variety of ailments. These preparations can be indicated in

- GI disturbances
- Respiratory tract infections
- Cough
- Helminthic infections
- Purgative
- Antiseptic
- Dental analgesic
- Piles
- Ulcers
- Appetite
- Demulcent

5. CONCLUSION

The prepared panchaudara churna and panchaudara tablet shows multidimensional usage with less side effects and low cost when compared to other allopathic medicine. On standardization of churna, it can be preapared on large scale.

The tablets have good organoleptic characters. The panchaudara tablets have less disintegration time. Further research is required on the pharmacology on these products.

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List of Tables

Table 1: Limits for weight variation test

S.No.	Average weight of tablets	Maximum percentage difference allowed
1	80mg or less	10
2	More than 80 mg but less than 250 mg	7.5
3	250 mg or more	5

Table 2: Results of physico-chemical properties of churna

S.No.	Property	Obtained values
1.	Water soluble extractive	38.96%
2.	Alcohol soluble extractive	23.26%
3.	Chloroform soluble extractive	65.34%
4.	Loss on drying	9.6%
5.	Total ash value	26.4%
6.	Acid insoluble ash	4.28%
7.	Water soluble ash	15.84%
8.	Bulk density	0.532 gm/ml
9.	Tapped density	0.597 gm/ml
9.	Angle of repose	31.39°
10.	Total viable aerobic count	Nil

Table 3: Results of preliminary phytochemical screening

S.No.	Constituents	Water extract	Alcohol extract	Chloroform extract
1.	Alkaloids	+	+	+
2.	Terpenoids	+	+	+
3.	Steroids	-	-	-
4.	Tannins	+	+	+
5.	Saponins	-	-	-
6.	Flavonoids	-	-	-
7.	Quinolones	-	-	-
8.	Phenols	+	+	+
9.	Protein	+	+	+
10.	Carbohydrates	+	+	+
11.	Glycosides	-	-	-
12	Gum	-	-	-
13.	Volatile oil	+	+	+

Table 4: Results of evaluation of granules

S.No.	Parameter	S1	S2	\$3	Mean
1	Moisture content	3.5	3.4	3.8	3.55
2	Angle of repose	23.41°	23.45°	23.49°	23.45°
3	Bulk density	0.532	0.552	0.562	0.549
4	Tapped density	0.597	0.585	0.576	0.586

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5	Hausner's ratio	1.122	1.059	1.024	1.068
6	Carr's index	10.887	10.846	10.892	10.864

Table 5: Results of Weight Variation Test:

S.No.	Individual weight(g)	Average weight(g)
1	249.1	253.4
2	249.5	253.4
3	250.2	253.4
4	251.1	253.4
5	250.6	253.4
6	252.8	253.4
7	254.1	253.4
8	253.4	253.4
9	256.1	253.4
10	257.1	253.4
11	251.3	253.4
12	254.6	253.4
13	249.1	253.4
14	248.9	253.4
15	251.2	253.4
16	250.0	253.4
17	250.6	253.4
18	257.2	253.4
19	253.2	253.4
20	253.4	253.4

Table 6 Ingredients of nutrient agar medium

S.No.	Ingredients	Quantity
1	Beef extract	10.0g
2	Peptone	10.0g
3	Sodium chloride	5mg
4	Agar	10.0g
5	Water	1000ml

List of Figures



Fig. 1 (a): Microscopy of Panchaudara churna



Fig. 1 (b): Microscopy of Panchaudara churna



Control

1:100 Dilutions



1:1000 Dilutions Fig. 2: Petriplates with different dilutions

1:10,000 Dilutions

Fig. 3: TLC of churna