



Research Article

Formulation and Standardization of Pushyang Churna

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ABSTRACT

In recent years a lot of folks throughout world square measure turning to use medicative plant merchandise in care system. Worldwide want of different medication has resulted in growth of natural product markets and interest in ancient systems of drugs. Proper integration of contemporary scientific techniques and content is very important. The identification of purely active moiety is an important requirement for Quality control and dose determination of plant related dug. Standardization of seasoning medication suggests that confirmation of its identity, Quality and purity. The present summary covers the standardization parameters with their standards worth of the some seasoning medication. There is a growing focus on the importance of medicinal plants in the traditional health care system and Ayush; viz. Ayurveda, Unani, Homoeopathy, Yoga and Siddha; in solving health care problems. Systematic approach and well-designed methodologies for the standardization of seasoning raw materials and seasoning formulations square measure developed.

Key words: *Pushyang Churna, Herbal standardization, Formulation.*

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INTRODUCTION

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 airtight containers. Hence there is a need for standardization of herbal formulation as prescribed by WHO. [4]

Ayurveda is a divine and holistic science of life. Ayurveda is a Sanskrit term, made up of words “ayur” and “Veda”. “Ayur” means life and “Veda” means knowledge or science. Ayurveda is the traditional healing modality of the Vedic culture from India. It is said to be 2000 to 5000 years old, meaning it has stood the test of time. Ayurvedic medicine views health as

much more than absence of disease. The wise seers and sages of the time, intuitively understanding the physiology and working of the mind-body-spirit long before the advents of modern medicine, explained the basic principles of Ayurveda. Ayurvedic medicine was originally an oral tradition taught and passed directly from teacher to apprentice, who would learn and work side by side. The oldest written codification of Ayurvedic principles is found in the Rigveda. The fundamentals are then laid out in several major treatises, including the texts from Charaka, Sushruta, and Vagbhat. [9] There are also numerous other smaller works, written over time to The beauty in the way these have been explained is that they rely on basic principles which can be applied practically in any day and age.

explain the various branches of Ayurveda, which include disciplines such as general medicine, pediatrics, surgery, toxicology, fertility, and rejuvenation.

Pharmaceutical ayurvedic research is aimed at meeting the medical needs of the population for whom appropriate therapeutic remedies are not available or at those that are available are but not effective for various disorders. While meeting medical needs of a polyherbal formulation set some parameters to ensure that the formulation shows desired pharmacological action against various diseases. The selection of an appropriate drug should take into account apart from medical needs and innovative potential for success. [8]The standardization of crude drug materials includes authentication, organoleptic evaluation, ash values, extractive values, moisture content determination and Carr's index etc. These parameters are required for authentication of any herbal drug and its formulation.

Basic Principles of Ayurveda [6, 9]

Ayurveda views the world in light of 3 constitutional principles: vata, pitta, and kapha. These are explained in more detail below.

Vaata

The term Vaata comes from the Sanskrit word Vaayu which means "that which move things". Vaata regulates the nervous processes involved with movements, thoughts, emotions, eating, drinking, elimination and our general functioning.

Pitta

The term pitta comes from the Sanskrit word pinj means "to shine". It carries the meaning of "that which digest" and is associated with the idea of being yellow-tinged or bilious. Pitta is often regarded as the "fire" within the body. Think of it as the energy stored in the chemical bonds of all the organic substances which make us up: it's encoded in our hormones, enzymes, organic acids and neurotransmitters. Charaka samhita, teaches that pitta functions in digestion, heat production, providing colour to the blood, vision and skin luster.[6]

Kapha

The term kapha derives from the Sanskrit word "shlish" which means "that which hold things together; to embrace; coherent". It is the force which provides structure to everything from an individual atom or cell to the sturdy musculoskeletal frame. It gives strength, stability, and endurance - both physical and psychological - and promotes human emotions and capacities.

Standardization

Standardization of herbal medicines is the process of prescribing a set of standards or inherent characteristics, constant parameters, definitive qualitative and quantitative values that carry an assurance of quality, efficacy, safety and reproducibility. It is the process of developing and agreeing upon technical standards. Specific standards are worked out by experimentation and observations, which would lead to the process of prescribing a set of characteristics exhibited by the particular herbal medicine. Hence standardization is tools in the quality control process. Several problems not applicable to synthetic drugs often influence the quality of herbal drugs. For instance:

- Herbal drugs are usually mixtures of many constituents.
- The active principles are most cases unknown selective analytical methods or reference compounds may not be available commercially.
- Plant materials are chemically and naturally variable.
- Chemo-varieties and cultivars exist.
- The source and quality of the raw material are variable.

Need of Standardization

This Technical Report compiles and analyzes the current scientific knowledge on herbal medicine and highlights the practical ways for ensuring the safety of herbal preparations and evaluating their claimed efficacy. Emphasis has been given to the methods for standardization of herbal medicine and the ways and

means for moving forward to achieve the difficult goal of preparing herbal medicines of consistent quality and effects. Pragmatic approaches have been recommended to overcome the difficulties in

- (i) protecting intellectual property rights (IPR);
- (ii) Producing safe, potent, standardized, and affordable herbal medicine; and
- (iii) Documenting the knowledge base on herbal medicine in an easily accessible format. It Safe, Healthy, Secure, High quality and 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. [21]

Pushyanug Churna

Pushyanug Churna has been selected for the study because it is one of the popular traditional formulations used widely in females suffering from diseases related to genito-urinary system.

The formulation comprises of twenty-five different herbs, which are believed to possess the astringent property in a synergistic way. Due to the astringent property of the ingredients, it is an excellent haemostatic drug and it acts especially in the genitourinary system of females. Pushyanug Churna is indicated for menstrual disorders as well as congestion in female reproductive system. Conditions involving menstrual irregularities such as menorrhagia, metrorrhagia, dysmenorrhoea and endometriosis are treated with this formulation. It is also useful in piles, diarrhea, bloody stools and different

types of discharges from vaginal tract as mentioned in Charaka Samhita.[12]

MATERIAL AND METHOD

Method of Preparation:-

The polyherbal formulation consisting of 25 ingredients in all, with specific morphological parts of the plants used. For standardization of Pushyanug churna, some modifications were made. Paatha (Cissampelos pareira), Samanga (Mimosa pudica), Musta (Cyperus rotundus), Indian Sarsaparilla, Aegle Marmelos, Sandal-Wood, Indian Berberry (Berberis aristata), Grapes, Arjuna Terminalia, Touch me not, Black pepper, Cyperus rotundus, Glycyrrhiza glabra, Cissampelos pareira, Ginger (Zingiber Officinale), Rubus ellipticus (Black Berry), Ceiba pentandra (White Silk Cotton), Nelumbo nucifera, Agropyron repens, Aconitum heterophyllum, Saffron (Adina cordifolia), Woodfordia fruticosa,

All the procured and authenticated individual drugs were dried in shade and cleaned by hand sorting. The individual drugs were then crushed using willing grinder and passed through mesh no. 40. The individual drugs were then weighed as per the quantity required. The drugs were mixed geometrically using a double cone blender. The mixed formulation was unloaded, weighed, and packed in labeled glass bottles.[17]

Physicochemical Properties

Organoleptic and Physio-chemical studies like water soluble extract, alcohol soluble extract, ether soluble extract, hydroalcoholic soluble extract, total ash, water soluble ash, acid insoluble ash, water, moisture constant at 105°C, bulk density, tap density, Hausner ratio, Carr's index pH of suspension were carried out as per the WHO guide lines.[9]

Ingredients of Pushyang Churna:[26]



Cissampelos pareira root (PLIM)



Mimosa pudica dried herb (Himalaya)



Cyperus rotundus rhizome



Aegle marmelos dried pulp



Santalum album heartwood



Berberis aristata stem bark



Vitis vinifera dried fruit



Terminalia arjuna bark



Piper nigrum fruit



Cyperus rotundus rhizome



Aconitum heterophyllum dried rhizome



Zingiber officinale dried rhizome

Description

1. Greenish colored, smooth powder with a characteristic odor of Paatha (*Cissampelos pareira*), Samanga (*Mimosa pudica*), Musta (*Cyperus rotundus*),
2. The powder completely passes through sieve number 44 and not less than 50 per cent through sieve number 85.

Determination of Ash Value

The ash of any organic material is composed of their non-volatile inorganic components. Controlled incineration of crude drug results in an ash residue consisting of inorganic material (metallic salts and silica). This value varies within fairly wide limits and is, therefore, an important parameter for the purpose of

evaluation of crude drugs. The ash value can be determined by three different methods to measure the total ash, the acid insoluble ash and the water soluble ash.

Determination of Total Ash

Total ash is designed to measure the total amount of material produced after complete incineration of the ground drug at as low as temperature as possible (about 450° C) to remove all the carbons. At higher temperature, the alkali chlorides may be volatile and may be lost by this process. The total ash usually consists of carbonates, phosphates, silicates and silica which include both physiological ash which is derived from the plant tissue itself and non-physiological ash which is the residue of the adhering material to the plant, e.g., sand and soil. Indian Pharmacopoeia, 1996, prescribes suitable methods for the determination of ash

values.[19] Method I for the crude vegetable drugs and Method II for the other substances.

Ash value

A high ash value is indicative of contamination, substitution, adulteration, or carelessness in preparing the drug or drug combinations for marketing. Marketed and prepared in-house formulations were found and mentioned in Table 4. These values were found to be reasonably low indicating low contamination. Total ash value of plant material indicated the amount of minerals and earthy materials present in the plant material.

Method I

Unless otherwise stated in the Individual monographs, weigh accurately 2-3 g of the air dried crude drug in the tarred platinum or silica dish and incinerate at a temperature not exceeding 450° C until free from carbon, cool and weigh. If a carbon free ash cannot be obtained by this way, exhaust the charred mass in hot water, collect the residue on an ash less filter paper, and incinerate the residue and filter paper until the ash is white or nearly white. Calculate the percentage of ash with reference to the air-dried drug. [12]

Method II

Heat the silica or platinum crucible to red hot for 30 minutes; allow cooling in desiccators and weighing. Unless otherwise specified in the individual monograph, weigh accurately about 1 g of the substance being examined and evenly distribute in the crucible. Dry at 100° C to 105° C for 1 hr and ignite to constant weight in a muffle furnace at 600±25°C. Allow the crucible to cool in desiccators after each ignition. The material should not catch fire in any time during the procedure. If after prolonged ignition a carbon free ash cannot be obtained, proceed as directed in method. Ignite to constant weight. Calculate the percentage of ash with reference to the air-dried substance.

Acid Insoluble Ash

Ash insoluble in hydrochloric acid is the residue obtained after extracting the sulfated or total ash with

HCl, calculate with reference to 100 g of drug. For the determination of acid insoluble ash as prescribed in IP 1996, method I is used unless otherwise directed in the Individual monograph.

Method I

Boil ash with 25 ml of 2M HCl for 5 minutes, collect the insoluble matter in a Gooch crucible or on an ash less filter paper, wash with hot water, ignite, cool in desiccators and weigh. Calculate the percentage of acid insoluble ash with reference to the air dried drug.[11]

Method II

Place the ash, as described or as directed in the individual monograph, in a crucible. Add 15 ml of water and 10 ml of hydrochloric acid, boil for 10 minutes and allow to cool. [6] Collect the insoluble matter on an ash less filter paper, wash with hot water until the filtrate is neutral, ignite to dull redness, cool in desiccators and weigh. Calculate the percentage of acid insoluble ash with reference to the air dried drug.

Water Soluble Ash

Water soluble ash is that part of the total ash content which is soluble in water. It is good indicator of either previous extraction of the water soluble salts in the drug or incorrect preparations. Thus, it is the difference in weight between the total ash and the residue obtained after treatment of Total ash with water. As described in the IP 1996 to determine the water soluble ash, boil the ash as described before for 5 minutes with 25 ml of water. Collect the insoluble matter in a Gooch crucible or an ash less filter paper, wash with hot water and ignite for 15 minutes for a temperature not exceeding 450°C. Subtract the weight of the insoluble matter from the weight of the ash; the difference of weight represents the water soluble ash. [16] Calculate the percentage of water soluble ash with reference to the air dried drug. The result is determined as follows.

RESULTS

Table-1: Different ash value of marketed and in home formulation.

Ash value	Marketed	In home
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	formulation	formulation
Total Ash	11.3%	13.4%
Acid insoluble Ash	6.4%	6.8%
Water soluble Ash	21.6%	19.2%
Sulfated Ash	7.4%	6.8%
Nitrated Ash	6.8%	6.2%

Determination of Extractive Values

This method determines the amount of active constituents in a given quantity of medicinal plant material when extracted with solvents. It is employed for that material for which no chemical or biological assay method exist. According to Indian Pharmacopoeia 1996 and British Pharmacopoeia 1980, the determination of water soluble and alcohol soluble extractives is used as a means of evaluating crude drugs which are not readily estimated by other means. [11]Such extractive values provide an indication of the extent of polar, medium polar and non-polar components present in the plant material.

Extractive Value

Water-soluble extractive value plays an important role in evaluation of crude drugs. Less extractive value indicates addition of exhausted material, adulteration or incorrect processing during drying or storage or formulating. [21] .The water-soluble extractive values of marketed formulations and their similar in-house prepared formulations were in 12.4% and 11.6%. [table 5]. The in-house Formulation 1 was the developed formulation of pushyanug churna and its extractable water soluble value (9.2%) was close to its standard drug (11.2%). The alcohol-soluble extractive value was also indicative for the same purpose as the water-soluble extractive value. Less extractive value indicates addition of exhausted material, adulteration or incorrect processing during drying, or storage or formulating. The alcohol-soluble extractive values of the marketed formulations and their similar in-house prepared formulations were 6.8% and 10.5%

Table No.2: Different extractive values of the marketed and in home formulation.

Extractive value	Marketed formulation	In home formulation
Water soluble extractive	12.4%	11.6
Alcohol soluble extractive	6.8%	10.5%
Ether soluble extractive	13%	10.3%
Hexane soluble extractive	7.5%	8.7%

Bulk density, Tapped density, Carr's index, Haunser's Ratio

Study of bulk density and tapped density are important as density of a powder defines its packaging, and are listed in table 6. Tapped density gives information on consolidation of a powder. A consolidated powder is likely to have a greater arch strength than a less consolidated one, and may therefore be more resistant to powder flow. [17] There was little significant difference between the densities of the in-house developed formulations and marketed formulations.

Table-3: Bulk density, Tapped density Carr's index, Haunser's Ratio.

Parameter	Marketed formulation	In home formulation
Bulk Density	0.55	1.22
Tapped Density	0.7	0.9
Carr's Index	23%	30.80%
Haunser's Ratio	1.0	1.4

Angle of Repose

This is the angle θ as defined by the equation $\tan \theta = h/r$ is the maximum angle that can be obtained between the freestanding stage of the surface of the powder heap and the horizontal plane this measurement give at least qualitative assessment of the internal cohesive and fractional effect under the level of external loading as might apply in powder mixing.[14]

Table-4: Angle of repose

Marketed formulation	Homemade formulation
42.59°	38.84°

Moisture Content

Moisture is one of the major factors responsible for the deterioration of the drugs and formulations. Low moisture content is always desirable for higher stability of drugs.

Table- 5: Moisture Content

Chemical	In visible range		In short range		In long range	
	Marketed preparation	Homemade preparation	Marketed preparation	Homemade preparation	Marketed preparation	Homemade preparation
NaOH	Light brown	Brown	Greenish	Greenish	Dark Purple	Dark Purple
Iodine	Brown	Brown	Greenish	Greenish yellow	Purple l	Purple
Sulfuric acid	Dark brown	Light brown	Greenish	Greenish	Purple	Dark
Acetic acid	Brown	Brown	Greenish yellow	Greenish	Purple	Dark
Nitric acid	Brown	Brown	Greenish	Greenish	Purple	Purple
Ferric chloride	Dark brown	Light brown	Greenish	Greenish yellow	Dark Purple	Purple
Bromine water	Brown	Light brown	Greenish	Greenish	Perpal	Dark
KOH	Light brown	Brown	Greenish yellow	Greenish	Dark Perpal	Dark

SUMMARY AND CONCLUSIONS

The result obtained would be used to lay down a set of new pharmacopoeial standards for the preparation of genito-urinary and menstrual irregularities churna to obtained optimal efficacy of the medicine. In the present study it was concluded that the physicochemical parameters such as the water-soluble, alcohol-soluble, and, moisture content, bulk density, tapped density, Carr's index, Hausner's ratio, pH, water-soluble ash, acid-insoluble ash, and organoleptic characteristics can be efficiently used for standardization of polyherbal formulation. The results obtained from the study could be utilized as a reference for setting limits for the reference standards for the quality control and quality assurance of these drugs.

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0.4	0.38
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Fluorescence Analysis Method

The different types of reagent are used for the fluorescence analysis of polyherb formulation such as NaOH, Iodine, Sulfuric acid, Acetic acid, Nitric acid, Ferric chloride, Bromine water, KOH. All the reagent were taken in Petri dish and seen the fluorescence background respectively. The fluorescence colour is seen under the visible range, short range and long range.[11]

Table-6: Fluorescence Analysis

Chemical	In visible range		In short range		In long range	
	Marketed preparation	Homemade preparation	Marketed preparation	Homemade preparation	Marketed preparation	Homemade preparation
NaOH	Light brown	Brown	Greenish	Greenish	Dark Purple	Dark Purple
Iodine	Brown	Brown	Greenish	Greenish yellow	Purple l	Purple
Sulfuric acid	Dark brown	Light brown	Greenish	Greenish	Purple	Dark
Acetic acid	Brown	Brown	Greenish yellow	Greenish	Purple	Dark
Nitric acid	Brown	Brown	Greenish	Greenish	Purple	Purple
Ferric chloride	Dark brown	Light brown	Greenish	Greenish yellow	Dark Purple	Purple
Bromine water	Brown	Light brown	Greenish	Greenish	Perpal	Dark
KOH	Light brown	Brown	Greenish yellow	Greenish	Dark Perpal	Dark

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