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Formulation, Standardization and Physiochemical evaluation of Novel Siddha Preparation *Naga Chendurum* as per AYUSH guideline

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Abstract

Siddha formulations offer atremendous advantage in clinical practice against metabolic and lifestyle disorders including neurodegenerative diseases. Often investigation on Siddha preparations attempted on reverse pharmacology basis. Hence nearly 80% of the formulation already have proven track record clinically and now several investigationsare being made on its preclinical aspect. Considering the global need the modern standardization method adopted for identity, purity and shelf life of the preparation. Different techniques have been followed to analyze the purity of the raw materials it includes a microscopic, macroscopic, Physical, chemical and biological method of analysis. Physicochemical evaluation of the preparation plays a vital role in establishing the monograph of the formulation, as it becomes the documentary evidence to substantiate the standards of the preparation. It renders the useful information like genuinity, stability, selective characteristic feature and nature of the compound's presence in the drug. WHO and other regulatory authorities in collaboration with government agency setup a benchmark for proper standardization of the raw drug as well the finished formulations. According to these guidelines parameters such as loss on drying, Total ash, Extractive value and pH provides some important details on identifying the stability and genuinity of the drugs as well. The main aim of the present investigation is to standardize the novel formulation *Naga Chendurum* (NC) as per AYUSH guideline and to reveal the property of the formulation to the scientific community for better understanding about the standards of the formulation. The results obtained from the physicochemical evaluation revealsthattotal ash value of NCwas found to 92.38%. In which the water-soluble ash was 33.51% and acid insoluble ash was 46 %. Similarly, loss on drying value at 105^{o}C was found to be 0% respectively. pH is an important indicator for the solvent solubility and ability to cross the biological barrier. pH of the formulation NC was found to be 6.77.From the results of the study, it was evident that the Siddha formulation NC complies with the standard and may be used for clinical management of Vathadiseases, Kasam, Vallikunmam, Erikunmam etc. But further studies need to be carried out to ascertain the exact role of phytotherapeutics present in the formulation might responsible for the expected pharmacological action in humans and animals as well.

Keywords: Siddha, Naga Chendurum, Physicochemical evaluation,standardization, Loss on drying, Total ash.

1. Introduction

The World Health Organization (WHO) has estimated that around 65%–80% of the world population, especially in developing countries, depends essentially on plants for their primary healthcare [1]. Traditional herbal medicine (THM) use has been steadily rising with almost 70%–95% of citizens in major developing countries using THM for their primary health care needs [2]. Use of THM is quite convincing since it is affordable for all people regardless of their income [3]. The WHO has defined herbal medicine as "herbs, herbal materials, herbal preparations and finished herbal products that contain active ingredients obtained from parts of plants, or plant materials, or combinations thereof" used to treat ailments [4,5,6] throughout the world [7].

Herbal medicine has become a popular form of healthcare; even though several differences exist between herbal and conventional pharmacological treatments, herbal medicine needs to be tested for efficacy using the conventional trial methodology and several specific herbal extracts have been demonstrated to be efficacious for specific conditions [8]

Approximately 25,000 effective plant-based formulations are available in Indian system of medicine which is commonly used by rural and ethnic people in India and the popularity of such medicine is also increasing among the common people. It was also estimated that >2000 tons of medicinal plant raw material are required annually. More than 1500 herbals are also sold as dietary supplements or ethnic traditional medicines. It was also estimated that nearly 960 species of medicinal plants are in the trade, among them 178 species have annual consumption levels more than 100 metric tons. Domestic trade of AYUSH industry is approximately INR. 80–90 billion, and export value of medicinal plants and related products from India is approximately l10 billion. The percentage share of AYUSH products in the total trade of India in 2013–2014 was 0.36%. The global market for herbal drugs is increasing in a steady manner and the global herbal trade will reach USD 7 trillion by 2050 [9].

Herbal-derived remedies need a powerful and deep assessment of their pharmacological qualities and safety issues due to the large and growing use of natural-derived substances all over the world, which cannot rely only on the tradition or supposed millenarian beliefs; explanatory and pragmatic studies are useful and complementary in the acquisition of reliable data both for health caregiverand patients . Herbal medicine is the use of medicinal plants for prevention and treatment of diseases: it ranges from traditional and popular medicines of every country to the use of standardized and titrated herbal extracts. Generally, cultural rootedness enduring and widespread use in a Traditional Medical System was having high level of safety and efficacy when compared to the conventional allopathic system, especially in herbal medicine where formulations and preparations are almost completely based on remedies containing active principles at very lower concentrations, or relying on magical-energetic principles.

Siddha pharmacopoeia established in recent times have imposed more on standardization aspect of the formulation. Starting from preparatory phase to storage each and individual step involved in formulating Siddha preparation has its own quality check evaluations. Bioactive phytocomponents nanoparticles present in preparations like Chenduram have the unique advantage of multiple modes of action. The synergy of using combined phytomedicinesand metals are well established in traditional medicine like Siddha. Siddha is the ancient healing system of medicine and it has fundamental aspects for drug formulation. Major formulations used in Siddha are based on herbs and minerals. The medicinal herbs are used as decoctions, infusions, tinctures, and powders [10].There is a global resurgence in the use of these medicines along with a growing scientific interest in them as a source of new drugs [11].There has been a boom in the usage of ASU drugs and export is appreciably high in the last two decades [12].There has been an increase in science-based research in ASU drugs for the purpose of globalization. One of the most critical issues involved in any research study is the quality of the test material.

2. Materials and Methods

2.1. Source of raw drugs

The required raw drugs for the trial medicineswill be purchased from a well-reputed country raw drug shop and drugs will be authenticated. Then the raw drugs will be purified separately then the trial drugs will be prepared in Gunapadam Laboratory ofArignar Anna government hospital,Government Siddha Medical College, Chennai, Tamil Nadu, India.

2.2. Ingredients

The Siddha formulation *Naga Chendurum* comprises of the following ingredients

Nagam (Zinc)	**- 35g**
Manosilai (Red Orpiment) Soodham (Mercury) Veeram (Hydrargyrum per chloride)	**- Each 35 g**
Gandhagam (Sulphur)	**- 70 g**
Ilupainei (Oil of *Madhuga longifolia)* Venkolinchiver **(***Baptisia bracfeata*) Potralaikayanthagarai **(***Eclipta prostrata*)	**- Q.S**

2.3.Purification

Nagam (zinc):Nagam (zinc) is melted and poured in the oil of *Madhuga longifolia* (illupainei). Repeatthis for 10 times. Now zinc is get purified

Rasam (Mercury): 35 grms of Mercury is triturated with brick powder and turmeric powder for one hour respectively and washed with water. Then the Mercury is boiled with the juice of Kuppaimaeni (1.3 litters) until it is detoxified[1].

Gandhagam (Sulphur): Sulphur is placed in an iron spoon. A small quantity of cow's butter is added and the spoon is heated till the butter melts; this mixture is immersed in aninclined position in cow's milk. This procedure is repeated for 30 times to get purified Sulphur. Each time, fresh milk is to be used.

Manosilai (Red Orpiment): Manosilai buried in limestone and poured by donkey urine to get purified.

Veeram (Mercury per Chloride): Camphor is mixed with tender coconut water and placed in a mud pot. Veeram is tied in a cloth and soaked in the pot without touching the water and the pot is burnt out for half an hour Then Veeram is taken out and washed

2.4. Formulation of *Naga Chendhuram* [13]

Nagam (zinc) is melted and poured in the oil of *Madhuga longifolia* (illupainei). Repeat this for 10 times. Now zinc is get purified, This purified Nagam (zinc) is placed inside the gugai and it is melted with the ulai. Here manosilai (Red orpiment) powder is added and stirred with the help of venkozhinji root (*Baptisia bracfeata*),then the whole content is turned into parpam. This prepared parpam, soodham (mercury), veeram (hydragramper chloride) are placed in a stone mortar and ground with milk for 4 samam(12 hours).Then sulphur is added and grinded well with potralaikarippan (*Eclipta prostrata*) and bring into incineration process with 10 cow dung cakes. Repeat this incineration process for 6 more times. Finally, it will turn into chendurum.

Dose: 130 mg. Twice a day for 48 days

Adjuvant: Honey

Indication: Vathadiseases, kasam, Vallikunmam, Erikunmam, kalleeralkatti, pun, soolai, krani, megham, Edappattuerralnoi, Manjanoi,Kaichal, Kulir, Mandharakasam.

2.5. Physicochemical Evaluation [14,15]

2.5.1. Percentage Loss on Drying

10gm of NC was accurately weighed in an evaporating dish and was air dried at 105^{o}C for 5 hours and then weighed.

2.5.2. Determination of Total Ash

3 g of test drug NC was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ^{o}C until it turns white in color which indicates the absence of carbon. Percentage of total ash will be calculated with reference to the weight of the air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

2.5.3. Determination of Acid Insoluble Ash

The ash obtained by total ash test will be boiled with 25 ml of dilute hydrochloric acid for 6mins. Then the insoluble matter is collected in a crucible and will be washed with hot water and ignited to constant weight. Percentage of acid insoluble ash will be calculated with reference to the weight of air-dried ash.

Acid-insoluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

2.5.4. Determination of Water Soluble Ash

The ash obtained by total ash test will be boiled with 25 ml of water for 5 mins. The insoluble matter is collected in a crucible and will be washed with hot water, and ignite for 15mins at a temperature not

exceeding 450ºC. The weight of the insoluble matter will be subtracted from the weight of the ash; the difference in weight represents the water-soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.

Water Soluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

2.5.5. Determination of pH

About 5 g of test sample NC will be dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and then subjected to pH evaluation.

3. Results

3.1. Physico-chemical Evaluation and standardization of *Naga Chendurum*

The results obtained from the physicochemical evaluation reveals that the total ash value of NC was found to 92.38%. In which the water-soluble ash was 33.51% and acid insoluble ash was 46 %. Similarly, loss on drying value at 105^{o}C was found to be 0% respectively. pH is an important indicator for the solvent solubility and ability to cross the biological barrier. pH of the formulation NC was found to be 6.77. All the results were tabulated in Table 01

Table 1: Physicochemical Evaluation of *Naga Chendurum*

S.No	Parameter	*Naga Chendurum*
1.	Loss on drying at 105^{0}C	Nil
2.	Total ash	92.38%
3.	Water soluble ash	33.51%
4.	Acid soluble ash	46%
5.	pH	6.77

4. Discussion

In the21st century, tremendous advances in healthcare sector coexist with inequities in accessibility, availability, and affordability of the healthcare facilities in many parts of the world. Since last few decades, there is a growing interest in traditional medicine in all over the globe. Variety, flexibility, easy availability, social acceptance, relative low side effect, and cost became the key factor for the growth of traditional medicine. Of course, these also provide us the opportunity to integrate such medicine in primary healthcare to facilitate the people health [16].

The knowledge of certain herbs, animals, and minerals that have curative and palliative effects were transmitted from one generation to another and it is the outcome of bold experimentation through trial and error method over hundreds of years. Ethnomedicine is the mother of all other systems of medicine such as Siddha, Ayurveda, Unani, Nature cure and even modern medicine. The traditional herbalists are part and parcel of the community and are often familiar with the details of each family and its environs so that they are in a better position to deal with their day-to-day problems. In fact, the native healers take care of the common ailments of the folk in their home setting [17].

Knowledge regarding the therapeutic, toxicological effect of plants, minerals, and other substances go back to the prehistoric times when people have migrated to into the Indian subcontinent. Several pieces of evidence indicated that in an Indians ubcontinents medical intervention like dentistry and trepanation were exercised as early as 7000 BCE. Current archaeo-botanical excavations pointed towards the evidence regarding the use of medicinal plants in the Middle Gangetic region since the 2nd millennium BCE which are still found in folk medicine [18].

WHO developed and launched ‘WHO Traditional Medicine Strategy 2014–2023’ and emphasised to integrate traditional and complementary medicine to promote universal healthcare and to ensure the

quality, safety and effectiveness of such medicine. Patients believed in Siddha preparation as it alleviates the symptoms by altering the impaired physiology which most of the allopathic medicines fails to do. Further, the Siddha medicines act mostly by rejuvenation and prevention thereby the disease once cured will have less chance of reoccurrence. By believing this philosophy Siddha practitioners judge the pathology of disease by assessing the fundamental elements of the human body.

The commonly elemental analysis included evaluation of vadham, kabam and pitham proportions. The results obtained from the physicochemical evaluation revels that the total ash value of NC was found to 92.38%. In which the water-soluble ash was 33.51% and acid insoluble ash was 46 %. Similarly, loss on drying value at 105^{o}C was found to be 0% respectively. pH is an important indicator for the solvent solubility and ability to cross the biological barrier. pH of the formulation NC was found to be 6.77.

Siddha also has standardized protocols for purification and detoxification of certain phytocomponents used in specific formulations. As this will greatly reduce the toxicity and also enhance the therapeutic efficacy of the formulation. The chances of occurrence of an adverse event are very minimal in Siddha when compare to any other therapies in the world this is mainly because the 90 % of ingredients used in the preparing formulations are compatible with the biological system of the humans and animals. Hence event of adverse events is less. Anti-dotes and counter therapy modifications are even available in Siddha system in case of rare occurrence of some unexpected interactions.

5. Conclusion

The physicochemical characteristic feature of the drug has its own index on revealing the identity of the each and individual Siddha formulation. In the present study the formulation *Naga Chendurum* has some unique feature on 0% in loss on drying other values such as total ash and soluble ash proven the purity of the drug and which compiles with the standard as per AYUSH recommendation and hence this documentary proof will be made available for future researcher who proposed to work in this formulation.

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