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Standardization and Physiochemical Evaluation of Novel Siddha Polyherbal Formulation *Peichori chooranam* as per AYUSH Guideline

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ABSTRACT: The Siddha system of medicine is one of the oldest traditional medical practices in India, and its formulations are still used today to treat metabolic disorders like diabetes mellitus. Although the global market for Siddha medicine is expanding, ensuring the quality of these formulations remains crucial. To meet this demand, modern standardized procedures are employed to verify the authenticity, purity, and shelf life of products, from raw materials to the final product. Various methods, including microscopic, macroscopic, and chemical analyses, are used for this purpose. This study focuses on standardizing the novel polyherbal formulation, *Peichori Chooranam* (PC), in line with AYUSH guidelines and sharing its properties with the scientific community. Physicochemical evaluations revealed that the total ash content of PC was 6.13 ± 0.83%, with an acid-insoluble ash value of 0.07±0.02%. Moisture content, determined by loss on drying at 105°C, was also 6.13±0.83%. The water-soluble extractive value was 21.77±2.43%, and the alcohol-soluble extractive value was 10.56 ± 0.61%. Phytochemical screening confirmed the presence of diverse bioactive compounds in the formulation. The findings demonstrate that *Peichori Chooranam* meets regulatory standards and is safe for therapeutic use in humans.

Keywords: Siddha, Polyherbal, Standardization, Physicochemical, Phytochemical, *Peichori chooranam.*

INTRODUCTION

Since ancient times, people from various regions have favored the use of plants and herbal medicines for their therapeutic properties. This tradition continues in the modern world, with approximately 80% of the global population still depending on herbal therapies to manage chronic health conditions (Orisatoki and Oguntibeju 2010). India, with one of the oldest and most established traditional medicine systems, has been practicing and refining its medicinal knowledge for centuries (Gupta *et al*., 2014). The growing interest in and awareness of traditional medicine, driven by globalization, has led to a steady rise in its use worldwide. As the demand for herbal medicine continues to expand, ensuring product quality and consistency across different batches has become increasingly important (Shastry, 1997).

A key component in maintaining the quality of herbal formulations is conducting physicochemical evaluations. These assessments are crucial in compiling the monograph of a formulation, as they provide valuable insights into the medicine's authenticity, stability, specific traits, and chemical makeup (Sivaraman *et al.,* 2019). Regulatory bodies such as the World Health Organization (WHO), in collaboration with other global and governmental organizations, have developed standardized guidelines to ensure the consistent quality of raw materials and finished products. These guidelines focus on crucial parameters such as loss on drying, ash value, and extractive indices, which are fundamental in verifying the authenticity and quality of herbal medicines (Saraf, 2010). The global market for health-related products, particularly herbal formulations, is rapidly expanding. These products are manufactured in different parts of the world and distributed globally. Standardization is essential to guarantee that these products maintain consistent quality and meet the same specifications across regions (Mensah *et al*., 2009; Bose and Sen 1971).

One such formulation, Peichori Chooranam (PC), consists of a unique blend of bioactive herbs, including *Azima tetracantha*, *Capparis sepiaria*, *Indigofera aspalathoids*, *Enicostemma axillare*, *Clerodendron inermis*, *Coldenia procumbens*, *Acalypha fruticosa*, *Cassia senna*, *Jatropha curcas*, *Smilax chinensis*, *Trachyspermum ammi*, and *Nigella sativa*. This combination offers various health benefits, particularly in treating conditions such as pruritus (itching) and eczema. Despite its potential therapeutic uses, there is no documented evidence regarding the standardization of Peichori Chooranam. Therefore, this study was undertaken to establish a contemporary approach to the standardization of this novel Siddha formulation, as per AYUSH guidelines, to ensure consistent quality and control over the manufacturing process.

MATERIALS AND METHODS

A. Source of raw drugs

The herbs were sourced from the southern region of Tamil Nadu, while additional necessary ingredients were obtained from a reputable indigenous drug store in Chennai, Tamil Nadu, India. The herbs were verified for authenticity by pharmacognosy specialists and other relevant experts in the field.

B. Ingredients

The siddha formulation *Peichori chooranam* (PPC) comprises of the herbs as the core ingredients listed below

1. Azima tetracantha-Each 30 varaagan
2. Capparis sepiaria -Each 30 varaagan
3. Indigofera aspalathoids-Each 30 varaagan
4. Enicostemma axillari-Each 30 varaagan
5. Clerodendron inermis-Each 30 varaagan
6. Coldenia procumbens-Each 30 varaagan
7. Acalypha fruticose-Each 30 varaagan
8. Cassia senna-Each 30 varaagan
9. Jatropa carcas-Each 30 varaagan
10. Smilax shinensis -Each 30 varaagan
11. Trachyspermum ammi -Each 1 palam
12. Nigella sativa-Each 1 palam

C. Preparation

The listed ingredients were first subjected to shade drying, then ground into a fine powder and passed through a standard sieving process to ensure consistency.

Dosage: Thirikadi
Route of administration: Oral
Adjuvant: Warm water
Indications: Peichori (Urticaria), various types of eczema, and kirandhi (skin disorders).

D. Physicochemical Evaluation

(i) Quantification Percentage Loss on Drying. The test material was precisely weighed in the evaporating dish at 10 grammes. The material was weighed after five hours of drying at 105 degrees Celsius.

When a sample is dried, the percentage of weight loss equals the sample's weight divided by 100.

(ii) Quantification of Total Ash. A silicon dish holding three grams of the test drug was precisely weighed and then cremated in a furnace at 400°C until the sample turned white, confirming the absence of carbon.

(iii) Quantification of Acid Insoluble Ash. The ash obtained from the total ash test will be heated with 25 milliliters of diluted hydrochloric acid for six minutes. The insoluble residue will be gathered in a crucible, washed thoroughly with hot water, and subjected to incineration until a stable weight is reached. The percentage of acid-insoluble ash will be determined in relation to the weight of the air-dried ash.

(iv) Quantification of Water Soluble Ash. In order to quantify the residues on the water soluble ash level the sample retrieved from the earlier total ash analysis will be subjected to heating with water (25ml) for five minutes period of time. The resulting insoluble residues was subjected to ignition of not less than 450ºC for fifteen minutes.

(v) Quantification of Alcohol Soluble Extractive. Five grams of the test sample will admixed with 100 ml of alcohol for 24 hours, with occasional shaking during the tenure . The solution will be filtered, and 25 ml of the filtrate will be evaporated to dryness in a pre-weighed dish, then dried at 105ºC until a constant weight is reached.

(vi) Quantification of Water Soluble Extractive. Five grams of the test sample constituted in 100 ml of chloroform water for 24 hours, with occasional shaking. The mixture will be filtered, and 25 ml of the filtrate will be evaporated to dryness in a pre-weighed dish, then dried at 105ºC until a constant weight is reached.

(vii) pH determination. Required quantity of test sample was admixed with distilled water and the subjected to screening using pH meter.

RESULTS

A. Physico-chemical Evaluation and standardization of PC

The results from the physicochemical evaluation of the formulation PC demonstrated that the total ash content was 6.13 ± 0.83%, with the acid-insoluble ash measured at 0.07 ± 0.02%. Additionally, the loss on drying at 105°C was 6.13 ± 0.83%. Extractive values, both water-soluble and alcohol-soluble, are key indicators in assessing the quality of crude and finished drugs. Low extractive values may suggest the presence of degraded material, adulteration, or improper drying, storage, or formulation techniques. In the case of PC, the water-soluble extractive value was found to be 21.77 ± 2.43%, while the alcohol-soluble extractive value was 10.56 ± 0.61%. These findings indicate that the formulation adheres to the standards of purity and authenticity as per the guidelines of Indian medicine. All results are presented in Table 1 and Fig. 1.

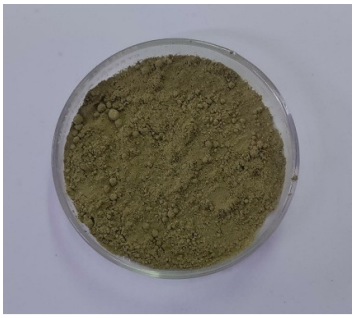

Fig. 1. Illustration of siddha formulation *Peichori chooranam.*

Table 1: Physicochemical Evaluation of *Peichori chooranam.*

Sr. No	Parameter	Mean (n=3) SD
1.	Loss on Drying at 105 °C (%)	6.13 ± 0.83
2.	Total Ash (%)	3.86 ± 1.50
3.	Acid insoluble Ash (%)	0.07 ± 0.02
4.	Water Soluble Extractive (%)	21.77 ± 2.43
5.	Alcohol Soluble Extractive (%)	10.56 ± 0.61
6.	pH	5.2

Each value represents the mean ± SD. N=3

B. Phytochemical investigation of PC

Phytochemicals, which are essential plant metabolites, exhibit significant pharmacological activities through various mechanisms of action. The results of the phytochemical analysis confirmed the presence of diverse bioactive functional phytocompounds. The detailed findings are presented in Table 2 and Fig. 2.

Table 2: Phytochemical investigation of *Peichori chooranam.*

Sr. No.	TEST	OBSERVATION
1.	Alkaloids	Positive as it signifies the colour change upon reaction with mayer's reagent
2.	Flavonoids	Positive as it signifies the colour change upon reaction with alkaline reagent
3.	Glycosides	Positive as it signifies the colour in Borntrager's test
4.	Steroids	Positive as it signifies the existence of fluorescence
5.	Triterpenoids	Positive as it confirms the presence of red ring
6.	Coumarin	Positive as it signifies the colour change upon reaction with sodium hydroxide
7.	Phenol	Positive as it signifies the emergence of precipitation upon reaction with lead acetate
8.	Tanin	Positive as it signifies the colour change upon reaction with ferrous chloride
9.	Protein	Negative as the sample fails to respond to the biuret test
10.	Saponins	Positive as the sample conform the foam formation
11.	Sugar	Positive as it signifies the colour change upon reaction with Benedic solution
12.	Anthocyanin	Negative as the sample fails to indicate the colour change
13.	Betacyanin	Negative as the sample fails to indicate the colour change

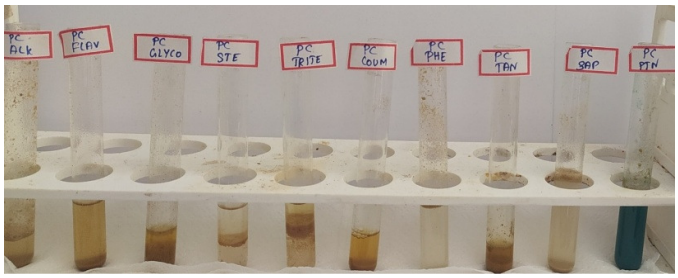

Fig. 2. Phytochemical analysis of the formulation PC.

DISCUSSION

The bioactive phytocomponents used in Siddha medicines have the distinct benefit of acting through more than one mechanism. It is well-established in biological systems how adjuvants, like ghee, can enhance the synergistic effects of phytotherapeutic drugs. Future researchers will have a solid foundation from which to choose suitable formulations for their investigations if monographs are developed for these indigenous and unique preparations. The formulation contained several types of bioactive components, as shown by phytochemical examination. These included sugars, phenols, tannins, steroids, coumarins, triterpenoids, flavonoids, alkaloids, and phenols. A substantial chunk of India's herbal market's over $1 billion worth comes from the export of polyherbal medications, which contribute over $80 million. The presence of contaminants, adulterants, pesticide residues, and poisons is magnified by the multi-component complexity of these polyherbal compositions. This highlights the significance of checking each batch for safety, sterility, and uniformity before it is sold to customers.

According to the World Health Organisation (WHO), herbal medicines are defined as complete medical formulations that are branded and contain active components that are sourced from whole plants or portions of plants. A set of specialised recommendations has been developed by the World Health Organisation (WHO) for assessing the quality, efficacy, and safety of herbal medicines (WHO, 1998, 2002). Seventy-five to ninety-five percent of the population in underdeveloped countries relies on herbal remedies for primary healthcare. This is typically the case because of budgetary constraints or difficulty gaining access to conventional drugs.

The European Union and North America control more than sixty percent of the global market, Japan owns sixteen percent, and ASEAN nations account for the remaining nineteen percent. India accounts for less than two and a half percent of the global market, despite the fact that more than eighty percent of the population relies on herbal medicines. By using proper agricultural techniques (Bauer, 1998), wild collecting tactics (Straus, 2002), and best manufacturing practices for extraction procedures and related factors, natural plant product authenticity may be confirmed at the source through standardisation. Precise identification, authentication, and concentration of active principles are crucial for a natural product to be deemed a viable therapeutic option (Zafar *et al.*, 2005; Yadav and Dixit 2008). This includes defined quantities of active components in polyherbal formulations (Sharma *et al.*, 2009 Ahmad *et al.*, 2006). Quality control procedures to identify adulterants, pesticide residues, aflatoxins, microbiological growth, and heavy metal contamination are necessary for regulatory approval of potential future therapeutics (Patra *et al.*, 2010).

Peichori Chooranam (PC) had a total ash content of 6.13 ± 0.83% and an acid-insoluble ash value of 0.07 ± 0.02%, according to the physicochemical examination. The loss upon drying at 105ºC was also determined to

be 6.13 ± 0.83%. When evaluating the quality of both raw and finished pharmaceuticals, the extractive values that are water-soluble and alcohol-soluble are quite important. Incorrect formulation techniques, adulteration, inadequate drying or storage, or exhausted material can be the cause of lower extractive values. The extractive value that was soluble in water was 21.77 ± 2.43% for PC, whereas the extractive value that was soluble in alcohol was 10.56 ± 0.61%.

CONCLUSION

Although the worldwide demand for siddha formulations is impressive, there is an immediate need to guarantee the quality of the preparation. The PC formulation is guaranteed to be authentic and pure according to the requirements set for Indian medicine by the results of the physicochemical examination. Phytochemicals including alkaloids, flavonoids, steroids, triterpenoids, coumarin, phenol, tannin, saponins, and sugar have been identified in PC by preliminary qualitative analysis. The results of this study indicate that the siddha formulation *Peichori chooranam* is safe for human health and meets all regulations.

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