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FORMULATION AND STANDARDIZATION OF NOVEL SIDDHA PREPARATION *POONAGA PARPAM* AS PER AYUSH GUIDELINES

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ABSTRACT

Standardization of Siddha formulation is essential to access the quality of drugs for therapeutic value. The World Health Organization (WHO) guidelines on evaluating the physico-chemical properties and other parameters for the identification and assessing quality of AYUSH formulations will offer a great value in global market. Standardization ensures the quality of medicines and gives authenticity to the medicines prepared by the manufacturers, satisfaction of the prescribing physicians and relief to the consumers. Characterization of Siddha formulation renders wide range of information in predicting the nature and structure of phyto constituents which renders the actual therapeutic efficacy of the formulation. The present study was attempted to evaluate the physicochemical parameters and Standardization of *Poonaga Parpam* as per siddha classical literature. This classic Siddha formulation is used for the treatment of *Kodiya Kaasam* (Asthma), *Mega Suram* (Syphilitic Fever), *Thagam* (Thirst).

KEYWORDS: *Poonaga Parpam*, Physicochemical analysis, Standardization.

1. INTRODUCTION

All over the world Siddha system of medicine has become significantly more popular because of the healing property, less toxic and minimal side effects. Siddha medicine is a unique one as it is not only a curative but also preventive and to achieve the healthy body and mind. Siddha medicines revitalize and rejuvenate the body. It is well known that all the eyes of the world are turning to the natural medicine, especially indigenous system of medicine to find out a more acceptable drug for incurable diseases. With the help of recent discoveries

and development in medical and communication sector we can decipher the golden secrets within the system. Development of modern research techniques for the quality assessment of Siddha formulations helped us to bring out many coveted medical secrets of Siddha system to the world and also to justify their acceptability in modern system of medicine.

Siddha system of Indian medicine uses many plant, animal and mineral products for the preparation of various drugs. *Choornam, kudineer, lehiyam* like preparations are made mainly from plant sources. *Chendhooram, Parpam, chunnam, kattu, kalangu* preparations are made from in-organic sources and raw materials from animal kingdom. Siddha pharmaceutics has very minute chemical processes in it. It has several chemical processes like purification of raw substances, grinding them with herbal juices for several days and subjecting the ground material to fire by way of *pudam* process. Medicines prepared according to the above methods undergo several chemical changes.[1]

Traditional system of medicine especially *Siddha* system has a remarkable role in the treatment of Bronchial asthma. *Poonaga parpam* is one such animal origin siddha formulation which is quoted in the text "*Sikicha Rathina Deepam*".[2]

For the standardization of this drug as per Siddha classical literature, floating on water, fine enough to enter the crevices of finger, irreversible reaction, tasteless, lusterless are evaluated. Organoleptic characters, physicochemical analysis like loss on drying, determination of ash values and extractive values, pH, solubility were carried out to establish quality control parameters for the drug.

2. MATERIALS AND METHODS

2.1. Standard Operative Procedure for preparation of "*Poonaga parpam*"[2]

The ingredients of this formulation are Veesai (1400gm) of purified *Poonagam* (Earthworm), 1 litre juice of *Aduthinna paalai* (*Aristolochia bracteata*) and 3 litres of butter milk.

2.2. Collection of Raw Drugs

The *poonagam* (Earthworm) and *Aduthinna paalai (Aristolochia bracteata*) was collected from in and around Thanjavur district, Tamilnadu. All the ingredients were purified and the medicine was prepared in the *Gunapadam* laboratory of National Institute of Siddha.

2.3. Identification and Authentication of the drug

The *poonagam* (Earthworm) was identified and authenticated by competent authority of *Gunapadam* Department, National Institute of Siddha, Tambaram sanatorium, Chennai.

Aduthinna paalai (*Aristolochia bracteata*) was identified and authenticated by Botanist, Department of Gunapadam, National Institute of Siddha, Tambaram sanatorium, Chennai.

2.4. Purification (*Suddhi*)[2,3,4]

The earth is considered to be a source of valuable drugs. Earthworms not only enriched with pharmaceutically useful compounds but also contain certain toxic materials. One of the most important tasks is removal of these toxic substances, which is called purification (*Suddhi*) of raw materials by Siddhars.

Poonagam[8]

Poonagam was soaked in buttermilk. When it repels the sand it was taken out and dried, then it was ground.

Aduthinnapaalai

Aduthinnapaalai was washed in the running tap water to remove the soil and impurities.

2.5. Preparation of *Poonaga parpam*[2]

Procedure

Purified *Poonagam* was ground well using mortar and pestle and juice of *Aduthinna Paalai* (*Aristolochia bracteolata*) was added little by little to it for one day and made into pellet and dried. The pellet was then placed in between two earthen saucers and it was covered by mud sealed cloth. Then it was subjected into *pudam* by using 100 cow dung cakes. The above mentioned procedure was repeated for 9 times and finally the *parpam* was powdered well and stored in an air tight container.

Drug Profile

Dose	:	½ - 1Kundri (65-130 mg) Twice daily after food
Adjuvant	:	Honey
Route	:	Enteral (Oral)
Indications	:	Kodiya Kaasam (Asthma) Mega Suram (Syphilitic Fever)

INGREDIENTS OF POONAGA PARPAM

Fig.No.1: *Poonagam* (Earthworms). Fig.No.2: *Aaduthinna paalai (Aristolochia bracteata)*

Fig.No.3: Mud Sealed Earthen Saucer.

Fig.No.4.1.

Fig No.4.2.

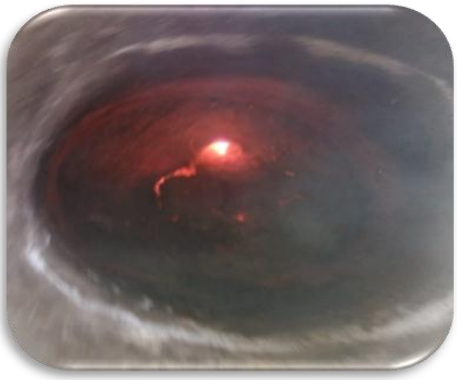

Fig.No.4.3.

Fig.No.4.4.

Fig.No.4 *Pudam* process.

Fig.No.5: *Poonaga parpam*.

3. STANDARDIZATION OF THE DRUG

3.1 Standardization of the drug *Poonaga parpam* as per Siddha classical literature

Testing parameters for *Parpam* -AYUSH guidelines[5]

S.NO	TESTS
1	Description, Colour, Odour
2	Identification - chemical
3	Particle size mesh size - 200 – 300
4	Loss on drying at 105 °C
5	Total – ash
6	Acid – insoluble ash
7	Water soluble ash
8	Assay of element (s)
9	Siddha specifications
10	Lusterless
11	Fine enough to enter the crevices of finger
12	Floats on water
13	Smokeless
14	Tasteless
15	Irreversible

➢ **Analysis as per classical Siddha literature**

- Floating on Water
- Fine enough to enter the crevices of finger
- Irreversible reaction
- Tasteless
- Lusterless

1. Floating on Water

A pinch of *Parpam* gently placed on the still surface of water in a vessel, did not sink immediately. It was found that the *Poonaga Parpam* particles floated over the surface of water indicated lightness of the trial.

2. Fine enough to enter the crevices of finger

Parpam in well prepared form should be fine. When taken between thumb and index finger, the fine powder will fill up the lines of the finger print. A pinch of *Poonaga Parpam* was taken in between the thumb and index finger and rubbed. It was found that the *Poonaga Parpam* entered into the lines of the finger, and was not easily washed out from the lines, confirmed its fineness.

3. Irreversible reaction

The well prepared *Parpam* does not reversible to its metallic state when heated with a mixture of cane jaggery, hemp powder, ghee and honey. A pinch of *Poonaga Parpam* was taken and mixed with cane jaggery, ghee and honey. It was observed that the *Poonaga Parpam* did not reversible to its metallic state.

4. Tasteless

The well prepared *Parpam* should be completely tasteless. Presence of any taste like sweet or bitter indicate incomplete preparation which needed another Calcination process. When a small amount of *Poonaga Parpam* was kept on the tip of the tongue, no specific taste was found.

5. Lusterless

If any shining particles present in *Parpam*, it indicates that the *Parpam* is not manufactured properly and contains unchanged substances like minerals, metals and other toxic substances. There should be no shining particles present in the well manufactured *Parpam*. The *Poonaga*

Parpam was taken in a Petri bowl and observed for any luster in daylight through magnifying glass. No luster was observed in the *Poonaga Parpam*

The results were tabulated in **Table.No.1**

Finger print test

Floating on water test

Fig.No.6: Standardization of *Poonaga parpam* as per Siddha literature.

3.2. Standardization of the drug *Poonaga parpam* by using Modern techniques

Standardization of drugs helps to prove its identity and determination of its quality and potency. Standardization of the siddha formulation is based on the qualitative and quantitative analysis through physico-chemical investigations and instrumental analysis.

As per AYUSH protocol for standardization, the following parameters were evaluated.

❖ **Organoleptic characters**

- Colour
- Odour
- Taste
- State of matter
- Consistency
- Shape
- Size

❖ **Physicochemical analysis**

- Determination of Ash Values
- Determination of Extractive Value
- Physical characterization

3.2.1 Organoleptic character

Colour

The *Poonaga Parpam* was taken into watch glasses and placed against white back ground in white tube light. It was observed for its colour by naked eye.

Odour

The *Poonaga Parpam* was smelled individually. The time interval among two smelling was kept 2 minutes to nullify the effect of previous smelling.

Taste

Small amount of *Poonaga Parpam* was kept over the tip of the tongue.

The results were tabulated in **Table.No.2.**

3.2.2 Physico chemical analysis[6]

Physicochemical Properties of *Poonaga Parpam* was analyzed at The Tamil Nadu Dr. MGR Medical University, Anna Salai, Guindy, Chennai-600032.

Physico-chemical studies of the test drug is necessary for standardization, as it helps in under-standing the significance of physical and chemical properties of the substance being analyzed in terms of their observed activities and especially for the determination of their purity and quality. The analysis includes the determination of ash value, Loss on drying of the sample at 105ºC, pH value and Extractive value. These were carried out as per guidelines.

1. Loss on drying of the sample at 105°C

4g of *Poonaga Parpam* was weighed in a previously weighed 100ml beaker and heated in an oven at 105ºC for 5hours. Cooled in a dessicator and weighed. Repeated the procedure till constant weight was obtained. The percentage loss in weight of the test drug was calculated by the following formula.

Calculation

$$\text{Percentage of Loss on Drying at 105°C} = \frac{\text{Loss in weight of the sample}}{\text{Weight of the test drug taken}} \times 100$$

2. Ash content

2.a. Total ash content

4g of *Poonaga Parpam* was weighed accurately in a previously ignited and tared silica dish. The material was evenly spread and ignited in a muffle furnace at 600°C until it became white indicating the absence of carbon. The dish was cooled in a dessicator and weighed. As carbon free ash cannot be obtained in this manner, the dish was cooled and the residue moistened with sufficient quantity of water. Dried on a water bath and then ignited in the electric furnace to get the constant weight. Cooled the dish in a dessicator and then weighed. The percentage of total ash of air-dried materials was calculated as per the formula given below.

Calculation

$$\text{Percentage of total ash} = \frac{\text{Weight of the ash}}{\text{Weight of test drug taken}} \times 100$$

2.b. Acid-insoluble ash

The total ash of *Poonaga Parpam* was found out as described above. To the dish containing the total ash was added 45 ml of 1: 5 hydrochloric acid in three portions of 13 ml each time. Boiled gently for 5 minutes and filtered. Collected the insoluble matter on an ashless filter paper (Whatman No.41) and washed with distilled water until the residue was free from acid. Transfer the filter paper containing the insoluble mater to the original dish. Dried and ignited to the constant weight. Cooled the dish in a dessicator, and then weighed. Calculation was made by given formula.

Calculation

$$\text{Percentage of acid-insoluble ash} = \frac{\text{Weight of the acid-insoluble residue}}{\text{Weight of test drug taken}} \times 100$$

2.c. Water Soluble Ash

The above obtained ash was boiled for 5minutes with 25mL water. The insoluble ash was collected using filter paper and washed with hot water and transferred to the silica crucible then ignites for 15 minutes at temperature not exceeding 450°C. The silica crucible and residue were weighed until constant weight was attained for determination of weight of insoluble ash. The weight of the water soluble ash was determined by subtracting the weight of insoluble ash from the weight of total ash.

3. Extractive value of the test drug

4 g of *Poonaga Parpam* was weighed accurately in a glass stoppered flask. Added 100 ml of distilled water and shaken occasionally for 6 hours and then allowed to stand for 18 hours. Filtered rapidly taking care not to lose any solvent and pipetted out 25 ml of the filtrate in a pre weighed 100 ml beaker and evaporated to dryness on a water bath .Kept in an air oven at 105ºC for 6 hours. Cooled in a desiccator and weighed. Repeated the experiment twice, and taken the average value. The percentage of water soluble extractive was calculated by the formula given below.

Calculation

$$\text{Percentage of water soluble extract} = \frac{\text{Weight of the extract}}{\text{Weight of sample taken}} \times \frac{100}{25} \times 100$$

3. a. Water-soluble extractive of the test drug

3g of *Poonaga Parpam* in a glass stoppered flask and add 100 mL of distilled water, shake occasionally for 6 h and then allow standing for 18 h, then filter rapidly taking care not to lose any solvent and pipette out 25 mL of the filtrate in a pre-weighed 100 mL beaker and evaporate to dryness on a water bath. Keep it in an air oven at 105°C for 6 h, cool in a desiccator and weighed. Repeat the experiment twice and take the average value.

$$\text{Percentage of water soluble extractive} = \frac{\text{Weight of the extract}}{\text{Weight of the sample taken}} \times \frac{100}{25} \times 100$$

3. b. Alcohol-soluble extractive of the sample

4 g of *Poonaga Parpam* was weighed accurately in a glass stoppered flask. Added 100 ml of distilled alcohol (approximately 95%) and shaken occasionally for 6 hours and then allowed to stand for 18 hours. Filtered rapidly taking care not to lose any solvent and pipetted out 25 ml of the filtrate in a pre-weighed 100 ml beaker and evaporated to dryness on a water bath.

Kept in an air oven at 105ºC for 6 hours and cooled in a desiccator and weighed. Repeated the experiment twice, and taken the average value. The percentage of alcohol soluble extractive was calculated by the formula given below.

Calculation

$$\text{Percentage of alcohol soluble extract} = \frac{\text{Weight of the extract}}{\text{Weight of the sample taken}} \times \frac{100}{25} \times 100$$

4. Determination of pH

5 g of *Poonaga Parpam* was weighed accurately and placed in clear 100 ml beaker. Then 50 ml of distilled water was added to it and dissolved well. After 30 minutes it was then applied in to pH meter at standard buffer solution of 4.0, 7.0, and 9.2. Repeated the test four times and average was recorded.

5. Solubility test

A. A little amount of the sample was taken in a clean, dry test tube and then shaken well with distilled water.

B. A little amount of the sample was taken in a clean, dry test tube and then shaken well with con. Hcl and Con. H_2SO_4. Sparingly soluble character of the sample indicates the presence of Silicate.

The results were tabulated in **Table.No.3.**

4. RESULTS AND DISCUSSION

4.1. Standardization of the drug *Poonaga parpam* as per Siddha classical literature

Siddha physicians used these following standardization methods to ensure the safety and efficacy of the *parpam*. It shows the effectiveness of the drug.

Table No. 1: Results of Siddha Standardization.

S.No.	Parameter	Results of *Poonaga parpam*	Interpretation
1.	Floating on Water	Floats on water	Lightness of drug.
2.	Finger Print Test	Impinged in the furrow of fingers	Indicates fine particles of powder.
3.	Luster	Lusterless	Change of specific character of raw material after incineration
4.	Taste	No specific taste, Mild irritation is felt	Change of specific character of raw material after incineration

INTERPRETATION

1. Floating on water

The test drug which floats on water has less specific gravity. Thus *Poonaga parpam* possesses specific gravity less than the water.

2. Finger print test

Only the particles which are in micro fine size can enter into the furrows of the finger print. Finger print test indicates the presence of micro fine particles in *Poonaga parpam.*

3. Lusterless & taste

Poonaga parpam is lusterless and tasteless because there is no free metal present.

4.2. Standardization of the drug *Poonaga parpam* by using Modern techniques

Following tables and charts are the results of organoleptic characters and physicochemical analysis.

Table No. 2: Organoleptic characters of *Poonaga parpam*.

S.No	Parameter	Results
1	Colour	Dark brown coloured
2	Odour	Odourless
3	Taste	Tasteless
4	State of matter	Solid
5	Consistency	Powder

Table No. 3: Physicochemical characterization of *Poonaga parpam*.

S.No	Parameters	Percentage
1	Loss on drying	Less than 1%
2.a	Total ash value	24.72%
2.b	Acid insoluble ash	0.72%
2.c	Water soluble ash	6.94%
3.a	Water soluble extraction	1.88%
3.b	Alcohol soluble extraction	3.54%
4	pH	8.4
5	Solubility	Soluble in acids (Hcl and H_2So_4)

Interpretation

The stability of a drug and its shelf–life are reliant on moisture content. Determination of moisture (Loss on drying) in a drug is one of the important tests in pharmaceutical analysis. The analytical parameters like total Ash value, Acid insoluble ash value, Loss on drying values are helping us to interpret the digestion and solubility capacity of the drug.

Physico-chemical analysis of *Poonaga parpam* showed that Loss on drying (LOD) is less than 1% which shows that low moisture content present in the prepared medicine. Increased moisture content is the issue for instability of a drug and lesser shelf life of a drug. Since *Poonaga parpam* was well prepared, it could get maximum stability and better shelf life. Longer shelf life i.e., 100 years for *Parpam* mentioned in Siddha literature is justified from the above observation.

By the above results, the trial drug shows that total ash value was found to be 24.72% whereas the acid insoluble ash and water soluble ash was 0.72% and 6.94% respectively. The value of total ash in the formulation is high because of the presence of inorganic ingredients and the method of preparation of this drug is calcination procedure. Total ash value used to estimate the inorganic material such as silicate, carbonates, oxalates and phosphates.

The water soluble extractive value indicates the presence of sugar, acids. The alcohol soluble extractive value indicates the presence of polar constituents like phenols, alkaloids, steroids, glycosides, flavonoids. Water soluble extractive and alcohol soluble extractive values of this formulation were 1.88% and 3.54% respectively.

pH of the trial drug was 8.4. It shows the alkalinity of the drug. The adjuvant of the drug is honey, which possesses acidic pH (3.4- 6.1). Hence, this adjuvant reduces the alkalinity of *Poonaga parpam*. According to pharmacokinetics, alkaline drugs are absorbed in alkaline environment i.e., the intestine.

The test drug is not soluble in water medium and well soluble in Hcl and H_2So_4.

5. CONCLUSION

Traditional remedies is advantageous, it does suffer some limitations. The main limitation is the lack of standardization of raw materials, of processing methods and of the final products, dosage formulation, and the non- existence of criteria for quality control. Standardization of the drug is more essential to derive the efficacy, potency of the drug by analyzing it through various studies. The present work was taken up in the view to standardize the Siddha formulation in accordance 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. Formulation was investigated for their organoleptic characters and physicochemical parameters and the research out comings can be used for evaluating the quality and purity of the formulations which will be stepping stone for clinical trial.

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