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Preliminary physicochemical analysis of Siddha mineral drug Pidaalavanam

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Abstract

Aim
To evaluate the Preliminary physicochemical and heavy metal analysis of *Pidaalavanam* a Siddha mineral formulation.
Methods
The Physicochemical analysis of Pidalavanam and one of its ingredient *yerumai kombu seeval* (Buffalo's horn powder) was performed according to Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of Indian medicine (AYUSH systems).
Results
The results showed that both *Pidaalavanam* and one of its ingredient of animal origin *yerumai kombu seeval* (Buffalo's horn powder) are alkaline in nature with PH of 9 and 10.2 respectively. Both are soluble in conc.HCL, nitric acid and sulphuric acid and it is dispersible in water. Both the samples showed high ash values such as total ash, acid insoluble, water soluble ash, alcohol soluble ash indicating the presence of inorganic contents. The heavy metal analysis of this drug indicated the safety of this formulation as the tested heavy metals were below detectable limits.
Conclusion
This preliminary study of standardizing *Pidaalavanam*, would enable to meet the criteria for further preclinical and clinical research and to support its use worldwide for the benefit of the society.

INTRODUCTION

The traditional Siddha system of medicine derives its medicinal formulation from mineral and animal origin apart from herbs. Most of the medicines are a mixture of compounds and because of its unique methods of drug preparation, it is found to have synergistic action, and its bioavailability is increased. *Pidaalavanam* is one such formulation indicated in Siddha literature Gunapaadam Thaathu–Jeeva vaguppu. (Siddha material medica-mineral and animal origin) for the management of Neerizhivu (Diabetes milletus)[1]. The ingredients consist of *Vediyuppu* (Potassium nitrate), *yerumai kombu seeval* (Buffalo's horn powder) and *Padigaaram* (Alum) as ingredients. Enormous research work has been conducted in recent years in herbal drugs, very minimal research is being done in drugs of mineral and animal origin. Till now no research work has been done on Pidaalavanam and therefore the study has been proposed with the aim to evaluate the physicochemical characters as a preliminary step of research.

MATERIALS AND METHODS

The raw materials of the study were procured from local markets of Chennai. The study drug

was prepared at Velumailu Siddha medical college and Hospital Pharmacy, Sriperumbudur and the analysis was conducted at Noble research solutions, Chennai

Ingredients of Pidaalavanam

1. Vediyuppu (Potassium nitrate) - 3500 grams
2. Ox horn powder - 1750 grams
3. Seenam (Alum) - 575 grams

Figure-1 : Showing Ingredients of Pidaalavanam

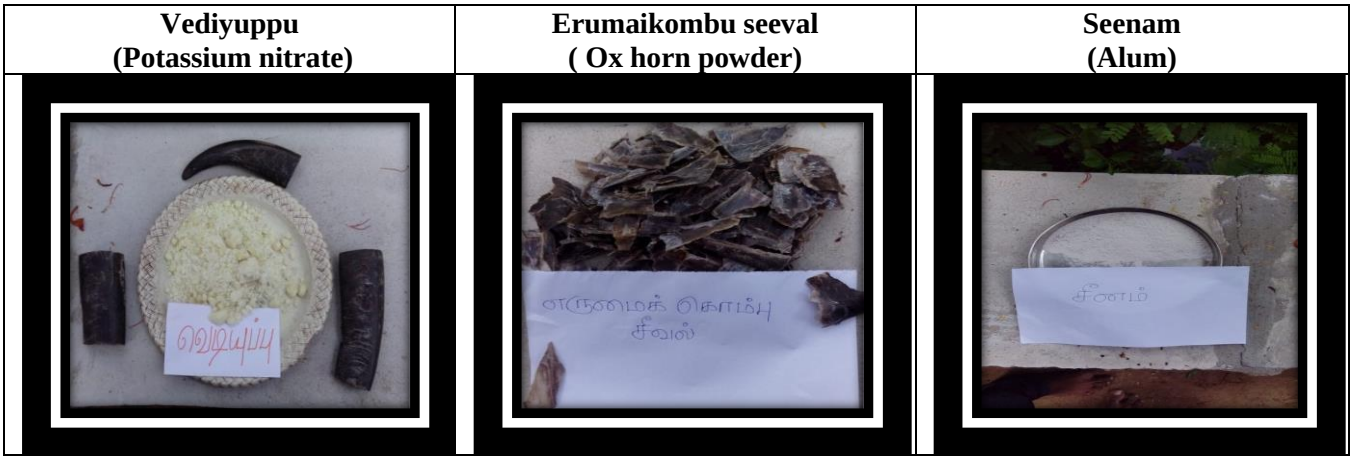


Figure-2. Preparation of pidaalavanam

Vediyuppu is to be heated in an iron bowl until it reaches its melting point. Then the Ox horn powder is to be added slowly until the salt reaches a stable state. It is then mixed with alum until it synergistically mixed after which it is heated and filtered twice and the mixture is allowed to dry under sunlight. The resultant Pidaalavanam is obtained as a string like salt**.**

Physicochemical analysis *yerumai kombu seeval* (sample-A) and *Pidaalavanam* (sample-B)

1. Percentage Loss on Drying

Test drug samples A and B were accurately weighed in evaporating dish .The samples were dried at 105ºC for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

2. Determination of Total Ash

Test drug samples A and B were accurately weighed in silica dish and incinerated at the furnace a temperature 400ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

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

3. Determination of Acid Insoluble Ash

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

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

4. Determination of Water Soluble Ash

The ash obtained by total ash test was boiled with 25 ml of water for 5 mins. The insoluble matter was collected in crucible and was washed with hot water, and was ignited for 15mins at a temperature not exceeding 450ºC. Weight of the insoluble matter was 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

5. Determination of Alcohol Soluble Extractive

Test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaken frequently during six hours and allowed to stand for eighteen hours. Filtererd rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weighed. The percentage of alcohol-soluble extractive with reference to the air-dried drug was obtained.

Alcohol sol extract = Weight of Extract/ Wt of the Sample taken X 100

6. Determination of Water Soluble Extractive

Test samples A and B was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaked frequently during six hours and allowed to stand and for eighteen hours. The samples were filtered rapidly, taking precautions against loss of solvent, 25 ml of the filtrate was evaporated to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weighed. The percentage of water-soluble extractive with reference to the air-dried drug was calculated.

Water soluble extract = Weight of Extract/ Wt of the Sample taken X 100

7. Determination of pH

Test samples A and B were dispersed in distilled water and filtered. The resultant solution was allowed to stand for 30 mins and the subjected to pH evaluation.[2,3]

8.Heavy metal Analysis

Standard: Hg, As, Pb and Cd – Sigma Methodology Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample BV was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test sample BV Sample Digestion Test sample BV digested with 1mol/L HCl for determination of arsenic and mercury. Similarly for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3. Standard reparation As & Hg-100 ppm sample in 1mol/L HCl Cd & Pb- 100 ppm sample in 1mol/L HNO3

RESULTS

Figure-3: Showing *yerumai kombu seeval* (sample-A) and *Pidaalavanam* (sample-B)

Ox horn powder (sample-A)	Pidaalavanam (sample-B)
	

Table-1: Macroscopic Characters of *yerumai kombu seeval* (sample-A) and *Pidaalavanam* (sample-B)

Parameters	***Yerumai kombu seeval* (Sample-A)**	***Pidaalavanam* (Sample-B)**
State	Solid	Solid
Appearance	Brownish Black	Dark Blackish
Nature	Fine powder (Combination of very fine to fine powder)	Moderately coarse powder
Odor	Characteristic	Characteristic
Touch	Dry	Moistened
Flowability	Free flowing	Cohesive flow (Non free flowing)

Figure-4: Showing Solubility of *yerumai kombu seeval* (sample-A) and *Pidaalavanam* (sample-B)

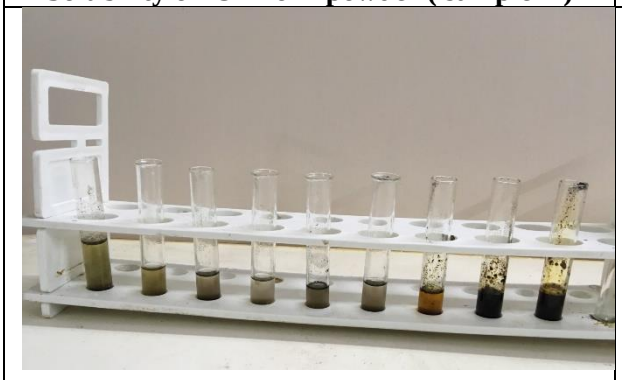
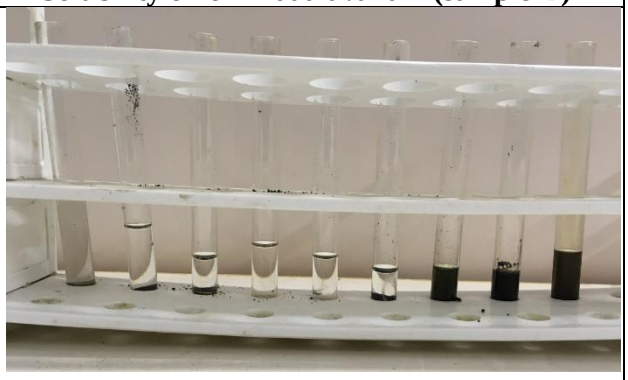
Solubility of Ox horn powder (sample-A)	Solubility of of Pidaalavanam (sample-B)
	

Table 2 : Solubility of Ox horn powder (sample-A)

S.No	Solvent Used	Solubility / Dispersiblilty
1.	Water	Completely Dispersible
2.	Ethanol	Sparingly Soluble
3.	Toulene	Moderately Soluble
4.	Ethylacetate	Insoluble
5.	Chloroform	Insoluble
6.	Xylene	Sparingly Soluble
7.	Conc.HCl	Moderately Soluble
8.	Conc.Sulfuric acid	Completely Soluble
9.	Conc. Nitric Acid	Completely Soluble

Table 3 : Physicochemical analysis of Ox horn powder (sample-A)

S.No	Parameter	Mean (n=3) SD
1.	Loss on Drying at 105 °C (%)	8.96 ± 1.13
2.	Total Ash (%)	47.53 ± 1.06
3.	Acid insoluble Ash (%)	2.93 ± 0.70
4.	Water Soluble Ash (%)	16.87 ± 2.0
5.	Alcohol Soluble Extractive (%)	13.87 ± 1.03
6.	Water soluble Extractive (%)	4.66 ± 0.39
7.	pH	10.2

Table 4 : Solubility of of Pidaalavanam (sample-B)

S.No	Solvent Used	Solubility / Dispersiblilty
1.	Water	Dispersible
2.	Ethanol	Insoluble
3.	Toulene	Insoluble
4.	Ethylacetate	Insoluble
5.	Chloroform	Insoluble
6.	Xylene	Insoluble
7.	Conc.HCl	Completely Soluble
8.	Conc.Sulfuric acid	Completely Soluble
9.	Conc. Nitric Acid	Completely Soluble

Table 5 : Physicochemical analysis of Pidaalavanam (sample-B)

S.No	Parameter	Mean (n=3) SD
1.	Loss on Drying at 105 °C (%)	8.13 ± 0.90
2.	Total Ash (%)	65.13 ± 2.37
3.	Acid insoluble Ash (%)	6.06 ± 1.13
4.	Water Soluble Ash (%)	14.87 ± 2.0
5.	Alcohol Soluble Extractive (%)	3.93 ± 0.85
6.	Water soluble Extractive (%)	1.70 ± 0.18
7.	pH	9

Table 5 : Heavy metal analysis of Pidaalavanam (Sample-A and B)

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis (Sample A and B)	Maximum Limit
Mercury	253.7 nm	BDL	1 ppm
Lead	217.0 nm	BDL	10 ppm
Arsenic	193.7 nm	BDL	3ppm
Cadmium	228.8 nm	BDL	0.3 ppm

DISCUSSION

The Siddha mineral drug Pidaalavanam is an ancient synthetic preparation that is indicated in Siddha classical text for the treatment of *Neerizhivu*. Presently the drug is not available in local markets or pharmaceutical companies nor being used in common Clinical practice. Hence we were interested to prepare the Pidaalavanam as per traditional methods and evaluated the orgnoleptic characters, physico-chemical characters like ash values, pH value, solubility were analyzed for the first time. The total ash value was found to be (65.13±2.37) in Pidaalavanam and (47.53±1.06%) in Ox horn powder , acid insoluble ash value was (6.06±1.13%) in Pidaalavanam and (2.93±0.70%) in Ox horn powder respectively , The pH value is Pidaalavanam(9) Ox horn powder (10.2). The pH of the drug indicates that this is an alkaline weak basic drug.

LOD test indicates the amount of volatile matter and moisture content of the drug. In the present study, loss on drying at 105ºc was (8.13±0.90%) in Pidaalavanam and (8.96±1.13) in Ox horn powder respectively which shows the mild reduction of water content in the final product. The LOD level of final drug is equal to the standard limit of Pharmacopoeial standards for Ayurveda Anonymous[4]. Total ash content was high in both Ox horn powder (47.53±1.06%),Pidaalavanam (65.13 ± 2.37%) Acid insoluble ash content in final product of pidaalavanam (6.06±1.13%), and Ox horn powder (2.93±0.70%) respectively indicates that this drug was prepared from non-volatile inorganic material and this is in agreement with the previous findings on insoluble nature of inorganic matters in acid medium.The study results are consistent with previous study by P. Rajalakshmi et al on Annabedhi chendhuram a Siddha mineral drug which also has showed high Ash contents[5].

The Heavy metal analysis of Pidaalavanam samples A and B showed that the heavy metals mercury, lead, cadmium and arsenic were below detectable levels indicating the safety of this Siddha mineral formulation..

CONCLUSION

Through this study the Siddha drug Pidaalavanam has been traditionally prepared and the priliminary Physicochemical properties of the mineral formulation has been evaluated. This study has been carried out as an earnest attempt to expose the traditional method of its preparation and also to scientifically validate its composition and safety. Further preclinical and clinical studies may be essential to confirm its bioavailability, particle size and mineral composition and its therapeutic efficacy in humans for the treatment of *Neerizhivu* (Diabetes mellitus).

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