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Research Article

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Evaluation of Analytical Specifications of Siddha Herbal Formulation Vallarai Ilagam

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Abstract

Siddha's system of medicine has its own treasure of knowledge. It describes various ailments and their remedies for the different age groups. Siddha's literature paid special attention to the pediatric age group. Siddha literature, Pillai Pini Maruthuvam provides various medications for treating childhood diseases. Vallarai ilagam is one of the herbal formulations given in the textbook for treating 18 types of karappan. In order to evident the effect of medication on specific diseases described in our textbook, there is a need to analyze the drug as per the latest techniques. Here, the analytical specification of vallarai ilagam as per PLIM guidelines are evaluated.

Keywords: Siddha's system, Pillai Pini Maruthuvam, karappan, analytical specification.

1. Introduction

Vallarai Ilagam is a polyherbal formulation, mainly used for the treatment of 18 types of karappan (skin disease) mainly for the pediatric age groups. Ilagam is one of the medications in 32 types of internal medicine detailed in our Siddha literature. It is defined as semisolid preparation of drugs, prepared with the addition of jaggery, sugar, or sugar candy and boiled with prescribed drug juice or decoction. It has 6 months expiry period as per our literature.

Karappan is defined as a noncontagious superficial inflammation of the skin characterized by erythema, scaling, papules, vesiculation, and oozing. The literature shows that the cause for the karappan is due to intake of allergy-causing food substances such as maize, millets, bitter gourd, plantain, and fish by lactating mothers and children. It also occurs during exposure to an unhygienic environment.

Thus the analytical specification of Vallarai Ilagam is evaluated for scientific validation and standardization of the Siddha formulary drug.

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2. Materials and Methods

2.1 Drug selection

The siddha formulation drug vallarai ilagam selected from the siddha pediatric literature Pillai Pini Maruthuvam Part II and this medication is indicated for treating skin disease called karappan (all 18 types).

2.2 Ingredients of vallarai ilagam

This poly herbal formulation contains both fresh herbs and raw drugs and the ingredients of the drug and its quantity are listed below in **Table 1.**

Table 1

S.No	Name	Botanical name	Family	Part used	Quantity
1.	Vallarai	*Centella asiatica*	Apiaceae	Leaves	1.3 l
2.	Poduthalai	*Phyla nodiflora*	Verbenaceae	Leaves	1.3 l
3.	Ponnankaani	*Alternanthera sessilis*	Amaranthaceae	Leaves	1.3 l
4.	Elumichai	*Citrus limon*	Rutaceae	Fruit	675 ml
5.	Saathikai	*Myristica fragrans*	Myristicaceae	Seed	10 g
6.	Saathipaththiri	*Myristica fragrans*	Myristicaceae	Aril	10 g
7.	Maasikai	*Quercus infectoria*	Fagaceae	Gall	10 g
8.	Karkadagasingi	*Rhus succedanea*	Anacardiaceae	Gall	10 g
9.	Adhimathuram	*Glycyrrhiza glabra*	Fabaceae	Root	10 g
10.	Kaataththi poo	*Bauhinia tomentosa*	Caesalpinaceae	Flower	10 g
11.	Vaal Milagu	*Piper cubeba*	Piperaceae	Fruit	10 g
12.	Elam	*Eletteria cardamomum*	Zingeberaceae	Fruit	10 g
13.	Kirambu	*Syzygium aromaticum*	Myrtaceae	Flower bud	10 g
14.	Sugar	-			70 g
15.	Cow's Milk	-			2.6 l
16.	Cow's Ghee	-			2.6 l

2.3 Collection of plant materials

Plants are collected near Tirunelveli town and the raw drugs were brought from a well reputed raw drug store in Tirunelveli Town.

2.4 Identification and authentication of the drug

The herbarium of plants specimen and raw drugs were identified and authenticated by the Head of the Department of Post graduate Department of Gunapadam, Government Siddha Medical College, Palayamkottai. The sample specimen of each raw material and herbarium is stored in the PG Department of Gunapadam for future reference.

2.5 Purification of the raw drugs

Purification of raw drugs were done as per classical *Siddha* literature.

2.6 Preparation of the drug

Make extract of above mentioned plants. Then all the raw drugs are powdered and make into paste with milk, next all the extracts are boiled, at this stage add the paste of raw drugs. It is heated till it reaches particular consistency then add sugar and ghee. Allow it to cool and store it in airtight container.

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Picture 1 - Sample Description

2.7 Administration of the drug

Form of the medicine: Ilagam
Route of administration: Oral
Dose: 2g
Indication: 18 types of karappan

2.8 Analytical specification of ilagam

As per the guidelines of PLIM (The Pharmacopoeial Laboratory For Indian Medicine), Analytical Specification Of Ilagam includes Physiochemical Description, Test For Heavy Metals, Sterility Test (detecting microbial contamination), Identifications TLC/HPTLC, Test For Specific Pathogen, Pesticide Residue and Test For Afla Toxins.

In this article, all the analytical specifications except TLC/HPTLC are evaluated.

The analysis was done by Noble research solutions Pvt. Ltd., Chennai, India.

2.9 Physicochemical analysis of vallarai ilagam

Physiochemical analysisincludes Sample Description, Solubility Test, Loss On Drying, Determination Of Total Ash, Water Soluble Ash, Acid Insoluble Ash, Water And Alcohol Soluble Extract. The analysis were done at Noble research solutions Pvt. Ltd., Chennai, India.Each analysis is done three times and the mean value is calculated.

3. Results and Discussion

3.1.1 Sample Description

(Table 2)

State	Semisolid
Nature	Dense viscous
Odor	Strongly aromatic
Touch / Consistency	Greasy
Flow Property	Non- free flowing
Appearance	Brownish

3.1.2 Solubility Profile

(Table 3)

S.No	Solvent Used	Solubility / Dispersibility
1	Chloroform	Insoluble
2	Ethanol	Soluble
3	Water	Soluble
4	Ethyl acetate	Insoluble
5	DMSO	Insoluble

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3.1.3 Percentage Loss on Drying

Test drug was accurately weighed in evaporating dish. The sample was dried at 105°C for 5 hours and then weighed.

3.1.4 Determination of Total Ash

Test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC 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.

3.1.5 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 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.

3.1.6 Determination of Alcohol Soluble Extractive

Test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it to stand for eighteen hours. Filter 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 weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

3.1.7 Determination of Water Soluble Extractive

Test sample was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it to stand and for eighteen hours. Filter 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 weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

The test report of the above analysis are mentioned in the **Table 4**.

Table 4

S.No	Parameter	Mean (n=3) SD
1.	Loss on Drying at 105 °C (%)	11.23 ± 0.89
2.	Total Ash (%)	1.73 ± 0.41
3.	Acid insoluble Ash (%)	0.003 ± 0.02
4.	Alcohol Soluble Extractive (%)	6.38 ± 1.33
5.	Water soluble Extractive (%)	12.7 ± 1.31
6.	pH	4

3.2 Test for heavy metals

Heavy Metal Analysis evaluated by **Atomic Absorption Spectrometry (AAS).** It is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test item.

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Sample Digestion:

Test sample was 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 ofHNO3.

The analysis report is detailed in **Table 5.**

Table 5

Name of the Heavy Metal	Absorption Max max	Result Analysis
Lead	217.0 nm	24.4
Arsenic	193.7 nm	4.95
Cadmium	228.8 nm	1.55

3.3 Sterility test (Microbial contamination)

Test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45°C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37° C for 24-48 hours and further extended for 72 hrs for fungal growth observation. Grown colonies of organism was then counted and calculated for CFU. The result shown in **Table 6** and it was observed that no growth/colonies in any of the plates inoculated with test sample.

Table 6

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^5CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^3CFU/g	

3.4 Test for specific pathogen

Test sample was directly inoculated in to the specific pathogen medium (Eosin Methylene Blue Agar- *E.coli*, Deoxycholate Agar - *Salmonella*, Mannitol salt Agar- *Staphylococcus aureus*, Cetrimide Agar- *Pseudomonas aeruginosa*) by pour plate method. The plates were incubated at 37°C for 24 - 72h for observation. Presence of specific pathogen identified by their characteristic colour with respect to pattern of colony formation in each differential media. It was observed that there is no growth after inoculation reveals that the absence of specific pathogen. (Shown in picture 1.1, 1.2, 1.3, 1.4)

1.1Culture plate with *E-coli* (EC) specific medium

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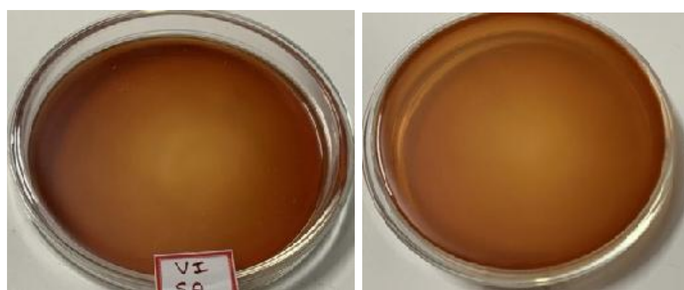
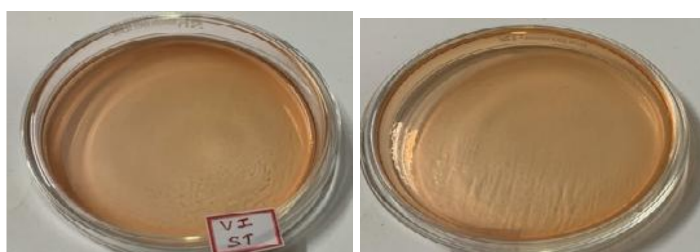
1.2Culture plate with Salmonella (SA) specific medium



1.3 Culture plate with *Staphylococcus aureus* (ST) specific medium



1.4 Culture plate with *Pseudomonas aeruginosa* (PS) specific medium

3.5 Pesticide residue

Test sample were extracted with 100ml of acetone and followed by homogenization for brief period. Further filtration was allowed and subsequent addition of acetone to the test mixture. Heating of test sample was performed using a rotary evaporator at a temperature not exceeding 40ºC until the solvent has almost completely evaporated. To the residue add a few milliliters of toluene and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter. Result analysis of drug detailed in **Table 7**and it showed that there were no traces of pesticides residues such as Organochlorine, Organophosphorus, Organocarbamates and pyrethroids in the sample provided for analysis.

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Table 7

Pesticide Residue **I.Organo Chlorine Pesticides**	Sample VI	AYUSH Limit (mg/kg)
Alpha BHC	BQL	0.1mg/kg
Beta BHC	BQL	0.1mg/kg
Gamma BHC	BQL	0.1mg/kg
Delta BHC	BQL	0.1mg/kg
DDT	BQL	1mg/kg
Endosulphan	BQL	3mg/kg
II. Organo Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2mg/kg
Dichlorovos	BQL	1mg/kg
III. Organocarbamates		
Carbofuran	BQL	0.1mg/kg
III. Pyrethroid		
Cypermethrin	BQL	1mg/kg

BQL-Below Quantification Limit

3.6 Test for Aflatoxins

Standard aflatoxin was applied on to the surface to precoated TLC plate in the volume of 2.5 µL, 5µL, 7.5µL and 10 µL. similarly, the test sample was placed and allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of chloroform, acetone and isopropyl alcohol(85:10:5) until the solvent front has moved not less than 15mm from the origin. Remove the plate from the developing chamber, mark the solvent form and allow the plate to air dry. Locate the spots on the plate by examination under UV light at 365 nm. The results shown that there were no spots were being identified in the test sample loaded on TLC plates when compared to the standard which indicates that the sample free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2 and it is detailed in **Table 8.**

Table 8

Aflatoxin	Sample VI	AYUSH Specification Limit
B1	Not Detected-Absent	0.5ppm
B2	Not Detected-Absent	0.1ppm
G1	Not Detected-Absent	0.5ppm
G2	Not Detected-Absent	0.1ppm

4. Conclusion

Vallarai Ilagam shows the satisfactory results for standardizing the drug on evaluation of analytical specifications of the Ilagam as per PLIM guidelines. It provide information about the safety and quality of the drug. Evaluation of those analytical parameters with the help of modern analytical tools widen the acceptance and scope of the siddha drugs. The information collected in this study will be helpful to analyze other siddha formulations.

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5. References

1. Avinash Seth And Biren Shah Textbook Of Pharmacognacy and Phytochemistry, 2009
2. Dr .Thiyagarajan, Gunapadam Thathu Seeva Vagupu
3. India Pharmacopeia I Volume I, Government of India, Ministry of Health and Family welfare, Indian Pharmacopeia commission, 2014.
4. Lohar. D.R. Protocol for testing of ASU medicines. Pharmacopoeial Laboratory for Indian Medicines, Ministry of AYUSH,2007.
5. Luciana de CASTRO determining aflatoxins B1 B2 G1 and G2 in maize using florisil clean up with Thin Layer Chromatography and Visual and Densitometric Quantification. Cienc Tecnol Aliment Vol.21 No.1 Campinas 2001
6. Pharmacopeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of Indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH, Ministry of Health & Family Welfare, Govt. of India
7. Pillaipini Maruthuvam part II Department of Indian medicine and Homeopathy. First edition.
8. Pon. Guru Sironmani, Kuzhanthai Maruthuvam- Balavagadam, Dept Of Indian Medicine And Homeopathy
9. WHO guideline for assessing the quality of herbal medicines with reference to contaminants and residues. WHO Geneva. 2007.

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