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QUALITY AND SAFETY EVALUATION OF THE SIDDHA FORMULATION POOSANI NEI USED IN RESPIRATORY AILMENTS

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ABSTRACT

The Siddha system of medicine, one of the oldest traditional medical systems of South South India, emphasizes maintaining health and treating disease through the balance of the three humors (*Vali, Azhal, Iyyam*). Imbalance in these humors leads to disease. Imbalance in these humors leads to diseases. The system is rich in formulations that use plants, minerals, and animal sources carefully prepared as described in classical texts. Establishing quality standards for traditional medicine is therefore critical to ensure their safety, therapeutic effectiveness and smooth integration into modern medical practices. *Poosani Nei* is a classical siddha drug for *kaasam and Suvasakasam* relating to respiratory disease of various etiologies, mentioned in the text book of *Sarabenthira vaithiya muraigal.*[1] Physicochemical analysis, phytochemical analysis, biochemical analysis and characterization of the drug is essential for commercialization to understand the science behind the formulation.

KEYWORDS: Siddha medicine, *Poosaani Nei, Swasakasam.*

INTRODUCTION

Poosani Nei is one such classical formulations described in siddha texts for the Management of respiratory ailments such as *Kaasam*(cough), *Suvasakasam* (breathlessness)and related disoders. Despite its potential efficacy, like many traditional medicines, *Poosani Nei* faces challenges related to quality control, consistency and safety. With evidence-based validation, Standardization and analytical evaluation of Poosani Nei according to the PLIM guidelines has become essential to ensure consistency, authenticity and scientific credibility.[2] Asthma is a chronic inflammatory disorder of the respiratory system that affects the bronchial airways, leading to episodes of breathlessness, wheezing, chest tightness, and cough. The hallmark feature is airway hyper responsiveness and reversible airflow obstruction, which differentiates it from other chronic obstructive airway diseases. Globally, asthma is one of the most common chronic non-communicable diseases. In Siddha systems of traditional medicine, Asthma (referred to as *Suvasakasam)* has been described with specific formulations and lifestyle recommendations.

OBJECTIVES OF THE STUDY

Primary Objective: To standardize the drug *POOSANI NEI* as per PLIM guidelines.
Secondary Objective: To validate the chemical constituents of *POOSANI NEI* for its indication as mentioned in Siddha Literature.

MATERIALS AND METHODS

STUDY DESIGN: Analytical Study
STUDY PLACE: 1.PG Gunapadam laboratory, Govt. Siddha Medical College & Hospital, Palayamkottai.
2. NABL reputed laboratory.

AUTHENTICATION

The raw drugs will be collected from the raw drug shop. Authentication will be obtained from faculty of PG Gunapadam department, Govt. Siddha Medical College & Hospital, Palayamkottai.

MATERIALS AND METHODS

INGREDIENTS OF *POOSANI NEI*.

SI.NO	TAMIL NAME	BOTANICAL NAME	QUANTITY
1.	*Poosanikai charu*	*Benincaspa hispida*	1.3 L
2.	Cow's ghee	*Bos indicus*	600 ml
3.	*Indhuppu*	Rock salt	3.8 g
4.	*Elakkai*	*Elettaria cardamomum*	3.8 g
5.	*Kirambu*	*Syzygium aromaticum*	3.8 g
6.	*Chukku*	*Zingiber officinale*	3.8 g
7.	*Athimadhuram*	*Glycyrrhiza glabra*	3.8 g
8.	*Sirunaaga poo*	*Mesua nagassarium*	3.8 g
9.	*Karipalaiver*	*Tylophora indica*	3.8 g
10.	*Vilamichuver*	*Plectranthus vettiveroides*	3.8 g
11.	*Pachilai*	*Garcinia xanthochymus*	3.8 g
12.	*Vilalarisi (Vaivilangam)*	Seed of reed grass	3.8 g

PROCEDURE

All the above raw drugs except cow's ghee were cleaned properly and purified.[3] The other drugs were powdered and triturated together in the form of karkam with 1.3 L of Poosani charu and mixed with 600 ml of cow's ghee, and soaked for 4 days. On the 5th day, the mixture is boiled to certain consistency (*Nei pakkuvam*) and filtered. The prepared ghee is then cooled and stored in airtight container.

DOSAGE: 3 Kalanju (5.1 g)

ADJUVENT: Cow's milk.

SHELF LIFE: 6 months.

INDICATION: *Suvasakaasam, Kaasam, Vikkal.*

RESULTS AND DISCUSSION

PHYSICOCHEMICAL ANALYSIS OF POOSANI NEI

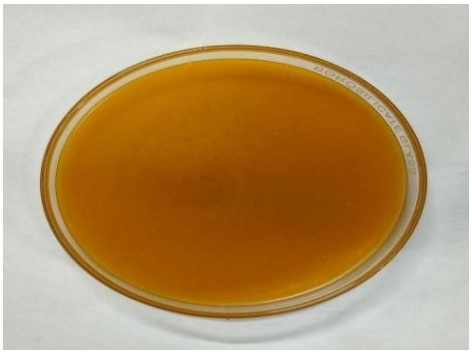


Fig: 1 Poosani Nei Final Product.

Table 1: Analytical Report.

S.No	Parameter	PN
1	Viscosity at 50^{o}C (Pa s)	69.52
2	Refractive index	1.72
3	Weight per ml (gm/ml)	0.79
4	Iodoine value (mg I2/g)	108.14
5	Saponification Value (mg of KOH to saponify 1gm of fat)	177.63
6	Acid Value mg KOH/g	0.79
7	Peroxidase Value mEq/kg	4.21

Table 2: Solubility profile.

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

Table 3: Physical nature profile.

State	Liquid
Nature	Viscous
Odor	Characteristic
Touch / Consistency	Greasy
Flow Property	Free Flowing
Appearance	Yellowish

HEAVY METAL ANALYSIS REPORT (BDL-Below Detection Limit)

Table 4: Heavy metal analysis.

NAME OF HEAVY METAL	ABSORPTION MAX	RESULT ANALYSIS	MAXIMUM LIMIT
Lead	217.0 nm	BDL	10 ppm
Arsenic	193.7 nm	BDL	3ppm
Cadmium	228.8 nm	BDL	0.3ppm
Mercury	253.7 nm	BDL	1ppm

STERILITY TEST REPORT

Table 5: Sterility Test.

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	

SPECIFIC PATHOGEN TEST REPORT

Table 6: Specific pathogen test report.

Organism	Specification	Result
E-coli	Absent	Absent
Salmonella	Absent	Absent
Staphylococcus Aureus	Absent	Absent
Pseudomonas Aeruginosa	Absent	Absent

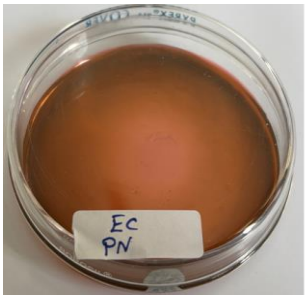


Fig:2 Culture plate with E-coli (EC) specific medium.

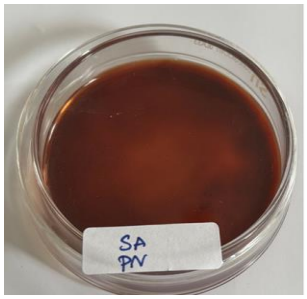
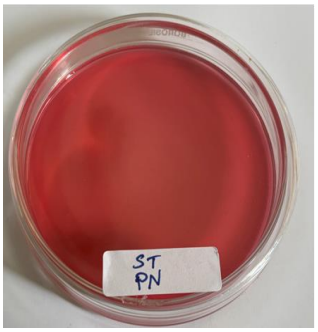


Fig:3 Culture plate with Salmonella (SA) specific medium.



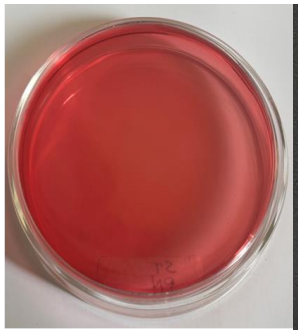
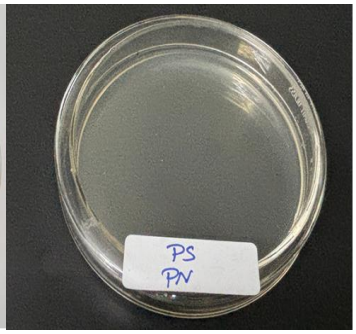


Fig:4 Culture plate with Staphylococcus Aureus (ST) specific medium.



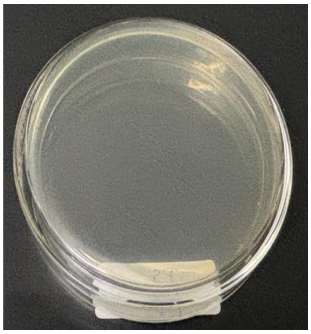


Fig:5 Culture plate with Pseudomonas Aeruginosa (PS) specific medium.

PESTICIDES RESIDUE ANALYSIS REPORT
(BQL- Below Quantification Limit)
Table 7: Pesticide residue analysis report.

PESTICIDE RESIDUE	Sample V/N	AYUSH Limit (mg/kg)
I.Organo Chlorine Pesticides		
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 Phosphorous pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
III.Oragano Carbamates		
Carbofuran	BQL	0.1mg/kg
III.Pyrethroid		
Cypemethrin	BQL	1mg/kg

AFLATOXINS ASSAY REPORT
Table 8: Aflatoxins assay report.

AFLATOXINS	SAMPLE	AYUSH Specification Limit
B1	Not Detected-Absent	0.5ppm(0.5mg/kg)
B2	Not Detected-Absent	0.1ppm(0.1mg/kg)
G1	Not Detected-Absent	0.5ppm(0.5mg/kg)
G2	Not Detected-Absent	0.1ppm(0.1mg/kg)

PHYTOCHEMICAL ANALYSIS REPORT

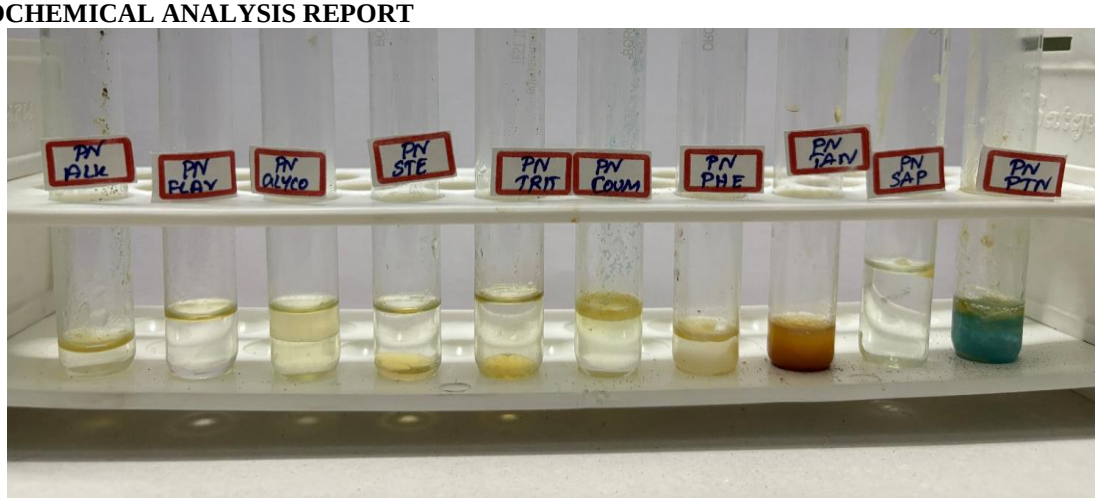


Fig 6: Qualitative Phytochemical Investigation.

Table 9: Phytochemical analysis report.

S NO.	TEST	OBSERVATION
1.	ALKALOIDS	-
2.	FLAVANOIDS	+
3.	GLYCOSIDES	-
4.	STEROIDS	+
5.	TRITERPENOIDS	+
6.	COUMARIN	-
7.	PHENOL	+
8.	TANNIN	-
9.	SAPONINS	+
10.	PROTEIN	+

11.	SUGAR	-
12.	ANTHOCYANIN	-
13.	BETACYANIN	-

BIOCHEMICAL ANALYSIS REPORT

Table 10: Acid radical's analysis report.

TEST FOR ACID RADICALS	
Test for carbonates	Positive- Indicates Presence
Test for sulphates	Positive- Indicates Presence
Test for chlorides	Negative- Indicates Absence
Test for sulphides	Negative- Indicates Absence
Test for phosphates	Negative- Indicates Absence
Test for fluoride and oxalates	Negative- Indicates Absence
Test for Borates	Negative- Indicates Absence
Test for Nitrates	Negative- Indicates Absence

Table 11: Basic radical's analysis report.

TEST FOR BASIC RADICALS	
Test for Lead	Negative- Indicates Absence
Test for Arsenic	Negative- Indicates Absence
Test for Mercury	Negative- Indicates Absence
Test for Copper	Negative- Indicates Absence
Test for Ferric and Ferrous	Negative- Indicates Absence
Test for Zinc	Negative- Indicates Absence
Test for Silver	Negative- Indicates Absence
Test for Magnesium	Negative- Indicates Absence

RESULTS AND INTERPRETATIONS

The Siddha formulation *Poosani Nei* was standardized using modern analytical tools to ensure its quality, safety and efficacy. The physicochemical analysis indicates that the sample *Poosani Nei* was a Yellowish, viscous liquid with characteristics odour and greasy consistency. Acid value and Peroxide value are within acceptable limits, ensures the formulation is fresh, safe and stable for therapeutic use. These findings are consistent with the standards assessing the quality of herbal medicines with reference to contaminants and residues prescribed by WHO for Siddha formulations.[4]

Heavy metal analytical report shows arsenic, mercury, cadmium and lead all are below detection limit. The Sterility test reveals absence of bacterial count. The Microbial contamination test for specific pathogen (E.coli, Salmonella, S.aureus, Pseudomonas aeruginosa) indicates no growth after the incubation period. The pesticide residue analysis shows Organo chlorine, Organo phosphorous, Organo carbamates all are below quantification limit. The Aflatoxin assay shows no detectable spots for Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2 on TLC Plates confirming the absence of Aflatoxins. The Phytochemical analysis of *Poosani Nei* shows the presence of Flavanoids, Steroids, Triterpenoids, Phenol, Saponin and Protein. These phytochemicals are all known for Anti-oxidant, Bronchodilation, Anti asthmatic, Anti-inflammatory and Anti-microbial properties possess the traditional claims of its use in Respiratory ailments, especially in conditions resembling Bronchial asthma (*Suvasakaasam*). The Absence of toxic elements or harmful radicals in biochemical evaluation strengthens the safety profile of the drug.[5] Overall, the findings demonstrates that *Poosani Nei* possess essential quality, purity and safety parameters making it suitable for therapeutic application.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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