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PHYSICOCHEMICAL, PHYTOCHEMICAL AND SAFETY EVALUATION OF SIDDHA HERBO-MINERAL FORMULATION *MILAGU MATHIRAI* PREPARED ACCORDING TO CLASSICAL SIDDHA LITERATURE

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ABSTRACT
The Siddha system of medicine includes numerous classical formulations used for the management of respiratory diseases. Scientific standardization of these medicines is essential in order to ensure their quality, purity, and safety. The present study was undertaken to evaluate the physicochemical characteristics, phytochemical constituents, and safety parameters of the traditional Siddha herbo‑mineral formulation *Milagu Mathirai* prepared according to the classical text *Anubava Vaithiya Kalanjiyam (M.S.S. Assan, 1992).* Analytical investigations were carried out in accordance with PLIM guidelines. The evaluation included organoleptic analysis, physicochemical testing, weight variation, disintegration study, preliminary phytochemical screening, microbial load determination, heavy metal estimation, pesticide residue analysis, and aflatoxin detection. The formulation showed acceptable physicochemical values including loss on drying (6.03 ± 1.30%), total ash (0.83 ± 0.16%), absence of acid‑insoluble ash, and a pH of 6.7. Phytochemical analysis revealed the presence of alkaloids, flavonoids, steroids, triterpenoids, coumarins, phenols, tannins, saponins, sugars, and betacyanins. Heavy metals, microbial contamination, pesticide residues, and aflatoxins were not detected within the tested limits. The results indicate that *Milagu Mathirai* satisfies standard safety and quality requirements and supports its traditional use in respiratory disorders. Further pharmacological and clinical studies are recommended.

KEYWORDS: Milagu Mathirai, Siddha Medicine, physicochemical analysis, phytochemical screening, safety evaluation.

INTRODUCTION
Siddha medicine represents one of the oldest traditional medical systems practiced in India, particularly in Tamil Nadu. The fundamental theory of Siddha medicine describes the human body as being composed of five primordial elements—earth, water, fire, air, and space. According to this concept, the maintenance of health depends on the equilibrium of the three vital humors known as Vatham, Pittam, and Kapham.[2]

Disturbance in the balance of these humors results in various pathological conditions. Classical Siddha texts describe numerous herbal and herbo-mineral preparations used for the treatment of respiratory ailments.[3,4]

Milagu Mathirai is one such traditional formulation commonly prescribed for cough, bronchial asthma, phlegm accumulation, and related disorders.[1]

Bronchial asthma is a chronic inflammatory disease of the respiratory tract characterized by airway obstruction, bronchial hyper-responsiveness, and recurrent episodes of wheezing and breathlessness.[8]

Although many Siddha formulations are widely used in clinical practice, systematic scientific validation is necessary to establish their identity, quality, and safety. Physicochemical standardization and safety evaluation using modern analytical techniques play an important role in ensuring the reproducibility and reliability of traditional medicines.[5]

Therefore, the present study aimed to analyze the physicochemical parameters, phytochemical profile, and safety aspects of the Siddha formulation *Milagu Mathirai* prepared according to classical procedures.

MATERIALS AND METHODS

STUDY DESIGN

Analytical laboratory‑based investigation.

INGREDIENTS OF MILAGU MATHIRAI

Table 1: Ingredients Of Milagu Mathirai And required quantity.

S.NO	INGREDIENTS	BOTANICAL/BINOMINAL/ENGLISH NAME	PURIFIED REQUIRED AMOUNT
1.	*Vengaram*	*Sodium biborate, borax*	50 gram
2.	*Vellai Milagu*	*Piper nigrum*	50 gram
3.	*Kirambu*	*syzygium aromaticum*	50 gram
4.	*Vettrilai Juice*	*Piper betle*	130 ml
5.	*Inji juice*	*Zingiber officinale*	130 ml

AUTHENTICATION OF RAW DRUG

The raw drugs will be collected from the raw drug shop, identification will be obtained from faculties PG Gunapadam department, Government Siddha Medical college and Hospital, Palayamkottai.

PURIFICATION OF RAW DRUGS

Vengaram (Borax) was heated gently until the moisture content was completely removed

Fig. 1: Purified Vengaram (Borax).

Vellai milagu was soaked in fermented buttermilk for approximately three hours (one saamam), then washed thoroughly, dried, and lightly roasted.

Fig. 2: $purified Vellai milagu (Piper nigrum).

Buds were cleaned and slightly roasted over low flame.

Fig. 3: Purified Kirambu (Syzygium aromaticum).

Vettrilai (Piper betle): Leaves were processed by removing the central vein.

Inji (zingiber officinale): Rhizomes were peeled to remove the outer skin.

PREPARATION OF *MILAGU MATHIRAI*

The formulation was prepared according to the procedure described in the classical Siddha text Anubava Vaidhiya Kalanjiyam.[1]

Purified borax (Vengaram) was finely powdered using a traditional grinding stone(Kalvam). The remaining ingredients were powdered separately and mixed together. The mixture was triturated with betel leaf juice for three hours followed by grinding with fresh ginger juice for an additional three hours until a uniform paste was obtained. The prepared mass was rolled into pills approximately the size of pepper seeds (*Milagu alavu, about 56 mg*). The pills were shade‑dried and stored in airtight containers for further analysis.

FIG. 4 & 5: Prepared milagu mathirai.

DOSAGE & ADJUVANT

1-2 Tablet –*Milagalavu*, Tds & honey, ginger juice, sittrarathai kashayam.

INDICATIONS

Kaasam (irumal), swasakasam (Bronchial asthma), kabam uraidhal (accumulation of phlegm, pasikuraivu (loss of appetite), jaladhosham (common cold).

RESULTS AND DISCUSSION

ORGANO LEPTIC CHARACTER

Fig. 6: Powdered sample of *Milagu mathirai.*

Table 2: Organoleptic characters of Milagu Mathirai.

State	Solid
Nature	Moderately coarse
Odor	Aromatic and slightly pungent
Touch / Consistency	Soft
Appearance	Brownish

SOLUBILITY PROFILE REPORT

Table 3: Solubility Profile of the sample.

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

PHYSICO CHEMICAL PARAMETERS REPORTS

Physicochemical parameters such as loss on drying, ash values, extractive values, and pH were determined following standard analytical procedures described in the Indian Pharmacopoeia.[6]

Table 4: Physico chemical parameters.

S.No	Parameter	Mean (n=3) SD
1.	*Loss on Drying at 105 °C (%)*	6.03 ± 1.30
2.	*Total Ash (%)*	0.83 ± 0.160
3.	*Acid insoluble Ash (%)*	0 ± 0
4.	*Water soluble Extractive (%)*	11.37 ± 0.32
5.	*Alcohol Soluble Extractive (%)*	5.66 ± 0.98
6.	*pH*	*6.7*

All the parameters are within the normal range, so it demonstrates its purity and quality

UNIFORMITY OF WEIGHT T

Table 5: Uniformity of Weight.

Average Weight of Tablet	Number of Tablets	Deviation (%)	Pharmacopoeial Category	Limit
0.0508	03	0 – 3 %	Less than 80mg	± 10% for Maximum 02 Tablets None should deviate by more than ±20%.
	03	Above 3 %		
	14	Negative deviation value		

From the result obtained, it was observed that the tablets has an average weight of 0.0508 g which is under the category of less than 80 mg as per pharmacopeia limit.

Table 6: Disintegration Time of Milagu Mathirai.

Sample ID	Start of Disintegration (mints)	25% Disintegration (mints)	50% Disintegration (mints)	100% Disintegration (mints)
MM	18.17±7.4	62.83±14.9	91.33±8.6	112.7±5.0

PHYTOCHEMICAL INVESTIGATION REPORT

Phytochemical screening was carried out using standard qualitative chemical tests for the identification of major secondary metabolites.[9]

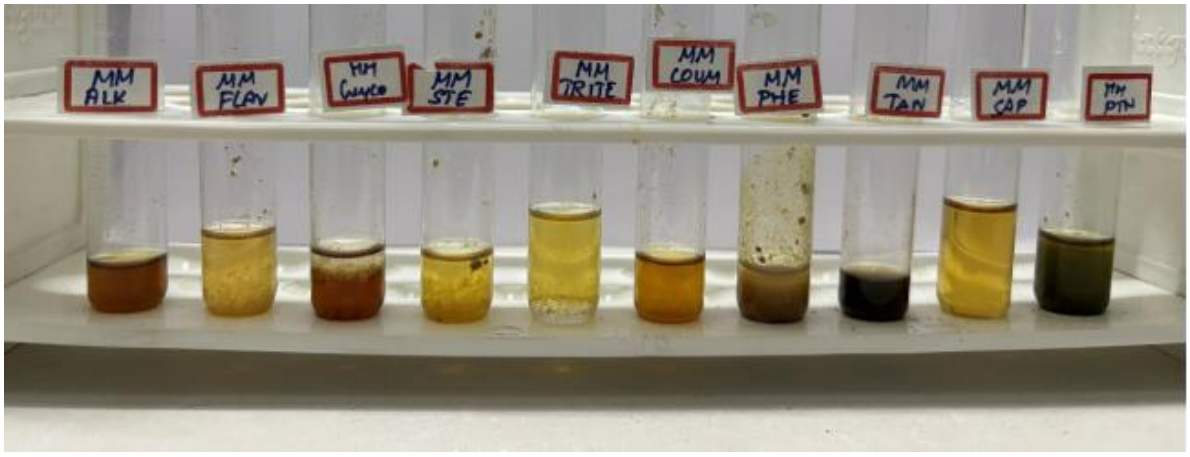

Fig. 7: Phytochemical Investigation of sample.

Table 7: Phytochemical screening results.

S.NO	TEST	OBSERVATION
1	ALKALOIDS	+
2	FLAVANOIDS	+
3	GLYCOSIDES	_
4	STEROIDES	+
5	TRITERPENOIDS	+
6	COUMARIN	+
7	PHENOL	+
8	TANNIN	+
9	SAPONINS	+
10	PROTEIN	_
11	SUGAR	+
12	ANTHOCYANIN	_
13	BETACYANIN	+

(+)-> Indicates Positive and (-) -> Indicates

SAFETY EVALUATION OF MILAGU MATHIRAI

Safety evaluation including heavy metal estimation, microbial load determination, pesticide residue analysis, and aflatoxin detection was performed according to standard guidelines recommended for traditional medicines.[5,7]

Table 8: Heavy metal analysis by AAS.

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

Heavy metal analysis confirmed that the levels of lead, arsenic, cadmium and mercury were below detectable limits and within the permissible limits prescribed by AYUSH.

STERILITY TEST REPORT BY POUR PLATE METHOD

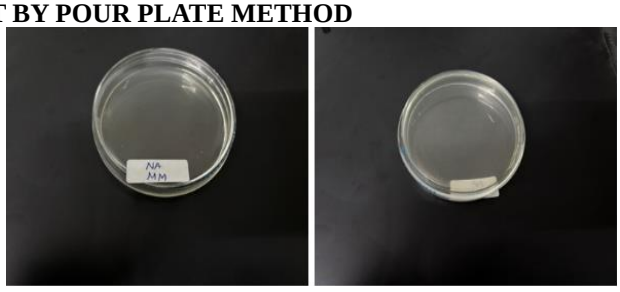

Fig. 8: Sterility test by pour plate method.

Table 9: Sterility test results.

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	

No growth was observed after incubation period reveals the absence of specific pathogen
No growth / colonies were observed in any of the plates inoculated with the test sample

TEST FOR SPECIFIC PATHOGEN REPORT

Table 10: Specific pathogen test.

Organism	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

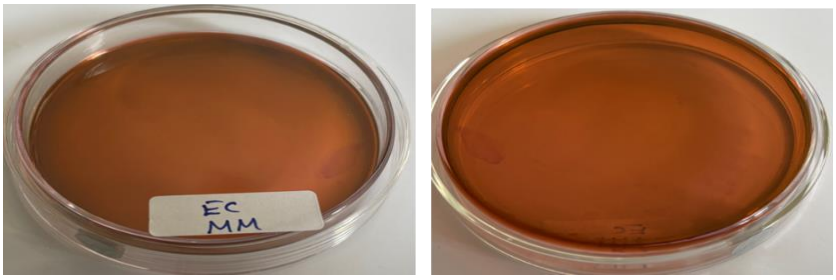

Fig .9: Culture plate for E-coli.

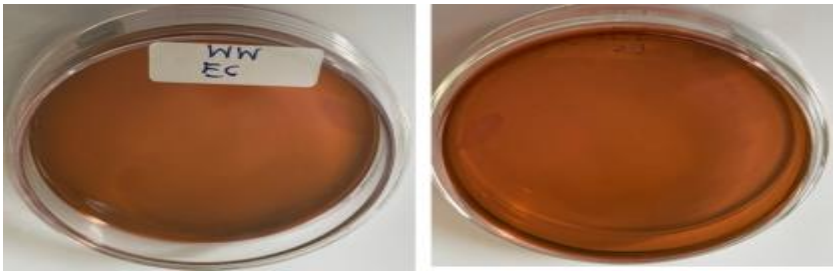

Fig. 10: Culture plate for Salmonella.

Fig. 11: Culture plate for Staphylococcus aureus.

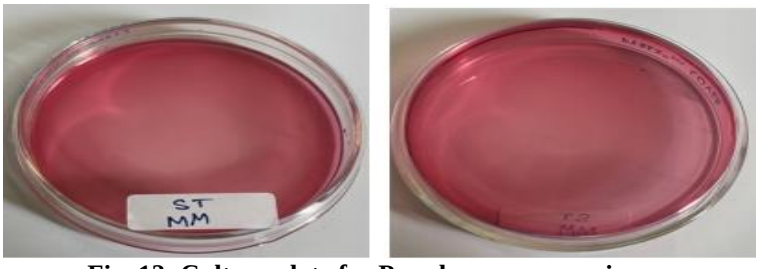

Fig. 12: Culture plate for Pseudomonas aeruginosa.

No microbial growth was observed after incubation, indicating absence of bacterial and fungal contamination

PESTICIDE RESIDUE REPORT

Table 11: Pesticide residue analysis.

Pesticide Residue	Sample MM	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 Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
III. Organo carbamates		
Carbofuran	BQL	0.1mg/kg
III.Pyrethroid		
Cypermethrin	BQL	1mg/kg

The results showed that there were no traces of pesticides residues such as Organo chlorine, Organo phosphorus, Organo carbamates and pyrethroids in the sample. It confirm the quality and safety of the test formulation.

Table 12: Aflatoxin assay report.

Aflatoxin	Sample MM	AYUSH Specification Limit
B1	Not Detected - Absent	0.5 ppm (0.5mg/kg)
B2	Not Detected - Absent	0.1 ppm (0.1mg/kg)
G1	Not Detected - Absent	0.5 ppm (0.5mg/kg)
G2	Not Detected - Absent	0.1 ppm (0.1mg/kg)

There were no aflatoxin found in this sample. These results confirm the quality and safety of the test formulation.

RESULT AND INTERPRETATION

Organoleptic evaluation indicated that the formulation appeared as a brown colored solid with moderately coarse texture and a characteristic aromatic odor. Solubility testing demonstrated that the sample was soluble in ethanol, water, and DMSO while remaining insoluble in chloroform and ethyl acetate. Physicochemical analysis showed that the loss on drying value was 6.03 ± 1.30%, indicating acceptable moisture content. The total ash value (0.83 ± 0.16%) suggested minimal inorganic impurities, and the absence of acid‑insoluble ash indicated the lack of silica contamination. The pH of the formulation was found to be near neutral.[6,7] Weight variation analysis confirmed that the tablets complied with pharmacopoeial standards for tablets weighing less than 80 mg. Preliminary phytochemical screening revealed the presence of several bioactive constituents including alkaloids, flavonoids, steroids, triterpenoids, coumarins, phenols, tannins, saponins, sugars, and betacyanins. These compounds are known to exhibit antioxidant, anti‑inflammatory, and immunomodulatory activities, which may contribute to the therapeutic potential of the formulation. Heavy metal analysis performed using atomic absorption spectroscopy confirmed that lead, arsenic, cadmium, and mercury were below detectable limits and within the permissible limits prescribed by AYUSH. Microbial analysis indicated the absence of bacterial and fungal growth. Specific pathogen tests confirmed that Escherichia coli, Salmonella species, Staphylococcus aureus, and Pseudomonas aeruginosa were not detected. Pesticide residue analysis demonstrated the absence of organochlorine, organophosphorus, carbamate, and pyrethroid residues. In addition, aflatoxin analysis confirmed that aflatoxins B1, B2, G1, and G2 were not detected in the sample. These results collectively suggest that the prepared formulation complies with the recommended safety and quality standards. Therefore, the study supports the traditional use of Milagu Mathirai and provides scientific evidence for its quality and safety.

CONCLUSION

The present study established the physicochemical characteristics, phytochemical composition, and safety parameters of the Siddha formulation *Milagu Mathirai*. The analytical findings confirmed that the formulation complies with acceptable quality standards and is free from harmful contaminants such as heavy metals, microbial pathogens, pesticide residues, and aflatoxins. The presence of several bioactive phytoconstituents may

contribute to its therapeutic potential in respiratory disorders. These results provide preliminary scientific evidence supporting the traditional use of this formulation. Further pharmacological and clinical investigations are required to validate its efficacy and mechanism of action.

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CONFLICT OF INTEREST
The Author declares no conflict of interest.

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