



Research Article

EVALUATION OF QUALITY AND SAFETY PARAMETERS OF *SHENBAGATHI MATHIRAI* USING PLIM GUIDELINES

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ABSTRACT

Shenbagathi Mathirai is a classical Siddha polyherbal formulation indicated for its laxative action. Analytical evaluation is necessary to determine its pharmaceutical quality and safety. **Objective:** To evaluate the physicochemical characteristics and safety parameters of *Shenbagathi Mathirai* prepared according to Siddha literature. **Materials and Methods:** The formulation was prepared using authenticated raw materials including *Michelia champaca*, *Syzygium aromaticum*, *Costus speciosus*, *Elettaria cardamomum*, *Glycyrrhiza glabra*, and purified *Croton tiglium*. Organoleptic and physicochemical parameters such as loss on drying, ash values, extractive values, pH, uniformity of weight, and disintegration time were assessed as per PLIM guidelines. Safety parameters including heavy metal analysis (AAS), microbial load, specific pathogens, pesticide residues, and aflatoxins were also evaluated. **Results:** The formulation showed acceptable physicochemical characteristics with loss on drying (8.3%), total ash (0.89%), water-soluble extractive value (10.53%) and alcohol-soluble extractive value (6.66%) and pH (7.5). Heavy metals were not detected. Microbial load, specific pathogens, pesticide residues, and aflatoxins were not detected. **Conclusion:** The findings confirm that *Shenbagathi Mathirai* complies with established quality and safety standards, supporting its suitability for therapeutic use.

INTRODUCTION

Siddha medicine is one of the oldest traditional systems of medicine practiced in South India, which emphasizes the maintenance of equilibrium among the three fundamental humours- *Vatham*, *Pitham*, and *Kabam*- to ensure health and well-being. The system employs herbal, mineral, and herbo-mineral formulations, along with appropriate dietary and lifestyle practices, for the prevention and management of various diseases in a holistic manner. According to Siddha principles, constipation is mainly caused by the aggravation of *Vatha kutram*, which regulates movement and elimination functions in the body^[1]. When *Vatham* becomes deranged, it leads to intestinal dryness, reduced peristaltic activity, and the formation of hard stools, resulting in difficulty in bowel evacuation.

Improper dietary habits, suppression of natural urges, insufficient intake of fluids, mental stress, and sedentary lifestyle are considered major contributing factors for the development of constipation. Management in Siddha medicine focuses on correcting the imbalance of humours through appropriate therapeutic approaches. Purgation therapy and the administration of laxative formulations are commonly employed to facilitate bowel movement and restore normal physiological functions. The classical Siddha literature *Agathiyar 2000* (third part) mentions *Shenbagathi Mathirai* as a formulation possessing laxative properties and used in the management of constipation^[2]. Although such formulations have been used traditionally for a long period, scientific validation and analytical evaluation are essential to ensure their quality, safety, and efficacy. Variations in raw materials, purification procedures, and preparation methods may influence the therapeutic outcome of the medicine. Therefore, physicochemical and microbiological analysis is necessary to establish the identity, purity, and safety of the formulation.

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MATERIALS AND METHODS**Collection of Active Ingredients**

The raw drugs required for the preparation of *Shenbagathi Mathirai* were procured from a reputed **Ingredients of *Shenbagathi Mathirai***

raw drug store in Thuckalay, Kanyakumari district, Tamil Nadu.

Table 1: Ingredients of SGM

S.No	Raw Drugs Tamil name/ Binomial Name	Parts Used	Quantity After Purification
1	<i>Shenbagamottu (Michelia champaca)</i>	Flower bud	35 grams
2	<i>Kirambu (Syzygium aromaticum)</i>	Flower bud	35 grams
3	<i>Kostam (Costos speciosus)</i>	Bark	35 grams
4	<i>Elam (Elettaria cardamomum)</i>	Seed	35 grams
5	<i>Athimathuram (Glycyrrhiza glabra)</i>	Bark	35 grams
6	<i>Nervalam (Croton tiglium)</i>	Seed	175 grams

Identification and Authentication

The experts in the Gunapadam department of the Government Siddha Medical College and Hospital in Palayamkottai, Tirunelveli, Tamil Nadu, identified and verified the raw materials used to prepare SGM.

Purification

The purification procedure was carried out in accordance with traditional Siddha literature^[3,4].

Preparation of SGM

The purified raw drugs were powdered and triturated in a stone mortar with the addition of water for approximately three hours to obtain a uniform paste. The paste was then rolled into tablets weighing approximately 1.2 g and dried in shade.

Administration of the Drug

Route of Administration: Oral

Dose :1/4 *Kalanju*

Adjuvant: Honey and dried ginger decoction

Indication: laxative

Organoleptic Evaluation

The organoleptic parameters of the sample SGM were evaluated by assessing its colour, odour, taste, and texture.

Physicochemical Evaluation

The SGM sample was evaluated for foreign matter, loss on drying, total ash content, acid insoluble ash, water soluble extract value, and alcohol soluble extract value according to PLIM guidelines^[5].

Weight Variation

Twenty randomly selected sample units were weighed individually using a calibrated analytical balance, and the average weight was calculated. The percentage deviation from the mean weight was determined^[8].

Heavy Metal Analysis

Heavy metal content was determined using Atomic Absorption Spectrometry (AAS) (Model AA 240 Series). The concentrations of lead (Pb), cadmium (Cd), mercury (Hg), and arsenic (As) were quantified.

Pesticide Residue

The presence of pesticide residues, including organochlorine pesticides, organophosphorus pesticides, organocarbamates, and pyrethroids, was evaluated using standard analytical methods^[9].

Microbial Contamination and Aflatoxins

Microbial analysis was performed to detect specific pathogens, including *Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. Total aerobic bacterial count was also determined. Aflatoxins (B1, B2, G1, and G2) were analyzed using validated analytical methods^[10].

RESULTS**Organoleptic Evaluation**

State - Solid

Nature - Fine

Odour - Characteristic

Touch - Soft

Appearance - Dark brownish

Physicochemical Analysis

Table 2: Physicochemical analysis of SGM

S.No	Parameter	Mean (n=3) SD
1.	Loss on drying at 105°C (%)	8.3 ± 0.43
2.	Total ash (%)	0.89 ± 0.05
3.	Acid insoluble ash (%)	0 ± 0
4.	Water soluble extractive (%)	10.53 ± 0.37
5.	Alcohol Soluble extractive (%)	6.66 ± 0.76
6.	pH	7.5
7.	Uniformity of weight	0.802g (none deviates beyond permissible limits)
8.	Disintegration time	17.67±5.3 mins

Heavy Metal Analysis

Table 3: Heavy metal analysis of SGM

Heavy Metal	Absorption 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

*BDL – Below Detection Limit

Microbial Contamination

Total aerobic bacterial count - Absent

Total fungal count – Absent

Test For Specific Pathogens

Escherichia coli – Absent

Salmonella spp. – Absent

Staphylococcus aureus – Absent

Pseudomonas aeruginosa – Absent



Fig 1: Culture plate with E-coli (EC) specific medium

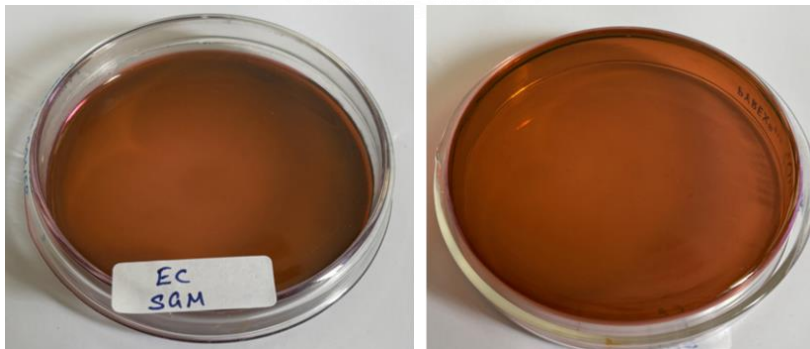


Fig 2: Culture plate with Salmonella (SA) specific medium



Fig 3: Culture plate with *Staphylococcus Aureus* (ST) specific medium

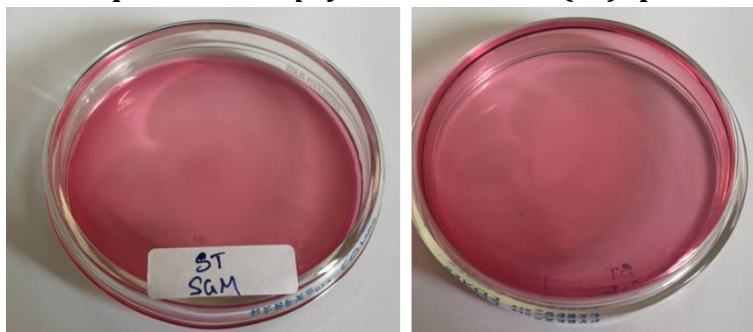
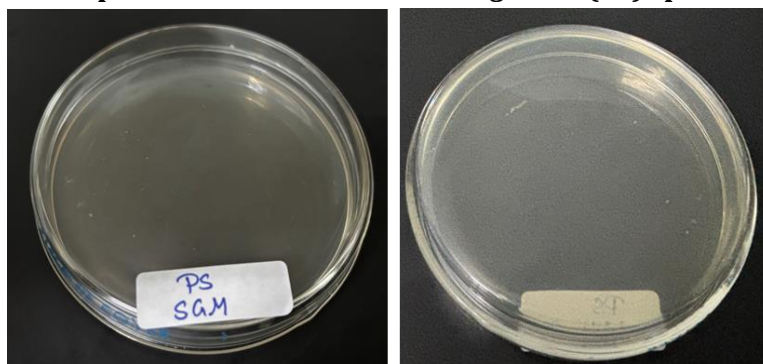


Fig 4: Culture plate with *Pseudomonas Aeruginosa* (PS) specific medium



Pesticide Residue

Table 4: Pesticide residue of SGM with AYUSH limit

Pesticide residue	Sample SGM	Ayush Limit (mg/kg)
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
Organo Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
Organo carbamates		
Carbofuran	BQL	0.1mg/kg
Pyrethroid		
Cypermethrin	BQL	1mg/kg

*BQL - Below quantification limit

Aflatoxin

Table 5: Aflatoxin assay of SGM with AYUSH limit

Aflatoxin	Sample SGM	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	0.5 ppm (0.5mg/kg)

DISCUSSION

The analytical evaluation of SGM was carried out to assess its quality and safety according to PLIM

guidelines. The organoleptic evaluation of SGM showed a dark brown solid tablet with a soft touch and fine

nature. Organoleptic characteristics serve as preliminary quality control parameters for herbal formulations and help in identifying the authenticity and consistency of the prepared drug.

Physicochemical parameters serve as key indicators of purity and stability of herbal formulations. The loss on drying value (8.3%) reflects the moisture content present in the formulation. Moisture content within acceptable limits is important for maintaining stability and preventing microbial growth during storage. The total ash value (0.89%) reflects minimal inorganic impurities, while the absence of acid-insoluble ash indicates that the formulation is free from silica or earthy contaminants. The water-soluble extractive value (10.53%) and alcohol-soluble extractive value (6.66%) indicate the presence of active phytochemical constituents that are soluble in respective solvents. The pH of the formulation (7.5) indicates that the preparation is slightly alkaline, which may contribute to its suitability for gastrointestinal administration.

The average tablet weight (0.802gm) confirms uniformity in preparation, ensuring consistent dosage. The disintegration time indicates that the tablet disperses adequately when administered with honey or dried ginger decoction, which supports its therapeutic action as a laxative.

Safety evaluation revealed that heavy metals such as lead, mercury, arsenic and cadmium were below detection levels. These findings confirm that the formulation does not pose toxicological risks related to heavy metal contamination. Microbial analysis confirmed the absence of bacterial and fungal contamination, as well as specific pathogens such as *Escherichia coli*, *Salmonella*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. This indicates that the preparation process and storage conditions are maintained at adequate hygienic standards. Furthermore, pesticide residue analysis demonstrated that all tested organochlorine, organophosphorus, organocarbamate, and pyrethroid pesticides were below quantification limits. Aflatoxins (B1, B2, G1, and G2) were not detected in the sample.

Overall, the analytical findings demonstrate that SGM possesses acceptable physicochemical properties and meets the required safety parameters, supporting its quality and suitability for therapeutic use.

CONCLUSION

The present analytical study demonstrates that *Shenbagathi Mathirai* possesses acceptable physicochemical characteristics according to PLIM guidelines. Heavy metals, microbial contamination, pesticide residues, and aflatoxins were found to be within permissible limits or absent. Therefore, the formulation can be considered safe and of good quality for therapeutic use as a laxative. However, further pharmacological and clinical studies are required to scientifically validate its therapeutic efficacy.

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