IJPSR (2026), Volume 17, Issue 4 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 24 October 2025; received in revised form, 19 December 2025; accepted, 31 December 2025; published 01 April 2026

PHARMACOPOEIAL STANDARDIZATION AND QUALITY PROFILING OF *PARANGI KASHAYAM*: A TRADITIONAL SIDDHA FORMULATION

P. V. Arunbalaji * and A. Muneeswaran

Department of PG Varma Maruthuvam, Government Siddha Medical College, Palayamkottai, Tirunelveli - 627002, Tamil Nadu, India.

Keywords:

Parangi kashayam, Siddha standardization, PLIM guidelines, HPTLC fingerprinting, *Perumootu vatham*

Correspondence to Author:
Dr. P. V. Arunbalaji

PG Scholar,
Department of PG Varma Maruthuvam, Government Siddha Medical College, Palayamkottai, Tirunelveli - 627002, Tamil Nadu, India.

E-mail: p.v.arunbalaji@gmail.com

ABSTRACT: *Parangi Kashayam* is a traditional Siddha decoction used for *Perumootu vatham* (Osteoarthritis) that lacks established pharmacopoeial standards despite its clinical use. This study aimed to develop comprehensive quality control parameters following PLIM guidelines through physicochemical profiling, chromatographic fingerprinting, and safety validation. Authenticated herbs including *Smilax china*, *Zingiber officinale*, and *Senna alexandriana* were formulated according to *Kumbamuni Vatha Nithanam 800*. Various physicochemical parameters were determined, and HPTLC fingerprinting was performed using toluene: ethyl acetate: formic acid (5:2:0.1 v/v/v) as the mobile phase with detection at 254 nm, 366 nm, and post-derivatization. Safety profiling included analysis of heavy metals by ICP-MS, pesticides by GC-MS, aflatoxins by HPLC, and microbial contamination testing. Physicochemical analysis revealed moisture content of 9.09±0.24% w/w, total ash of 4.74±0.18% w/w, acid-insoluble ash of 0.10±0.02% w/w, and pH of 5.20±0.03. The water-extractive value (15.37±0.32% w/w) was significantly higher than the alcohol-extractive value (10.50±0.21% w/w). HPTLC analysis generated reproducible fingerprints with 20 distinct spots having Rf values ranging from 0.04 to 0.82. Heavy metals, pesticides, and aflatoxins remained below quantification limits. The total bacterial count was 565 CFU/g and yeast-mould count was 26 CFU/g, both complying with pharmacopoeial limits, while pathogenic organisms were absent. These established parameters provide quality control benchmarks for pharmaceutical production and pharmacological investigation of this clinically relevant formulation.

INTRODUCTION: Osteoarthritis affects over 250 million individuals globally, with prevalence increasing due to aging populations and obesity [1]. While conventional pharmacotherapy provides symptomatic relief, concerns regarding adverse effects have intensified interest in traditional medicine systems [2].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.17(4).1190-98

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(4).1190-98

Osteoarthritis management within Siddha therapeutics emphasizes herbal medicines targeting joint pathology through *Vatham kutram* modulation [3].

Parangi Kashayam represents one such formulation prescribed for *Perumootuvatham* (Osteoarthritis), yet remained analytically uncharacterized. Despite documented therapeutic utility in classical Siddha text [4] *Parangi Kashayam* requires comprehensive analytical characterization to establish standardized quality parameters essential for pharmaceutical production and clinical research. *Parangi Kashayam*, described in classical siddha text, [4] comprises three herbal constituents:

Smilax china L. (Parangipattai), Zingiber officinale Roscoe (Sukku), and *Senna alexandriana Mill. (Nilavagai).* Phytochemical investigations reveal anti-inflammatory saponins in *S. china,* [5] gingerols with COX-2 inhibitory activity in *Z. officinale,* [6] and sennosides with immunomodulatory properties in *S. alexandriana* [7]. Despite promising ethnopharmacological rationale, Siddha Varmam-specific decoctions remain under-represented in pharmaceutical literature. The Pharmacopoeial Laboratory for Indian Medicine (PLIM) mandates specific quality parameters like physicochemical constants, chromatographic fingerprints, and safety profiling for herbal drug standardization [8]. Recent WHO guidelines emphasize the necessity of quality-assured traditional medicines to ensure therapeutic consistency and consumer safety [9]. This study addresses the critical knowledge gap by establishing comprehensive pharmacopoeial standards for *Parangi Kashayam* following PLIM protocols. The specific objectives of this study were:

1. To establish physicochemical quality control parameters following PLIM guidelines.
2. To develop HPTLC fingerprints for formulation standardization and identity verification.
3. To validate safety through comprehensive toxicological and microbiological profiling.
4. To propose pharmacopoeial specifications for pharmaceutical-grade production.

MATERIALS AND METHODS:

Study Formulation -*Parangi Kashayam:* *Parangi Kashayam* is a traditional Siddha Varmam polyherbal decoction prepared from *Smilax china, Zingiber officinale, and Senna alexandriana* as described in the Siddha literature '*Kumbamuni Vatha Nithanam 800,*[4] indicated for *Perumootu vatham* (Osteoarthritis). Since the PLIM guidelines primarily provide analytical parameters for *Kashaya Chooranam* (coarsely powdered); the corresponding standards were adapted for the present study [8].

Plant Materials and Authentication: Raw ingredients were procured from authenticated suppliers in Thakkalai, Kanyakumari District, with dust-free, moisture-protected storage. Botanical authentication was performed at Siddha Regional Research Institute, Poojappura, Kerala (Authentication Numbers: *Senna alexandriana Mill*. - SRRI1202202519; *Zingiber officinale Roscoe* - SRRI200215; *Smilax china L*. - SRRI1202202518). Authenticated specimens were deposited in the institutional herbarium. Authenticated samples were subsequently processed for formulation preparation.

Formulation Preparation: *Parangi Kashayam* was prepared following '*Kumbamuni vatha nithanam 800* [4] specifications. Individual herbs were shade-dried, pulverized using a mechanical grinder, and passed through a 40-mesh sieve. The ingredients were mixed in prescribed proportions **Table 1** with 540 mL purified water in a stainless-steel vessel. The mixture was heated until volume reduced to approximately 90 mL, filtered hot through Whatman Grade 1 filter paper, and the filtrate was used for analysis.

TABLE 1: COMPOSITION OF *PARANGI KASHAYAM*

S. no.	Botanical Name	Tamil Name	Part Used	Quantity
1	*Smilax china* L.	*Parangipattai*	Root	9 parts
2	*Zingiber officinale* Roscoe	*Sukku*	Rhizome	6 parts
3	*Senna alexandriana* Mill.	*Nilavagai*	Leaves	7.5 parts

Organoleptic Evaluation: Physical characteristics including appearance, colour, odour, texture, taste, and flow properties were systematically following standard protocols [10].

In addition, comprehensive physicochemical analyses and High-Performance Thin Layer Chromatography (HPTLC) profiling were performed at the Siddha Central Research Institute, Arumbakkam, Chennai, Tamil Nadu.

Physicochemical Analysis: All determinations were performed following PLIM guidelines [11].

Loss on Drying (Moisture Content): Two grams of formulation powder was heated at 105°C for 5 hours until constant weight was achieved. Moisture content was calculated as percentage weight loss [11].

Ash Values: Total ash was determined by Incinerating a 2 g sample in a silica crucible at

450°C until white ash formed. Acid-insoluble ash was obtained by boiling total ash with 25 mL of 6N HCl, filtering through ashless filter paper, and re-igniting. Water-soluble ash was calculated as difference between total ash and water-insoluble residue after aqueous extraction [12].

Extractive Values: Five grams of formulation was macerated separately with 100 mL of 95% ethanol and distilled water for 24 hours with intermittent shaking for initial 6 hours. After filtration and solvent removal, residues were evaporated to dryness at 105°C and weighed. Extractive values were calculated as percentage w/w [13].

pH Determination: Hydrogen ion concentration was determined potentiometrically using a glass electrode in combination with a reference electrode connected to a digital pH meter [14].

High-Performance Thin Layer Chromatography (HPTLC):

Sample Preparation: One gram of formulation was extracted with 10 mL methanol under sonication for 15 minutes, filtered through 0.45 µm membrane, and used as test solution.

Chromatographic Conditions: Samples (5 µL and 7 µL) were applied as 8 mm bands on pre-coated silica gel 60 F_{254} aluminum plates (10 × 10 cm, Merck) using CAMAG applicator with ATS4 autosampler. Plates were developed in twin-trough chamber pre-saturated for 20 minutes with mobile phase toluene: ethylacetate: formic acid (5:2:0.1 v/v/v) to 80 mm distance [15].

Development and Detection: Developed plates were visualized under UV 254 nm and 366 nm using CAMAG UV Cabinet and documented with CAMAG Visualizer. Densitometric scanning was performed using CAMAG TLC Scanner 4 controlled by WinCATS software. For derivatization, plates were dipped in vanillin-sulphuric acid reagent, heated at 105°C for 5 minutes, and scanned at 520 nm [16].

Safety Profiling: All safety assessments were conducted at NABL-accredited Tamil Nadu Test House, Chennai.

Heavy Metal Analysis: Lead, cadmium, mercury, and arsenic were quantified by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) following AOAC methods after microwave-assisted acid digestion [17].

Aflatoxin Detection: Aflatoxins B1, B2, G1, and G2 were analysed by High-Performance Liquid Chromatography (HPLC) with fluorescence detection following Ayurvedic Pharmacopoeia procedures [18].

Pesticide Residue Analysis: Organochlorine and organophosphorus pesticides were quantified by Gas Chromatography-Mass Spectrometry (GC-MS) following EPA 8081B and APHA 6630 protocols [19].

Microbial Quality Assessment: Total bacterial count and yeast-mould count were determined by pour-plate method (IS 5402:2012RA2018, IS 5403:1999RA2005). Specific pathogens (*Escherichia coli*, *Salmonella* spp., *Pseudomonas aeruginosa*, *Staphylococcus aureus*) were tested following respective IS standards [20].

Statistical Analysis: All physicochemical determinations were performed in triplicate (n=3). Results are expressed as Mean ± Standard Deviation (SD). Data were analysed using GraphPad Prism version 8.0.

RESULTS:

Organoleptic Characteristics: *Parangi Kashayam* presented as yellowish-brown granular material with characteristic herbal aroma, rough texture, non-free flowing property, and bitter-sweet taste. Its dual bitter-sweet taste corresponded with the sensory properties of its botanical components **Table 2.**

TABLE 2: ORGANOLEPTIC EVALUATION OF *PARANGI KASHAYAM*

Parameter	Observation
State	Solid
Nature	Granular
Odour	Characteristic Herbal Odour
Touch	Rough
Flow Property	Non-Free Flowing
Appearance	Yellowish-Brown
Taste	Bitter and Sweet

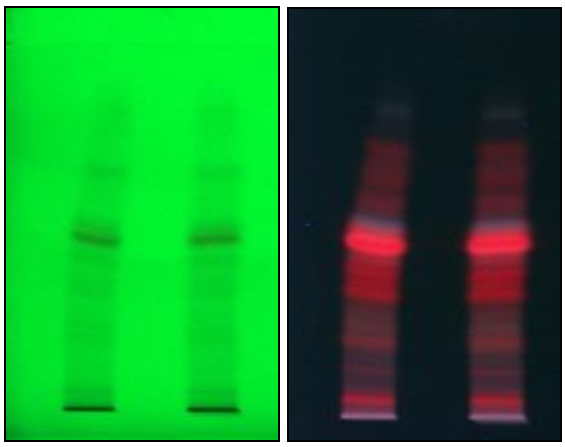
Physicochemical Parameters: Physicochemical analysis demonstrated moisture content of 9.09±0.24% w/w suggests sufficient drying to ensure stability during storage, acid-insoluble ash

value of 0.10±0.02% w/w demonstrated negligible silica-based impurities, while total ash 4.74±0.18% w/w remained within acceptable limits for herbal preparations. The water-extractive value (15.37±0.32% w/w) was higher than the alcohol-extractive value (10.50±0.21% w/w) suggesting predominant hydrophilic bioactive composition consistent with decoction-based extraction methodology. Slightly acidic pH (5.20±0.03) may enhance certain phytochemical stability and bioavailability. These analytical measurements confirmed the formulation's quality attributes and storage stability **Table 3.**

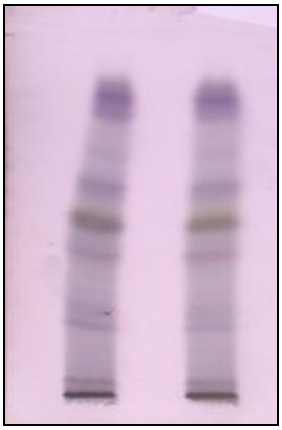
TABLE 3: PHYSICOCHEMICAL PARAMETERS OF *PARANGI KASHAYAM*

Parameter	Result (Mean ± SD, n=3)
Loss on drying at 105°C	9.09 ± 0.24% w/w
Total ash	4.74 ±0.18% w/w
Acid-insoluble ash	0.10 ± 0.02% w/w
Water-soluble ash	1.32 ± 0.08% w/w
Alcohol-soluble extractives	10.50 ± 0.21% w/w
Water-soluble extractives	15.37 ± 0.32% w/w
pH (4% aqueous solution)	5.20 ± 0.03

HPTLC Fingerprinting: Chromatographic analysis revealed distinct phytochemical patterns under different detection modes. UV 254 nm detection identified four major spots (Rf: 0.06, 0.46, 0.65, 0.81) representing aromatic compounds. UV 366 nm fluorescence demonstrated ten spots (Rf: 0.04, 0.12, 0.19, 0.32, 0.38, 0.47, 0.58, 0.64, 0.71, 0.81) indicating flavonoids and phenolic constituents. Post-derivatization with vanillin-sulphuric acid revealed six additional spots (Rf: 0.19, 0.38, 0.47, 0.50, 0.57, 0.82) with varied chromogenic responses confirming terpenoid and glycosidic content **Fig. 1, Table 4.**



(A) UV254 NM **(B) UV366 NM**



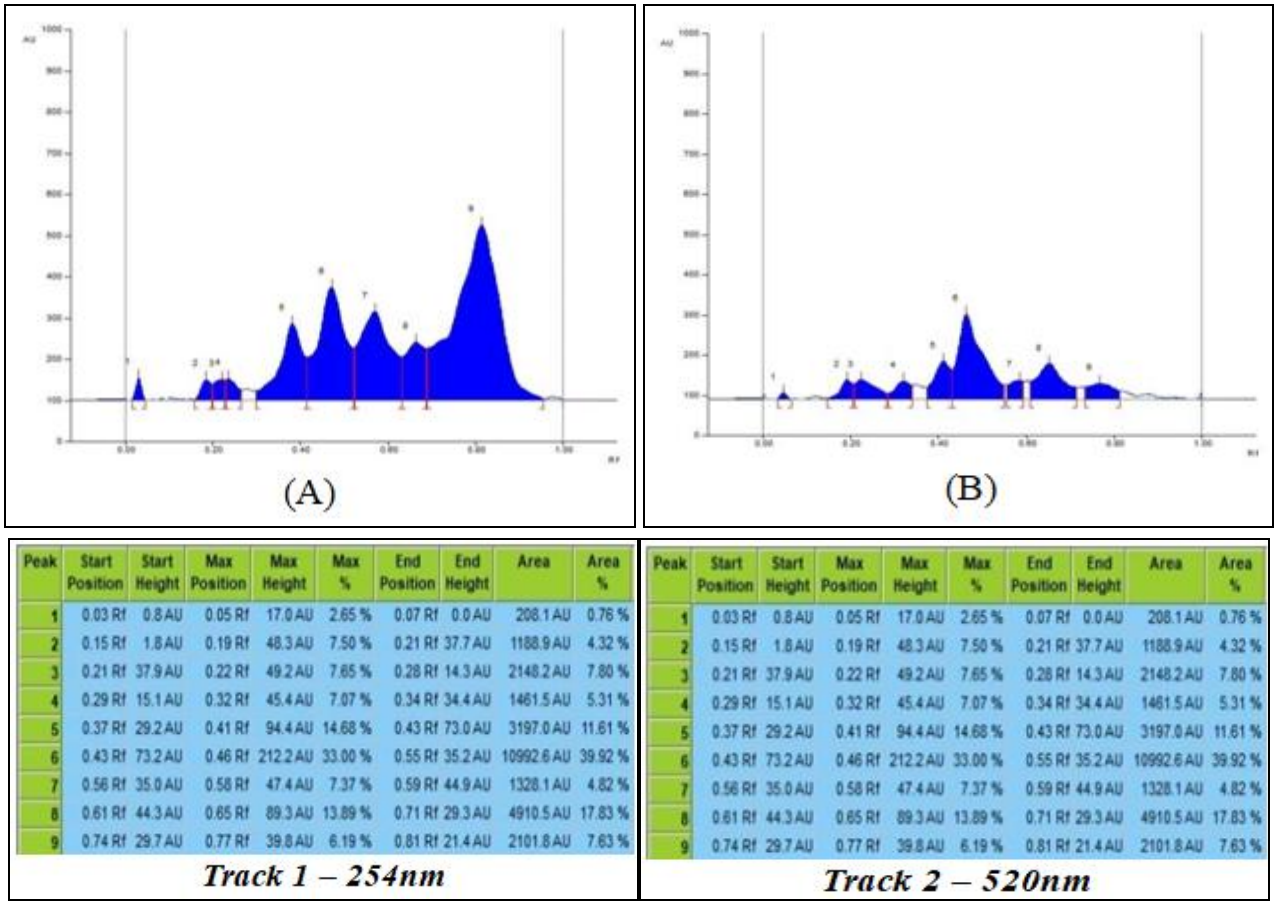
(C) WHITE LIGHT AFTER DIPPINGIN VANILLINSULPHURIC ACID

FIG. 1: HPTLC FINGERPRINTS OF PARANGI KASHAYAM AT (A) UV 254 nm, (B) UV 366 nm, AND (C) WHITE LIGHT AFTER DIPPING IN VANILLIN-SULPHURIC ACID

TABLE 4: RETENTION FACTOR (Rf) VALUES OF *PARANGI KASHAYAM* UNDER DIFFERENT DETECTION MODES

Detection mode	No. of Spots	Rf Values	Major Phytochemical Constituents Indicated	Visual characteristics
UV 254 nm	4	0.06, 0.46, 0.65, 0.81	Aromatic compounds	Dark spots on green background
UV 366 nm	10	0.04, 0.12, 0.19, 0.32, 0.38, 0.47, 0.58, 0.64, 0.71, 0.81	Flavonoids and phenolic constituents	Fluorescent spots (blue, green, yellow)
Post-derivatization (Vanillin-Sulphuric acid)	6	0.19, 0.38, 0.47, 0.50, 0.57, 0.82	Terpenoids and glycosides	Coloured spots (violet, brown, orange)

Densitometric scanning at 254 nm and 520 nm generated reproducible peak patterns with multiple maxima, establishing formulation-specific chromatographic signatures **Fig. 2.**



Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.03 Rf	0.8 AU	0.05 Rf	17.0 AU	2.65 %	0.07 Rf	0.0 AU	208.1 AU	0.76 %
2	0.15 Rf	1.8 AU	0.19 Rf	48.3 AU	7.50 %	0.21 Rf	37.7 AU	1188.9 AU	4.32 %
3	0.21 Rf	37.9 AU	0.22 Rf	49.2 AU	7.65 %	0.28 Rf	14.3 AU	2148.2 AU	7.80 %
4	0.29 Rf	15.1 AU	0.32 Rf	45.4 AU	7.07 %	0.34 Rf	34.4 AU	1461.5 AU	5.31 %
5	0.37 Rf	29.2 AU	0.41 Rf	94.4 AU	14.68 %	0.43 Rf	73.0 AU	3197.0 AU	11.61 %
6	0.43 Rf	73.2 AU	0.46 Rf	212.2 AU	33.00 %	0.55 Rf	35.2 AU	10992.6 AU	39.92 %
7	0.56 Rf	35.0 AU	0.58 Rf	47.4 AU	7.37 %	0.59 Rf	44.9 AU	1328.1 AU	4.82 %
8	0.61 Rf	44.3 AU	0.65 Rf	89.3 AU	13.89 %	0.71 Rf	29.3 AU	4910.5 AU	17.83 %
9	0.74 Rf	29.7 AU	0.77 Rf	39.8 AU	6.19 %	0.81 Rf	21.4 AU	2101.8 AU	7.63 %

FIG. 2: DENSITOMETRIC SCANS OF *PARANGI KASHAYAM* AT (A) 254 NM AND (B) 520 NM

Safety Validation:

Heavy Metal Analysis: All heavy metals remained below quantification limits: lead <0.01 ppm (limit: 10 ppm), cadmium <0.01 ppm (limit: 0.3 ppm), mercury <0.01 ppm (limit: 1.0 ppm), and arsenic <0.01 ppm (limit: 3.0 ppm) **Table 5.**

TABLE 5: HEAVY METAL ANALYSIS OF *PARANGI KASHAYAM*

Parameter	Method	Result	Limit (unit – ppm)
Lead (Pb)	ICPMS	BQL (LOQ:0.01)	NMT 10mg/kg
Cadmium (Cd)	ICPMS	BQL (LOQ:0.01)	NMT 0.3mg/kg
Mercury (Hg)	ICPMS	BQL (LOQ:0.01)	NMT 1.0mg/kg
Arsenic (As)	ICPMS	BQL (LOQ:0.01)	NMT 3.0mg/kg

BQL: Below Quantification Limit; LOQ: Limit of Quantification; NMT: Not More Than

Aflatoxin Screening: All aflatoxins were undetectable: B1, B2, G1, and G2 <0.001 ppb (limits: 2, 5, 5, 5 ppb respectively) **Table 6.**

TABLE 6: AFLATOXIN ANALYSIS OF *PARANGI KASHAYAM*

Parameter	Method	Result	Limit unit- ppb
Aflatoxins B1	Ayurvedic pharmacopoeia	BQL (LOQ:0.001)	<2
Aflatoxins B2	Ayurvedic pharmacopoeia	BQL (LOQ:0.001)	<5
Aflatoxins G1	Ayurvedic pharmacopoeia	BQL (LOQ:0.001)	<5
Aflatoxins G2	Ayurvedic pharmacopoeia	BQL (LOQ:0.001)	<5

Pesticide Residue Testing: Comprehensive screening of 43 pesticides (organochlorine, organophosphorus, and pyrethroid compounds) showed all analytes below detection limits (LOQ: 0.01 mg/kg) **Table 7** - abbreviated version.

TABLE 7: PESTICIDE RESIDUE ANALYSIS OF *PARANGI KASHAYAM*

Pesticide residues	Results
Alachalor	BQL (LOQ:0.01)
OC – pesticides	Method: EPA8081B (mg/kg)
Aldrin	BQL (LOQ:0.01)
Dieldrin	BQL (LOQ:0.01)
Chlordane	BQL (LOQ:0.01)
Oxychlordane	BQL (LOQ:0.01)
o,p, -DDT	BQL (LOQ:0.01)
pp-DDT	BQL (LOQ:0.01)
p,p-TDE	BQL (LOQ:0.01)
P,p-DDE	BQL (LOQ:0.01)
Endosulfan-alfa	BQL (LOQ:0.01)
Endosulfan-beta	BQL (LOQ:0.01)
Endosulfansulphate	BQL (LOQ:0.01)
Endrin	BQL (LOQ:0.01)
Heptachlor	BQL (LOQ:0.01)
Heptachlorepoxide	BQL (LOQ:0.01)
Hexachlorobenzene	BQL (LOQ:0.01)
Alfa-HCL	BQL (LOQ:0.01)
Beta-HCL	BQL (LOQ:0.01)
Delta-HCL	BQL (LOQ:0.01)
Lindane	BQL (LOQ:0.01)
Quintozene	BQL (LOQ:0.01)
Methyl pentachlorophenyl sulphide	BQL (LOQ:0.01)
Pentachloroaniline	BQL (LOQ:0.01)
OP- Pesticides –L	Method: EPA8081B (mg/kg)
Dichlorvos	BQL (LOQ:0.01)
Diazinon	BQL (LOQ:0.01)
Chlorpyrifos-methyl	BQL (LOQ:0.01)
Parathion-methyl	BQL (LOQ:0.01)
OP-pesticides G	BQL (LOQ:0.01)
Azinphos-methyl	BQL (LOQ:0.01)
Chlorfenvinphos	BQL (LOQ:0.01)
Chlorpyrifos	BQL (LOQ:0.01)
Ethion	BQL (LOQ:0.01)
Fenitrothin	BQL (LOQ:0.01)
Fonofos	BQL(LOQ:0.01)
Malathion	BQL (LOQ:0.01)
Methidathion	BQL (LOQ:0.01)
Parathion	BQL (LOQ:0.01)
Phosalone	BQL (LOQ:0.01)
Pyrethroids	BQL (LOQ:0.01)
Cypermethrin and isomers	BQL (LOQ:0.01)
Deltamethrin	BQL (LOQ:0.01)
Fenvalerate	BQL (LOQ:0.01)
Permethrin	BQL (LOQ:0.01)
Pyrethrins	BQL (LOQ:0.01)

Microbial Quality Assessment: Total bacterial count (565 CFU/g) and yeast-mould count (26 CFU/g) remained well below pharmacopoeial limits (1000 and 100 CFU/g respectively). Testing confirmed absence of pathogenic organisms: *Escherichia coli*, *Salmonella* spp., *Pseudomonas aeruginosa*, and *Staphylococcus aureus* **Table 8.**

TABLE 8: MICROBIAL QUALITY ASSESSMENT OF *PARANGI KASHAYAM*

Total plate Count	IS14648:2011	CFU/g	565	NMT1000
Yeast and Mould Count	IS14648:2011	CFU/g	26	NMT100

TABLE 9: PATHOGENIC MICROBIAL CONTAMINATION SCREENING RESULTS FOR *PARANGI KASHAYAM*

Pseudomonas aeruginosa	IS14648:2011	Perg	Per ml	Absent
Escherichia coli	IS14648:2011	Perg	Per ml	Absent
Staphylococcus aureus	IS14648:2011	Perg	Per ml	Absent
Salmonella spp.,	IS14648:2011	Perg	Per ml	Absent

Total bacterial count (565 CFU/g) and yeast-mould count (26 CFU/g) remained significantly below regulatory limits (1000 and 100 CFU/g respectively). Testing confirmed no contamination with disease-causing bacteria including *Escherichia coli*, *Salmonella* species, *Pseudomonas aeruginosa*, or *Staphylococcus aureus* **Table 9.**

DISCUSSION AND CONCLUSION: This investigation successfully establishes comprehensive pharmacopoeial standards for *Parangi Kashayam*, addressing a significant gap in Siddha formulation quality control. The study integrates traditional Siddha pharmaceutical wisdom with modern analytical validation, presenting a robust framework that ensures authenticity, reproducibility, and safety in *Parangi Kashayam* production and clinical application, particularly in Siddha Varmam therapeutics.

The physicochemical parameters revealed essential insights into formulation quality. The moisture content (9.09%) was within the acceptable pharmaceutical limit (<10%), indicating optimal storage stability under ambient conditions and reflecting proper adherence to traditional processing techniques. This value aligns with standardized Siddha formulations such as *thoothuvalaiyathi chooranam* (9.10±0.100%), [21] emphasizing the role of optimal moisture levels in preserving phytochemical integrity and preventing microbial proliferation. The low acid-insoluble ash (0.10%) demonstrates minimal silica contamination, confirming the superior purity of raw materials [22]. The total ash value (4.74%), remaining well below permissible limits, further substantiates meticulous adherence to classical Siddha processing practices. The extractive values highlight the predominance of polar bioactive constituents essential to *Kashayam* formulations, as a significantly higher water-extractive value (15.37%) compared to alcohol-extractive (10.50%) validates the traditional Siddha emphasis on aqueous extraction for efficient recovery of polar phytochemicals [23]. This observation correlates with the constituent phytochemistry: *Smilax china* contributing water-soluble steroidal saponins (Smilasaponins), [5] *Zingiber officinale* offering hydrophilic gingerols and shogaols with COX-2 inhibitory activity, [6] and *Senna alexandriana* yielding sennosides with immunomodulatory potential [7]. The slightly acidic pH (5.20) supports polyphenolic stability and enhances gastric absorption, consistent with Siddha principles that favour mild acidity for improved bioavailability [24].

HPTLC fingerprinting produced reproducible chromatographic profiles that serve as diagnostic tools for identity confirmation and adulteration detection, which are key requirements in Siddha drug standardization. The differential fluorescent spots under UV 254 nm and 366 nm revealed the presence of aromatic compounds, flavonoids, terpenoids, and saponins. Spots observed at Rf 0.47 and 0.58 (UV 366 nm) potentially represent flavonoid aglycones involved in anti-inflammatory activity, [5] supporting the traditional indication of *Parangi Kashayam* for inflammatory and arthritic disorders. Likewise, vanillin-reactive spots at Rf 0.19 and 0.38 may correspond to steroidal saponins from S. china, compounds known for cartilage-protective effect [5, 25]. These chromatographic signatures align with previously standardized Siddha formulation such as *Mathan thailam* [26], establishing a strong analytical precedent for polyherbal quality assessment.

The generated fingerprint thus provides a baseline reference for future marker-based standardization, fulfilling an essential need for analytical consistency in traditional Siddha pharmaceutics. The complete absence of heavy metals confirms compliance with international safety standards. Lead, cadmium, mercury, and arsenic pose significant neurotoxicity concerns in herbal products [17]. Similarly, undetectable aflatoxin [27] and pesticide residues ensure safety for long-term use in chronic conditions. The microbial load (565 CFU/g bacterial, 26 CFU/g yeast-mould) remained substantially below pharmacopoeial thresholds with absence of pathogens, confirming the microbiological safety of the formulation. This is particularly crucial since Siddha *Kashayams* traditionally rely on the intrinsic antimicrobial properties of their constituent herbs rather than synthetic preservatives. In comparison to previous Siddha formulation studies, often limited to single-drug standardization, this work demonstrates a more comprehensive, polyherbal standardization approach encompassing both physicochemical and chromatographic validation. The established PLIM-compliant framework not only supports quality assurance, [13] but also serves as a replicable model for other Varmam-specific *Kashayams* prescribed in classical Siddha texts. Overall, this study lays a solid foundation for the standardized, safe, and pharmacologically validated production of *Parangi Kashayam*. The established parameters ensure quality-assured manufacturing, enable identity verification, and safeguard therapeutic consistency. Beyond contributing to the modernization of Siddha pharmaceutics, these outcomes strengthen the bridge between ancient healing wisdom and modern scientific validation, paving the way for the evidence-based integration of Siddha medicine into mainstream healthcare systems.

Limitations and Future Directions: This study establishes quality parameters but does not correlate chromatographic markers with biological activity. Future bioassay-guided fractionation should identify specific phytomarkers responsible for anti-arthritic properties. Clinical correlation studies examining formulation efficacy in osteoarthritis patients using standardized outcome measures would validate therapeutic claims. Accelerated stability studies per ICH guidelines should determine shelf-life under tropical conditions.

Proposed Quality Control Specifications: Based on study findings, the following specifications are recommended for *Parangi Kashayam,*

TABLE 10: PROPOSED QUALITY CONTROL SPECIFICATIONS FOR *PARANGI KASHAYAM*

Parameter	Specification	Test Method
Moisture content	NMT 10.0% w/w	PLIM
Total ash	NMT 6.0% w/w	PLIM
Acid-insoluble ash	NMT 0.5% w/w	PLIM
Water-soluble extractives	NLT 12.0% w/w	PLIM
pH (4% solution)	4.5 - 6.0	IP 2018
HPTLC marker Rf values	0.19, 0.47, 0.58 (at 366 nm)	In-house method
Heavy metals	As per API limits	AOAC/ICPMS
Aflatoxins	Total NMT 5 ppb	API
Pesticide residues	Individual NMT 0.05 mg/kg	EPA 8081B
Total bacterial count	NMT 1000 CFU/g	IS 14648:2011
Yeast and mould count	NMT 100 CFU/g	IS 14648:2011
Pathogens	Absent/g	IS 14648:2011

NMT: Not More Than; NLT: Not Less Than; API: Ayurvedic Pharmacopoeia of India.

ACKNOWLEDGEMENTS: The authors gratefully acknowledge Dr. N. Venkatappan, MD (S), Principal, Government Siddha Medical College, for institutional support, and Dr. A. Muneeswaran, MD (S), Professor and Head, Department of PG Varma Maruthuvam, for his exceptional mentorship. Sincere thanks to Siddha Regional Research Institute, Poojappura, Kerala, for botanical authentication; Siddha Central Research Institute, Chennai, for analytical facilities; and Tamil Nadu Test House, Chennai, for safety assessments.

Funding: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Author Contributions: P. V. Arunbalaji: Conceptualization, methodology, investigation, formal analysis, writing original draft. A. Muneeswaran: Supervision, validation, writing - review and editing, project administration. Both authors have read and approved the final manuscript.

CONFLICT OF INTEREST: The authors declare no conflict of interest.

REFERENCES:

1. GBD 2021 Osteoarthritis Collaborators: Global, regional, and national burden of osteoarthritis, 1990–2020 and projections to 2050: a systematic analysis for the Global Burden of Disease Study 2021. Lancet Rheumatol 2023; 5(9): 508-522.
2. Luo C, Wang J and Guo J: Complementary, alternative, and integrative medicine therapies for knee osteoarthritis: a visual analytics analysis of the research domain. Front Med 2025; 12: 1586357.
3. Gangadharan T and Arumugam M: Siddha medicine and modern neuroscience: a synergistic approach to neurological care. 3 Biotech 2025; 15: 96.
4. Mohanaraj T: Kumbamuni Vatha Nithanam 800: Moolamum Uraiyum. 2nd Edition. Kanyakumari: Siddha Maruthuva Nool Veliyitalar 2021; 299.
5. Jiang S, Wei Q, Ye X, Luo D, Zhang X, Li Z, You P, Huang X and Liu Y: The Anti-Inflammatory Effect of Smilax china L. Extract on LPS-Stimulated THP-1 *via* Downregulation of MAPK and NF-κB Signaling Pathway. Evid Based Compl Alte Med 2021; 2021(1): 9958808.
6. Yücel Ç, Karatoprak GŞ, Açıkara ÖB, Akkol EK, Barak TH, Sobarzo-Sánchez E, Aschner M and Shirooie S: Immunomodulatory and anti-inflammatory therapeutic potential of gingerols and their nanoformulations. Front Pharmacol 2022; 13: 902551.
7. Le J, Ji H, Zhou X, Wei X, Chen Y, Fu Y, Ma Y, Han Q, Sun Y, Gao Y and Wu H: Pharmacology, toxicology, and metabolism of sennoside A, A medicinal plant-derived natural compound. Front Pharmacol 2021; 12: 714586.
8. Sahoo M, Dash S, Sahoo AC, Sahoo PK, Rath SS and Muduli P: Modern analytical methods for standardization of classical polyherbal formulations: A review. J Popul Ther Clin Pharmacol 2023; 30(17): 368-380.
9. Jain SD, Shrivastava SK, Agrawal A and Gupta AK: WHO guidelines for quality control of herbal medicines: From cultivation to consumption. Int J Pharm Chem Anal 2024; 11(3): 212-225.
10. Wang H, Chen Y, Wang L, Liu Q, Yang S and Wang C: Advancing herbal medicine: enhancing product quality and safety through robust quality control practices. Front Pharmacol 2023; 14: 1265178.
11. Ministry of AYUSH: Quality Control Manual for Ayurvedic, Siddha and Unani Formulations. New Delhi: Pharmacopoeial Commission for Indian Medicine & Homoeopathy 2022.
12. Ayurvedic Pharmacopoeia of India. Part I, Volume X. New Delhi: Department of AYUSH, Ministry of Health and Family Welfare, Government of India 2022; 145-148.
13. Noviana E, Indrayanto G and Rohman A: Advances in fingerprint analysis for standardization and quality control of herbal medicines. Front Pharmacol 2022; 13: 853023.
14. Indian Pharmacopoeia Commission: Indian Pharmacopoeia 2022. Volume I. Ghaziabad: Indian Pharmacopoeia Commission 2022.
15. Latimer GW: Official Methods of Analysis of AOAC International. 22nd Ed. Oxford: Oxford Uni Press 2023.
16. Patel K, Singh GK and Patel DK: A review on pharmacological and analytical aspects of diosgenin: A concise report. Nat Prod Bioprospect 2022; 12(1): 3.
17. Luo L, Wang B, Jiang J, Fitzgerald M, Huang Q, Yu Z, Li H, Zhang J, Wei J, Yang C and Zhang H: Heavy metal contaminations in herbal medicines: determination, comprehensive risk assessments, and solutions. Front Pharmacol 2021; 11: 595335.
18. Victor Jeyaraj SV, Loy MJ, Goh KW, Ming LC, Ser HL and Goh BH: Aflatoxin tests in herbal products and its quantification: Latest updates. Front Nutr 2022; 9: 956077.
19. Pandey AK: Good Agricultural and Collection Practices of Important Medicinal Plants. In: Textbook of Forest Science. Singapore: Springer Nature Sing 2025: 549-569.
20. Opuni KF, Kretchy JP, Agyabeng K, Boadu JA, Adanu T, Ankamah S, Appiah A, Amoah GB, Baidoo M and Kretchy IA: Contamination of herbal medicinal products in low-and-middle-income countries: A systematic review. Heliyon 2023; 9(9): 19191.
21. Thirunavukkarasu S, Prabhakaran R and Shree Devi MS: Physicochemical and phytochemical analysis of siddha formulation thoothuvalaiyathi chooranam. World J Adv Res Rev 2024; 23(03): 1699-1705.
22. Indrayanto G, Putra GS and Suhud F: Validation of in-house analytical methods: A complete guideline for pharmaceutical analysis. Profiles Drug Subst Excip Relat Methodol 2023; 48: 1-39.
23. Sivagami B and Sailaja B: Determination of phytochemical markers andrographolide, eugenol and zingerone in nilavembu kudineer by RP-HPLC method. J Appl Pharm Sci 2024; 14(10): 128-134.
24. Anand A, Gautam P and Ojha S: Application of nanotechnology for herbal medicine development: A review. Lett Drug Des Discov 2024; 21(8): 1325-1333.
25. Zhang Y, Li Q, Wang M and Liu X: Flavonoids induce apoptosis in leukemia cells through STAT3 inhibition and mitochondrial pathway activation. Phytomedicine 2023; 108: 154528.
26. Arunadevi R, Susila R, Murugammal S and Divya S: Preparation and standardization of Mathan Tailam: A classical Siddha formulation for diabetic ulcerative wound healing. J Ayurveda Integr Med 2020; 11(1): 10-15.
27. Rodrigues P, Santos C, Venâncio A and Lima N: Mycotoxin contamination in medicinal plants and herbal products: A global food safety concern. Food Control 2023; 142: 109245.

How to cite this article:
Arunbalaji PV and Muneeswara A: Pharmacopoeial standardization and quality profiling of *Parangi Kashayam*: a traditional siddha formulation. Int J Pharm Sci & Res 2026; 17(4): 1190-98. doi: 10.13040/IJPSR.0975-8232.17(4).1190-98.