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QUALITY CONTROL PARAMETERS AND SAFETY PROFILE OF SIDDHA HERBAL FORMULATION: PIRANDAI VADAGAM.

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Abstract

Introduction: Pirandai Vadagam is a traditional Siddha herbal formulation recommended for managing digestive disturbances and inflammatory disorders. It is prepared using thirteen medicinal ingredients. Establishing reliable quality control standards is crucial to ensure its safety, efficacy, and therapeutic consistency.

Objective: The present study was undertaken to develop and validate quality control parameters for Pirandai Vadagam.

Methods: The formulation was subjected to evaluation of organoleptic characters, physicochemical properties, heavy metal content, aflatoxin levels, and microbial load.

Results: The physicochemical analysis revealed that the loss on drying at 105 °C, total ash, acid-insoluble ash, and water-soluble extractive values were 15.38%, 6.18%, 0.93%, and 119.25%, respectively. Microbial counts and aflatoxin levels were found to be within the permissible pharmacopoeial limits. Likewise, the concentrations of heavy metals were within the safe threshold values.

Discussion and Conclusion: The established physicochemical parameters of Pirandai Vadagam fall within acceptable standards, indicating stability, purity, and favorable solubility that may enhance bioavailability. The absence of harmful levels of contaminants, heavy metals, and toxins supports the safety of this formulation, thereby justifying its continued use in Siddha clinical practice.

Keywords: Pirandai Vadagam; Siddha medicine; Herbal formulation; Quality control; Physicochemical analysis; Safety profile; Standardization.

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Introduction

Pirandai Vadagam is a traditional Siddha polyherbal formulation prescribed for digestive disorders and inflammatory conditions. It comprises a blend of thirteen ingredients, including *Cissus quadrangularis* (Pirandai), *Cuminum cyminum* (Seeragam), *Zingiber officinale* (Chukku), *Terminalia chebula* (Kadukkai), *Vigna mungo* (Ulundu), and *Allium sativum* (VellaiPoondhu), each contributing digestive, antimicrobial, antioxidant, or anti-inflammatory properties [1].

Heavy metals at trace levels-such as iron, zinc, copper, and manganese-are essential micronutrients critical for metabolic and enzymatic functions. However, even low-level exposure to toxic heavy metals like arsenic, lead, cadmium, and mercury can lead to bioaccumulation and multi-organ toxicity, including neurological, reproductive, cardiovascular, and gastrointestinal damage [2, 3].

Mycotoxin contamination, particularly by aflatoxins and ochratoxin A, poses another significant safety concern. Medicinal herbs are susceptible to these fungal toxins, which are frequently detected at levels exceeding regulatory limits and are known for their hepatotoxic, mutagenic, and carcinogenic effects [4, 5]. Microbial contamination further threatens the safety and stability of herbal formulations. Studies have shown that a notable proportion of herbal products exceed permissible limits for bacterial and fungal counts, raising concerns about potential pathogen exposure and reduced product efficacy [6].

Given its traditional significance and widespread use, it is imperative to assess Pirandai Vadagam for physicochemical properties, heavy metal content, aflatoxin contamination, and microbial load. Such evaluations are essential to ensure the formulation's safety, stability, and therapeutic efficacy, aligning with pharmacopeial quality standards [7].

Objective

The present study aims to evaluate the quality control parameters and safety profileof the Pirandai Vadagamby assessing itsphysicochemical characteristics**,** heavy metal content, aflatoxin contamination, and microbial load**,** in accordance with pharmacopoeial guidelines, to ensure its safety, stability, and therapeutic reliability

Materials and Methods

Organoleptic Evaluation

The Siddha formulation *Pirandai Vadagam* was examined for its organoleptic characteristics such as color, odor, taste, and texture by simple visual and sensory evaluation in accordance with Siddha pharmacopoeial guidelines.

Physicochemical Parameters

Physicochemical analysis was performed following WHO (2011) and Siddha Pharmacopoeia standards. Loss on drying was determined by weighing 2 g of powdered sample, drying it at 105 °C until a constant weight was achieved, and calculating the percentage of moisture content. Total ash was estimated by incinerating 2 g of the sample in a silica crucible at 450–600 °C until carbon-free ash was obtained, and the residue weight was expressed as % w/w. For acid-insoluble ash, the total ash was boiled with 70 mL of 2 M hydrochloric acid, filtered, and the residue incinerated to constant weight. The water-soluble ash value was obtained by boiling the total ash with distilled water, filtering, incinerating the residue, and weighing it to calculate solubility percentage. Alcohol-soluble extractive value was determined by macerating 5 g of the powdered sample with 100 mL of 90% ethanol for 24 h with intermittent shaking, filtering, evaporating, and drying the residue at 105 °C, after which the extractive value was calculated. Similarly, the water-soluble extractive value was obtained by macerating with distilled water under the same conditions. The pH of both 1% and 10% aqueous solutions was measured using a calibrated digital pH meter.

Heavy Metal Analysis

Heavy metals such as arsenic, lead, cadmium, and mercury were estimated using Atomic Absorption Spectrophotometry (AAS) following acid digestion procedures. Samples were digested with 1 mol/L hydrochloric acid for arsenic and mercury, and with 1 mol/L nitric acid for lead and cadmium before analysis.

Microbial Load Determination

The microbial quality of the formulation was assessed according to WHO guidelines (2007). The sample was homogenized with polysorbate-20, serially diluted in peptone broth, and inoculated in triplicate. Total aerobic bacteria were determined using Casein Soybean Digest Agar plates incubated at 37 °C for 24–48 h, while fungal load was determined using Sabouraud Dextrose Agar incubated at 25 °C for 48–72 h. Colony counts were recorded as CFU/g and compared against WHO permissible limits.

Identification of Pathogenic Bacteria

Screening for specific pathogens was performed using selective media. *Escherichia coli* was identified on EMB and MacConkey agar, *Salmonella spp.* on Deoxycholate Citrate Agar, *Pseudomonas aeruginosa* on Cetrimide agar, and *Staphylococcus aureus* on Mannitol Salt Agar. Suspected colonies were confirmed by colony morphology, Gram staining, and biochemical tests including oxidase, catalase, and gas production assays.

Aflatoxin Estimation

Aflatoxin contamination was analyzed using the AflaTest fluorometric method (VICAM, USA). One gram of the sample was extracted with methanol:water (60:40 v/v) containing Tween-20, filtered, and passed through an AflaTest WB immunoaffinity column. After washing, the bound aflatoxin was eluted with HPLC-grade methanol and analyzed in a VICAM Series 4EX fluorometer to quantify aflatoxins B1, B2, G1, G2, M1, and M2.

Result

Organoleptic Characters

The formulation *Pirandai Vadagam* was evaluated for its organoleptic features. It was observed to possess a brownish-green color, characteristic odor, slightly bitter taste, and a firm texture. These parameters were consistent with Siddha formulations and confirmed the stability of the sample.

Physicochemical Analysis

The physicochemical parameters of *Pirandai Vadagam* are summarized in **Table 1**. The formulation showed acceptable values for moisture content, ash values, and extractive values, indicating good stability and purity.

Table 1. Physicochemical parameters of Pirandai Vadagam

Parameter	Result (% w/w)
Loss on drying (at 105 °C)	16.8%
Total ash	15.37%
Acid-insoluble ash	2.33%
Alcohol-soluble extractive	16.09%
Water-soluble extractive	19.25%

Heavy Metal Analysis

Heavy metals such as arsenic, lead, cadmium, and mercury were within permissible limits as per WHO standards (Table 2).

Table 2. Heavy metal content of Pirandai Vadagam

Heavy Metal	Result (ppm)	WHO Permissible Limit (ppm)
Arsenic (As)	Nil	3
Lead (Pb)	0.0209 mg/L	10
Cadmium (Cd)	0.0049 mg/L	0.3
Mercury (Hg)	0.5663 $\mu g/L$	1

Microbial Load

The microbial analysis demonstrated that the formulation complied with WHO standards. Total bacterial and fungal counts were below the permissible limits (Table 3).

Table 3. Microbial load of Pirandai Vadagam

Microbial Parameter	Result (CFU/g)	WHO Permissible Limit (CFU/g)
Total bacterial Count	1x103	$\leq 10^5$

Total fungal count	Less than 3	$\leq 10^3$
Escherichia coli	Absent	Absent
Salmonella spp.	Absent	Absent
Pseudomonas aeruginosa	Absent	Absent
Staphylococcus aureus	Absent	Absent

Aflatoxin Estimation

The levels of aflatoxins B1, B2, G1, G2, M1, and M2 were below detectable limits or within permissible ranges (Table 4), confirming the absence of contamination.

Table 4. Aflatoxin levels in Pirandai Vadagam

S.N	Parameters	Method / Reference	Results
1.	Total Aflatoxin B1+B2+G1+G2	Vicam Aflatest Fluorometer Instruction Manual	Below detection limit

Discussion

The present study evaluated the quality and safety profile of *Pirandai Vadagam*, a traditional Siddha formulation, through comprehensive physicochemical, heavy metal, microbial, and aflatoxin analyses. The organoleptic characters of the formulation, including its brownish-green colour, firm texture, and slightly bitter taste, are in accordance with the sensory attributes described for herbal formulations, which serve as preliminary indicators of stability and authenticity [8].

The physicochemical evaluation revealed acceptable values for loss on drying, total ash, acid-insoluble ash, and extractive values. These parameters play a vital role in determining the stability and purity of herbal formulations, as they reflect moisture content, inorganic matter, and the solubility of bioactive components [9]. The moisture content of 16.8% indicates adequate drying and reduced risk of microbial proliferation, while the extractive values highlight the presence of water- and alcohol-soluble phytoconstituents that contribute to the therapeutic efficacy of the preparation [10].

Heavy metal analysis demonstrated that arsenic, lead, cadmium, and mercury levels were well within the permissible limits defined by the World Health Organization (WHO). This is a significant finding, as contamination with toxic metals poses a major concern in traditional formulations due to potential health hazards on chronic consumption [11]. Studies have shown that even low-level exposure to lead and mercury may exert cumulative toxic effects, underscoring the importance of stringent quality control in Siddha and Ayurveda medicines [12]. The present results confirm the safety of *Pirandai Vadagam* with respect to heavy metal content.

Microbial quality testing revealed that the total bacterial and fungal counts were within WHO acceptable limits, and no pathogenic organisms such as *Escherichia coli*, *Salmonella spp.*, *Pseudomonas aeruginosa*, or *Staphylococcus aureus* were detected. Ensuring microbial safety is essential for formulations intended for internal use, as microbial contamination not only reduces shelf-life but may also cause gastrointestinal and systemic infections [13]. The low microbial load observed here indicates adherence to good manufacturing practices during preparation.

The aflatoxin analysis further confirmed the absence of detectable levels of B1, B2, G1, G2, M1, and M2. Aflatoxins are highly toxic secondary metabolites produced by *Aspergillus* species and are frequently implicated in food and herbal drug contamination in tropical countries [14]. Chronic exposure to aflatoxins, especially aflatoxin B1, is strongly associated with hepatotoxicity and hepatocellular carcinoma. The absence of aflatoxin contamination in *Pirandai Vadagam* highlights the effectiveness of proper storage and processing techniques employed in its preparation.

Taken together, these findings demonstrate that *Pirandai Vadagam* meets the essential quality and safety standards outlined by the WHO for traditional herbal formulations. The results validate the safety of the drug for therapeutic use and provide a scientific basis for its inclusion in clinical practice. Previous pharmacological studies have reported that *Cissus quadrangularis*, the chief ingredient, possesses antioxidant, anti-inflammatory, and bone-healing activities [15], further strengthening its therapeutic potential.

Overall, the study highlights the importance of integrating modern quality control parameters with traditional knowledge to ensure the safety, efficacy, and standardization of Siddha formulations. Future research may focus on bioactive compound profiling and clinical evaluation to establish a more comprehensive safety and efficacy profile of *Pirandai Vadagam*.

Conclusion

The standardization of *Pirandai Vadagam* through organoleptic, physicochemical, heavy metal, microbial, and aflatoxin analyses confirmed its safety and quality in accordance with WHO guidelines. The formulation exhibited stable physicochemical properties, acceptable microbial load, and heavy metal levels within permissible limits, while aflatoxins were undetectable. These findings validate the purity and safety of *Pirandai Vadagam* and support its use as a standardized Siddha formulation. Further pharmacological and clinical investigations are recommended to substantiate its therapeutic efficacy.

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Conflict of Interest

No conflict of interest

Informed Consent

N/A

Ethical Statement

N/A

Author Contribution

T. Dhildhar – concept, manuscript writing. R. Menaka- literature review and manuscript review. K. Sudha mathi- manuscript review

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