WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 11, 686-692. Research Article ISSN 2277–7105

EVALUATION OF HEAVY METAL SAFETY AND MICROBIAL STERILITY OF SIDDHA FORMULATION VENPADAILEPAM

V. Sandhiya*[1], K. Shyamala[2], T. Maharasi Maniselvi[3], J. Sriram[4]

[1]PG Scholar, Department of Kuzhanthai Maruthuvam, GSMC, Palayamkottai.

[2]Guide, Assistant Professor, Department of Kuzhanthai Maruthuvam, GSMC, Palayamkottai.

[3]Associate Professor, Head of The Department, Department of Kuzhanthai Maruthuvam, GSMC, Palayamkottai.

[4]Assistant Professor, Department of Kuzhanthai Maruthuvam, GSMC, Palayamkottai.

Article Received on 29 April 2026,
Article Revised on 19 May 2026,
Article Published on 01 June 2026,

https://doi.org/10.5281/zenodo.20440048

***Corresponding Author**

V. Sandhiya

PG Scholar, Department of KuzhanthaiMaruthuvam, GSMC, Palayamkottai.

How to cite this Article: V. Sandhiya*[1], K. Shyamala[2], T. Maharasi maniselvi[3], A. Anbumalar[4]. (2026). Evaluation of Heavy Metal Safety and Microbial Sterility of Siddha Formulation Venpadailepam. World Journal of Pharmaceutical Research, 15(11), 686–692.

ABSTRACT

Traditional Siddha formulations are widely utilized in the management of dermatological conditions; however, their safety profile requires systematic scientific validation to ensure quality and acceptability. *Venpadai Lepam* is a classical Siddha formulation indicated for skin disorders such as Venpadai (vitiligo), as documented in standard Siddha texts. The present study aimed to evaluate the safety of *Venpadai Lepam* through heavy metal analysis and microbial sterility assessment using standard analytical techniques. Heavy metal estimation for lead (Pb), arsenic (As), cadmium (Cd), and mercury (Hg) was performed using Atomic Absorption Spectrometry (AAS) following acid digestion procedures. Microbial sterility was assessed by the pour plate method under appropriate incubation conditions for both bacterial and fungal growth. The study provides a scientific approach for assessing toxicological and microbiological safety parameters and contributes to the establishment of quality control standards for the formulation. These findings are intended to support its safe therapeutic application and serve as a basis for further pharmacological and clinical investigations in dermatological conditions.

KEYWORDS: Venpadai Lepam, Siddha medicine, heavy metal analysis, Atomic Absorption Spectrometry, sterility test, safety evaluation, traditional medicine.

INTRODUCTION

Siddha medicine is one of the ancient traditional systems of medicine widely practiced in South India, particularly in Tamil Nadu. It utilizes herbal and herbo-mineral formulations for the management of various diseases, including dermatological disorders.[1] *Venpadai Lepam* is a classical Siddha formulation indicated for skin diseases such as Venpadai (vitiligo), as described in traditional texts like *Pathardha Guna Vilakkam* and *Anuboga Vaithiya Thirattu*.[1,2]

Traditional Siddha formulations, particularly herbo-mineral preparations, are known for their potent therapeutic efficacy due to synergistic interactions between herbal and mineral components. However, the presence of metals in such formulations has raised concerns regarding their safety, especially in the context of chronic exposure and bioaccumulation.[3] Heavy metals like lead, arsenic, cadmium, and mercury are associated with toxicological effects including nephrotoxicity, neurotoxicity, and hepatotoxicity when present beyond permissible limits.[3]

Moreover, contamination during raw drug collection, processing, storage, or handling can introduce microbial load into the formulation. Microbial contamination not only affects the shelf life and stability but may also lead to opportunistic infections, especially when applied over compromised skin conditions such as vitiligo.[6] Therefore, ensuring microbial sterility is a critical parameter in evaluating topical Siddha formulations.

Recent global trends emphasize the integration of traditional medicine into evidence-based healthcare systems. Regulatory authorities such as WHO and AYUSH have laid down stringent guidelines for quality control, including heavy metal limits and microbial standards for herbal drugs.[3,4] In this context, scientific validation of classical formulations like Venpadai Lepam becomes essential to ensure safety, efficacy, and global acceptability.

Despite its traditional usage, concerns regarding the safety of Siddha formulations have increased due to the possible presence of toxic heavy metals and microbial contamination. Heavy metals such as lead, arsenic, cadmium, and mercury are known to produce toxic

effects when present above permissible limits.[3] Similarly, microbial contamination can lead to product degradation and potential health hazards.[6]

To ensure safety and global acceptability, it is essential to evaluate traditional formulations using modern analytical techniques. Atomic Absorption Spectrometry (AAS) is a widely accepted method for the detection of trace levels of heavy metals[5], while microbiological methods such as the pour plate technique are used to assess sterility.[6] Therefore, the present study was undertaken to evaluate the heavy metal content and microbial sterility of *VenpadaiLepam* in accordance with AYUSH and WHO guidelines.[3,4]

MATERIALS AND METHODS

Sample Collection

The sample of VenpadaiLepam was obtained from a standard preparation and subjected to analytical evaluation.

Heavy Metal Analysis

Heavy metal estimation was performed using Atomic Absorption Spectrometry (AAS) (Model: AA 240 Series), a sensitive and reliable technique for detecting trace metals.[5]

Sample Preparation

- The sample was digested using:
  - Hydrochloric acid (HCl) for arsenic and mercury
  - Nitric acid (HNO_3) for lead and cadmium

Parameters Analyzed

- Lead (Pb)
- Arsenic (As)
- Cadmium (Cd)
- Mercury (Hg)

The obtained values were compared with permissible limits as per AYUSH/WHO guidelines.[3,4]

Sterility Test

Sterility testing was carried out using the pour plate method as described in standard microbiological procedures.[6]

Procedure

The sample was inoculated into sterile petri dishes followed by the addition of molten agar (approximately 45°C). The plates were incubated at 37°C for 24–48 hours for bacterial growth and extended up to 72 hours for fungal growth.

OBSERVATION

The presence or absence of colony-forming units (CFU) was recorded and compared with standard limits.

RESULTS

Table 1: Heavy Metal Analysis.

S.NO	Heavy Metal	Result	Permissible limit	Absorption max. A max
1	Lead(Pb)	BDL	NMT 10 ppm	217.0 nm
2	Arsenic (As)	BDL	NMT 3 ppm	193.7 nm
3	Cadmium (Cd)	BDL	NMT 0.3 ppm	228.8 nm
4	Mercury (Hg)	BDL	NMT 1 ppm	253.7 nm

BDL – Below Detection Limit

Table 2: Sterility Test.

Parameter	Result	Permissible limit
Total bacterial count	Absent	NMT 10^5 CFU/g
Total fungal count	Absent	NMT 10^3 CFU/g

The sterility test results (Table 2) showed no bacterial or fungal growth, confirming the microbiological safety of the formulation. The sterility plates are illustrated in **Figure 1.**

QUALITY CONTROL AND STANDARDIZATION

Standardization of traditional formulations is essential to ensure batch-to-batch consistency, safety, and therapeutic efficacy. In Siddha medicine, standardization involves organoleptic

evaluation, physicochemical analysis, and advanced instrumental techniques.

Heavy metal analysis using Atomic Absorption Spectrometry (AAS) provides high sensitivity and specificity for detecting trace elements.[5] The absence of detectable heavy metals in the present study indicates proper purification and processing of raw materials, which is a crucial step in Siddha pharmaceutics.

Similarly, sterility testing using standard microbiological methods ensures that the formulation is free from pathogenic contamination. The pour plate technique employed in this study is a widely accepted method for determining microbial load in pharmaceutical preparations.[6]

In addition to these, future standardization parameters may include chromatographic fingerprinting techniques, including HPTLC and GC-MS analysis to identify bioactive compounds and ensure formulation consistency. These techniques will further strengthen the scientific validation of Siddha formulations.

DISCUSSION

The safety evaluation of traditional formulations is crucial for their integration into modern healthcare systems. Heavy metal contamination is one of the major concerns associated with herbo-mineral preparations. In the present study, heavy metal analysis performed using AAS revealed that lead, arsenic, cadmium, and mercury were below detection limits, indicating compliance with AYUSH and WHO safety standards.[3,4] This suggests that the formulation is free from toxic metal contamination and safe for therapeutic use.

The absence of heavy metals in Venpadai Lepam highlights the significance of traditional purification methods (Suddhi procedures) described in Siddha literature, which are designed to detoxify raw materials and enhance their therapeutic potential. These findings align with previous studies that report reduced toxicity in properly processed herbo-mineral formulations.[3]

Furthermore, the microbiological safety observed in the present study indicates adherence to good manufacturing practices (GMP). This is particularly significant for topical preparations, as contaminated formulations may aggravate skin conditions or delay healing.

From a clinical perspective, ensuring safety is the first step toward validating the therapeutic potential of the formulation. Since Venpadai Lepam is indicated for vitiligo, a condition associated with autoimmune and oxidative stress mechanisms, future studies may explore its antioxidant, immunomodulatory, and melanocyte-stimulating properties. Additionally, the results of this study provide baseline data for further pharmacological and clinical investigations. Establishing safety through such analytical studies enhances the credibility of Siddha medicine in the global healthcare system and supports its integration into mainstream therapeutics.

Microbial contamination can compromise both the safety and efficacy of medicinal products. The absence of bacterial and fungal growth in the sterility test confirms that the formulation is microbiologically safe and prepared under hygienic conditions.[6] This is particularly important for topical formulations used in dermatological conditions.

The findings of this study are consistent with standard quality control requirements for traditional medicines and support the safe external application of *VenpadaiLepam* as mentioned in Siddha literature.[1,2] However, the study is limited to safety evaluation, and further investigations such as pharmacological and clinical studies are necessary to establish its therapeutic efficacy.

FUTURE SCOPE

Although the present study confirms the safety of Venpadai Lepam, further research is necessary to establish its therapeutic efficacy. Pharmacological studies, including anti-inflammatory, antioxidant, and melanocyte proliferation assays, can provide insight into its mechanism of action.

Clinical trials in pediatric vitiligo patients can help determine its effectiveness, dosage regimen, and long-term safety. Additionally, advanced analytical techniques such as HPTLC fingerprinting and stability studies can be conducted to ensure quality consistency over time.

The integration of traditional knowledge with modern scientific validation will enhance the global acceptance of Siddha formulations and promote their use in evidence-based medicine.

CONCLUSION

The present study demonstrates that *VenpadaiLepam* is free from detectable levels of heavy metals and microbial contamination. The formulation complies with AYUSH/WHO safety

standards, confirming its safety for therapeutic use. These findings provide scientific validation for the traditional use of the formulation. Further pharmacological and clinical studies are recommended to evaluate its efficacy and mechanism of action in dermatological disorders.

REFERENCES

1. Siddhar Thirumoolar. *Pathardha Guna Vilakkam*. Chennai: Department of Indian Medicine, 384.
2. Anonymous. *Anuboga Vaithiya Thirattu*. Chennai: Department of Indian Medicine, 87–88.
3. World Health Organization. *Quality Control Methods for Herbal Materials*. Geneva: WHO, 2011.
4. Government of India. *AYUSH Pharmacopoeia Guidelines*. New Delhi: Ministry of AYUSH, 2016.
5. Skoog DA, Holler FJ, Crouch SR. *Principles of Instrumental Analysis*. 6th ed. USA: Thomson, 2007.
6. Pelczar MJ, Chan ECS, Krieg NR. *Microbiology*. 5th ed. New York: McGraw Hill, 1998
7. Khandelwal KR. Practical Pharmacognosy. 23rd ed. Pune: Nirali Prakashan, 2005.
8. Kokate CK. Pharmacognosy. 49th ed. Pune: Nirali Prakashan, 2014.
9. World Health Organization. WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues. Geneva: WHO, 2007.
10. Mukherjee PK. Quality Control of Herbal Drugs. New Delhi: Business Horizons, 2002.