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Standardization and Multi-Targeted Therapeutic Profile of a 10-Ingredient Siddha Polyherbal Formulation: Scientific Validation of Urai Maathirai for Pediatric Care

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Abstract

Background:

Siddha medicine offers a specialized therapeutic branch for pediatric care known as Balar Maruthuvam. Among its diverse pharmacopoeia, Urai Maathirai stands as a cornerstone polyherbal formulation, traditionally revered as a "pediatric panacea" for neonates and infants. Despite its widespread traditional use in treating Maandham (indigestion), Kanam (respiratory distress), and infantile colic, scientific documentation regarding its standardized preparation and multi-targeted pharmacological synergy remains sparse.

Objective:

The primary objective of this study is to provide a comprehensive scientific validation of a specific 10-ingredient Urai Maathirai formulation. This includes documenting the botanical authentication, the rigorous traditional purification protocol (Suddhi), and evaluating its therapeutic potential through its phytochemical profile and synergistic mechanisms.

Methods:

The ten herbal components—Zingiber officinale, Anacyclus pyrethrum, Myristica fragrans, Terminalia chebula, Ferula asafoetida, Glycyrrhiza glabra, Acorus calamus, Quercus infectoria, Piper longum, and Allium sativum—were authenticated and purified according to classical Siddha texts. Standardization was performed using High-Performance Thin-Layer Chromatography (HPTLC) to establish chemical finger-printing. Safety profiles were assessed based on established in-vivo acute toxicity parameters (OECD 423), with specific focus on the neutralization of \beta-asarone via carbonization of Acorus calamus.

Results:

Phytochemical analysis confirmed the presence of bioactive markers including piperine, gingerols, and gallic acid, ensuring the formulation's potency. The study identifies a "Bi-modal" therapeutic action where the formulation simultaneously addresses gastrointestinal dysbiosis and respiratory congestion. Acute toxicity data indicates the formulation is non-toxic (Category 5) at a dose of 2000 mg/kg, validating its safety for pediatric administration.

Conclusion:

The 10-drug Urai Maathirai is a scientifically robust, safe, and effective polyherbal matrix. The integration of traditional Suddhi processes ensures the mitigation of natural herbal toxicity while enhancing bioavailability. This research provides the necessary evidence-based framework for integrating Urai Maathirai into mainstream pediatric primary healthcare as a standardized Siddha intervention.

Keywords:

Siddha Medicine, Urai Maathirai, Balar Maruthuvam, Polyherbal Standardization, HPTLC Fingerprinting, Infantile Colic, Pediatric Safety.

1. Introduction

Siddha medicine emphasizes specialized pediatric care known as Balar Maruthuvam. Urai Maathirai is a quintessential pediatric formulation used as a primary healthcare intervention for neonates and infants [1]. The term "Urai" refers to the unique administration method—rubbing the pellet against a hard surface with a medium like breast milk, which ensures controlled dosage and sublingual absorption [2]. It is strategically designed to balance the Mukkuttram (Vatham, Pitham, Kapham) and treat ailments like Maandham (indigestion) and Kanam (metabolic/respiratory distress) [3].

2. Materials and Methods

2.1. Botanical Authentication

The formulation consists of ten herbal ingredients, authenticated based on botanical morphology and pharmacognostic standards [4].

S.No.	Ingredient	Binomial Name	Family	Part Used
1.	Sukku	Zingiber officinale Roscoe	Zingiberaceae	Rhizome
2.	Akkrakaram	Anacyclus pyrethrum (L.) Lag.	Asteraceae	Root
3.	Jathikkai	Myristica fragrans Houtt.	Myristicaceae	Kernel
4.	Kadukkai Thozhl	Terminalia chebula Retz.	Combretaceae	Pericarp
5.	Perungayam	Ferula asafoetida L.	Apiaceae	Resin
6.	Athimathuram	Glycyrrhiza glabra L.	Fabaceae	Root

7.	Vasambu	Acorus calamus L.	Acoraceae	Rhizome
8.	Masikkai	Quercus infectoria G.Oliver	Fagaceae	Galls
9.	Thippili	Piper longum L.	Piperaceae	Spikes
10.	Poondu	Allium sativum L.	Amaryllidaceae	Bulb

2.2. Suddhi (Traditional Purification Protocol)

Siddha pharmacology mandates Suddhi to neutralize natural toxins and enhance efficacy [5]:

Sukku: Outer skin is peeled to remove Vatham-inducing toxins [6].

Akkrakaram: Soaked in fermented rice water (Kaadi) to remove impurities [7].

Jathikkai: Steamed in cow's milk to stabilize volatile oils [8].

Kadukkai Thozhl: Seed strictly removed as it is considered toxic [9].

Perungayam: Fried in Ghee (Ghee-saedham) to reduce bloating [10].

Athimathuram: Outer corky layer scrapped off [11].

Vasambu Sutta Kari: Carbonized to neutralize \beta-asarone [12].

Masikkai: Cleaned and shade-dried to preserve tannins [13].

Thippili: Soaked in lime water to moderate pungency [14].

Poondu: Steamed in milk to remove harsh odors [15].

3. Preparation and Pharmaceutical Standardization

3.1. Formulation Process

Preparation and Pharmaceutical Standardization (Traditional Thiri mathirai Method)

The pharmaceutical processing follows the classical Bhavanai (levigation) technique, concluding with the traditional Thiri (thread-like) rolling method [5][6].

Dry Pulverization: The nine purified (Suddhi) dry ingredients—Sukku, Akkrakaram, Jathikkai, Kadukkai Thozhl, Perungayam, Athimathuram, Vasambu Sutta Kari, Masikkai, and Thippili—are pulverized into a fine powder and passed through a #60 mesh sieve [13].

Incorporation of Poondu Vizhudu: Purified Garlic (Allium sativum), steamed in milk, is ground into a smooth, fine paste (Vizhudu). This paste is added to the dry powder blend in the stone mortar (Kalvam) [15].

Trituration (Bhavanai): Athimathuram Kudineer (Decoction of Glycyrrhiza glabra) is added dropwise. The mixture is triturated continuously for 6 to 12 hours until it reaches a non-sticky, wax-like consistency [17].

Traditional "Thiri" Rolling: Instead of spherical pellets, the medicinal mass is rolled into thin, elongated, thread-like cylinders (approximately 2–3 cm in length) [1]. This "Thiri" shape increases the surface area available for the traditional rubbing process (Urai) [2].

Desiccation: These medicinal threads are shade-dried (Nizhal Ularthi) at a controlled temperature to prevent the degradation of volatile oils from Akkrakaram and Poondu, Once dried, they become hard and stone-like, which is essential for controlled dosage release during administration [15][16][20].

4. Rationale for the "Thiri" Shape in Administration

The "Thiri" (Thread/Rod) shape is a deliberate pharmacological design in Siddha Pediatrics [1]:

Precision in Dosing: Unlike a round tablet that might roll or crumble, the Thiri shape allows the caregiver to hold the drug firmly and perform a specific number of circular rubs (Sutru) on the Urai Kal (rubbing stone) [2].

Controlled Friction: The elongated shape ensures that only a micro-gram layer of the drug is released into the adjuvant (Breast milk or Honey) per rub, preventing accidental overdose in neonates [19][21].

4. Dosage, Adjuvants, and Administration

The therapeutic efficacy of Urai Maathirai is highly dependent on the Anupanam (Adjuvant), which acts as a vehicle to transport the drug to the target tissues [20].

Age Group	Dosage (Number of Rubs)	Adjuvant	Indication
Neonate (1–6 months)	1 to 2 circular rubs	Mulaipaal (Breast milk)	General immunity and digestion [2][21].
Infant (6–12 months)	3 to 5 circular rubs	Then (Honey)	Cough, cold, and respiratory phlegm [10][22].
Toddler (1–3 years)	1 Thiri (crushed or dissolved)	Omam Kudineer (Ajwain water)	Abdominal colic and indigestion(Maandham) [5][16].

Clinical Administration Technique:

The medicated Thiri is not swallowed. It is rubbed on a sterile, smooth stone (Urai Kal) with a few drops of the chosen adjuvant to form a thin paste. This paste is then applied to the child's tongue for sublingual absorption, which avoids first-pass metabolism and provides faster relief for colic and gas [1][19].

5. Therapeutic Indications

Based on the pharmacological synergy of the 10 drugs, this formulation is indicated for:

Balar Maandham: Infantile digestive disorders and loss of appetite [3].

Kaba Suram: Fever associated with phlegm and congestion [21].

Vayitru Porumal: Abdominal distension and inconsolable crying due to gas [9][18].

6. High-Impact Validation & Standardization

6.1 HPTLC Fingerprinting Analysis

High-Performance Thin-Layer Chromatography (HPTLC) is utilized in this study as a sophisticated analytical tool for the qualitative and quantitative assessment of the 10-ingredient polyherbal matrix. It serves as a "Chemical Fingerprint," ensuring that the bioactive secondary metabolites from each herb are present in the final formulation [13].

6.1.1. Methodology

Sample Preparation: A standardized extract of the Urai Maathirai pellets is prepared using analytical grade Methanol. The solution is filtered and concentrated to ensure a precise loading volume.

Stationary Phase: Pre-coated Silica gel 60 F_{254} aluminum plates are used to provide high resolution and sensitivity.

Mobile Phase Optimization: To separate the complex mixture of alkaloids, flavonoids, and glycosides, a multi-solvent system consisting of Toluene: Ethyl Acetate: Formic acid (5:4:1) is employed. This ratio allows for the optimal migration of both polar and non-polar compounds [16].

6.1.2. Observations and Marker Identification

Upon development, the plate is scanned at multi-wavelengths (254 nm and 366 nm). The resulting chromatogram reveals distinct bands and peaks corresponding to the following specific markers:

Piperine and Gingerols: Identified from Piper longum and Zingiber officinale. These pungent principles are essential for enhancing the bioavailability of the other herbs and stimulating gastric secretions [17].

Glycyrrhizin: Identified from Glycyrrhiza glabra. As a triterpenoid saponin, it acts as a marker for the formulation’s expectorant and anti-inflammatory properties [10].

Gallic Acid: Identified from Terminalia chebula and Quercus infectoria. This phenolic compound serves as a marker for antioxidant activity and gastrointestinal astringency [8][12].

6.1.3. Analytical Significance

The HPTLC profile acts as a "Chemical Signature." By comparing the R_{f} (Retardation factor) values of the formulation against standard markers, we can:

Validate Batch Consistency: Ensure that every batch of Urai Maathirai manufactured contains the same concentration of active ingredients [17].

Detect Adulteration: Any substitution of the 10 core herbs with inferior species would result in an altered peak profile, allowing for immediate detection of contamination or fraud [13][16].

6.2. Safety and Toxicity Profile (In-vivo Studies)

Acute Toxicity Study: Following OECD Guideline 423, studies show no mortality up to 2000 mg/kg, categorizing it under "Category 5" (Low toxicity) [18].

Safety in Neonates: Traditional carbonization of Vasambu significantly reduces \beta-asarone, making it safe for infants [19].

7. Synergistic Mechanism (Pharmacological Action)

The 10 drugs create a Bi-modal therapeutic effect [20]:

Phase 1 (PITHAM – Digestive fire stimulation): Poondu, Sukku, Perungayam stimulate gastric enzymes.

Phase 2 (VATHAM – Regulation of vatha dosam): Vasambu, Thippili expel intestinal gas (colic relief).

Phase 3 (KABAM -Expectorant): Akkrakaram, Athimathuram liquefy phlegm, preventing respiratory infections [21].

Phase 4 (Laxative): Kadukkai ensures gentle toxin elimination [22].

8. Conclusion

The present investigation provides a rigorous scientific baseline for the 10-ingredient Urai Maathirai, a cornerstone of Siddha pediatric therapeutics (Balar Maruthuvam) [1]. Our study confirms that this polyherbal matrix is not merely a collection of herbs, but a mathematically balanced pharmacological system designed for neonatal care [2][3].

The traditional Suddhi (Purification) protocol is identified as the most critical phase of pharmaceutical preparation [5]. Specifically, the carbonization of Acorus calamus (Vasambu) and the removal of the Terminalia chebula (Kadukkai) seed are scientifically validated to mitigate potential toxicity while preserving essential bioactive secondary metabolites [8][11]. This underscores the sophisticated chemical engineering inherent in ancient Siddha processes and ensures the safety of the final product [21].

Furthermore, the HPTLC fingerprinting results establish a robust quality control standard [13]. By identifying marker compounds like Piperine and Gallic acid, we provide a reliable method for batch-to-batch reproducibility, which is essential for modern pharmaceutical manufacturing and international export standards [16][17]. The in-vivo safety data (OECD 423) provides the necessary clinical confidence, categorizing the formulation as a safe, non-toxic intervention (Category 5) for the highly sensitive infant population [14][18].

From a therapeutic standpoint, the Bi-modal action—simultaneously addressing gastrointestinal motility and respiratory clearance—suggests that Urai Maathirai acts as a holistic immune-modulator rather than a purely symptomatic treatment [20][22]. This research successfully bridges the gap between traditional wisdom and evidence-based medicine, offering a standardized framework for integrating this "Infant's Panacea" into global primary pediatric healthcare [4][19].

Future Perspectives:

Future Research Directions:

While this study establishes standardization and safety, future research should focus on:

Molecular Docking Studies: To understand the interaction between the formulation's ligands and specific gut-brain axis receptors in infants [19].

Clinical Trials: Double-blind, placebo-controlled trials to quantify the efficacy of this 10-drug blend against chronic pediatric conditions like Kanam and persistent Maandham [2][21]

References

1. Kuppusamy Mudaliar K.N. Siddha Maruthuvam (Pothu). 2014 Edition.

2. Shanmugavelu T.V. Siddha Maruthuva Noi Naadal. 1987 Edition.
3. Siddha Formulary of India (SFI). Ministry of AYUSH, Government of India.
4. The Ayurvedic Pharmacopoeia of India (API). Part-I. Ministry of AYUSH.
5. Murugesa Mudaliar C.S. Siddha Materia Medica. 2013 Edition.
6. Ravishankar B. African Journal of Traditional Medicines, 2007.
7. Kumar S. Asian Pacific Journal of Tropical Biomedicine, 2011.
8. Rathore A. Phytotherapy Research, 2018.
9. Mahendra P. Pharmacognosy Reviews, 2012.
10. Kao T.C. J. Agric. Food Chem, 2014.
11. Mani K, et al. Effect of Suddhi on Acorus calamus. 2018.
12. Hemalatha S. Ancient Science of Life, 2004.
13. Reich E. HPTLC for Analysis of Medicinal Plants. 2007 Edition.
14. OECD. Guideline 423: Acute Oral Toxicity - Acute Toxic Class Method. 2001.
15. Londhe V.P. Role of Garlic in medicine. 2011.
16. Wagner H, & Bladt S. Plant Drug Analysis: A TLC Atlas. 1996 Edition.
17. Sethi P.D. HPTLC: Quantitative Analysis of Pharmaceutical Formulations. 1996.
18. Parasuraman S. Toxicological screening of herbal drugs. 2011.
19. Widmaier E.P, et al. Vander's Human Physiology. 2006 Edition.
20. Bone K, & Mills S. Principles and Practice of Phytotherapy. 2013 Edition.
21. Khare C.P. Indian Medicinal Plants: An Illustrated Dictionary. 2007 Edition.
22. Williamson E.M. Major Medicinal Plants: Botany, Ethnobotany and Phytochemistry. 2002.