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Physicochemical Evaluation of Siddha Drug Soothaga Sanniku Nei

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Abstract
Ethnomedical practices persist globally due to their effectiveness within regional populations. Standardizing and documenting these traditional practices are indispensable for integration into modern evidence-based healthcare systems. Soothaga Sanniku Nei (SSN) is a classical Siddha formulation prepared using cow's ghee along with nine crude herbal and mineral drugs. It is primarily indicated in traditional literature for complex gynecological conditions including Soothaga Sanni, Soothaga Vayu, and Azhal Noigal (which are analogous with modern nosology such as endometriosis, pelvic inflammatory disease, and PCOS). In this study, SSN was standardized following Pharmacopeial Laboratory of Indian Medicine (PLIM) guidelines. Physicochemical evaluation revealed an acid value of 87.10 mgKOH/g, a density of 1.113 g/ cm^3, loss on drying at 7.90%w/w and a refractive index of 1.350. Heavy metals (Arsenic, Cadmium, Lead, Mercury), pesticide residues, specific foodborne pathogens (*E. coli, Salmonella, S. aureus, P. aeruginosa*), and aflatoxins (B1, B2, G1, G2) were absent, ensuring compliance with AYUSH safety metrics. The standard parameters generated establish a baseline profile of Soothaga Sanniku Nei. Further studies are required to understand its mechanism of action and pharmacodynamic profile at molecular level.

Keywords: Siddha Medicine, Soothaga Sanniku Nei, Standardization, Endometriosis Physicochemical Analysis.

Introduction

Siddha medicine comprises a wide range of formulations prepared through diverse pharmaceutical processes using herbal, mineral and animal-derived substances. Among these formulations, *Nei* is a lipid-based preparation in which ghee serves as the base medium along with processed crude drugs. Lipid-based drug delivery systems have gained increasing attention in modern pharmaceutical research due to their ability to enhance drug solubility, bioavailability, and permeability. Traditional Siddha medicine has utilized ghee and sesame oil as therapeutic carriers since ancient times for their unique medicinal value and drug delivery properties.

Soothaga Sanniku Nei (SSN), a classical Siddha formulation mentioned in the Theraiyar Tharu, is indicated for conditions such as Soothaga Sanni, Soothaga Vaayu and Azhal noi which are broadly correlated with various gynecological ailments. In order to establish scientific standards and ensure quality safety and reproducibility of the formulation, physicochemical evaluation of Soothaga Sanniku Nei was

carried out according to standard guidelines. The present study focuses on the physicochemical characterization of the formulation to provide baseline analytical data for standardizing the drug and future research applications.

Materials and methods

Collection and Authentication of Materials

Raw plant drugs and ingredients required for drug SSN were procured from specialized traditional suppliers and subjected to classical purification protocols as mentioned in the siddha literature Sarakku-suthi Seimuraigal. Botanical raw drugs were authenticated by the Department of PG Gunapadam, Government Siddha Medical College, Palayamkottai, Tamil Nadu, India.

Composition of Formulation

The complete list of ingredients, local names, botanical name, used parts and precise composition weights are tabulated below:

S.No	English / Common Name	Tamil Name	Botanical / Chemical Name	Part(s) Used	Quantity
1	Coriander	Kothamalli	*Coriandrum sativum* L.	Seed	250 g
2	Ginger (Processed)	Chukku	*Zingiber officinale* Roscoe	Tuber / Rhizome	31.25 g
3	Black Pepper	Milagu	*Piper nigrum* L.	Fruit / Seeds	31.25 g
4	Lesser Galangal	Chitharatthai	*Alpinia officinarum* Hance	Tuber / Rhizome	31.25 g
5	Thymol Seeds / Ajwain	Omam	*Trachyspermum ammi* L.	Seeds	31.25 g
6	Giant Taro	Merugan kizhangu	*Alocasia indica* (Lour.) Spach	Tuber	31.25 g
7	Red Leadwort	Kodiveli	*Plumbago zeylanica* L.	Root	31.25 g
8	Chaste Tree	Nochi	*Vitex negundo* L.	Leaves	31.25 g
9	Table Salt	Uppu	Sodium chloride	Purified Mineral Crystal	31.25 g
10	Cow's Ghee	Pasu nei	Clarified Butter	Core Liquid Base	500 g

Table 1. Ingredients of Soothaga Sanniku Nei

Preparation of SSN

All the above raw drugs except cow's ghee & ginger were cleaned properly according to purification protocol in siddha literature & taken in above said quantities and ground properly. The grinded mixture was then soaked well in ginger extract for 3 hours and mixed with cow's ghee then boiled together until moisture present in the ghee is completely evaporated and then filtered. The prepared nei (medicated ghee) was taken in a glass container after completely cooled down, kept in ner pudam (buried in rice husk) for 15 days and stored.

Study methodology

The physicochemical analysis, test for microbial contamination, heavy metals, pesticide residues were performed at a research facility in Sophisticated Analytical Instrumentation Centre (SAIF) at IIT, Madras.

Results and Discussions

Physicochemical Evaluation

Standard physicochemical analysis ensures the drug is authentic and stable. It provides measurable scientific parameters. Table 2 compiles the physicochemical outcomes observed for SSN.

Parameter Analyzed	Experimental Value Identified
Physical Appearance / Color	Yellow
Acid Value	87.10 mgKOH/g
Density (at Room Temp)	1.113 g/cm³
Loss on Drying	7.90% w/w
Refractive Index	1.350
Iodine Value	101.12
Peroxide Value	79.1 meq/kg

Table 2: Physicochemical Constants of Standardized SSN

The acid value reflects the presence of free fatty acids formed during the thermal processing and interaction between herbal constituents and the lipid base. In medicated ghee, a relatively elevated acid value can occur due to hydrolysis and incorporation of active phytochemicals into the ghee. This may indicate enhanced liberation of bioactive compounds. Density obtained suggest that successful incorporation of herbal constituents dissolved in ghee hence the slightly increased density than plain ghee. The moisture content is within the standard range, thereby preventing microbial growth and maintains stability. The refractive index indicates uniform dispersion of phytoconstituents within medicated ghee. The iodine value indicates the presence of unsaturated compounds in ghee which aids for absorption and therapeutic activity. The peroxide value represents the oxidation of lipid formulation. The higher value may indicate the oxidative transformation of medicated ghee resulting in the formation of newer bioactive compounds that could be responsible for therapeutic efficacy.

Unlike western medicine, siddha formulations mentioned in literature classifies internal medicine into 32 distinct categories based on their method of preparation, consistency, potency and therapeutic benefits. These 32 types are 32 forms prepared in different methodologies and have different consistency. Based on the method of preparation and raw drug used each type has been assorted specific shelf life. For example, Higher order medicines like parpam have a shelf life of 100 years, chendooram has 75 years, whereas kyaazham/kudineer have shorter shelf life of 3 hours. Likewise, Nei has a shelf life of 6 months which minimizes the risk of any contamination or rancidity within the prescribed period of use. Nevertheless, physicochemical evaluations serve as basic research work for further pharmacological and pharmaceutical research.

Test for Specific Pathogen and Microbial contamination

Pathogen exclusion was verified by inoculating specific growth media selective for common regional infectious biological contaminations**.**

Target Microorganism	Selective Agar Medium Employed	Colony Presence Status
Escherichia coli	Eosin Methylene Blue (EMB) Agar	Absent
Salmonella spp.	Deoxycholate Citrate Agar	Absent
Staphylococcus aureus	Mannitol Salt Agar	Absent
Pseudomonas aeruginosa	Cetrimide Agar	Absent

Table 3. Test for Specific Pathogen

Aflatoxin Subtype Group	Identified Concentration Value	AYUSH Permissible Threshold Limits
Aflatoxin B1	Not Detected	0.5 ppm (0.5 mg/kg)
Aflatoxin B2	Not Detected	0.5 ppm (0.5 mg/kg)
Aflatoxin G1	Not Detected	0.1 ppm (0.1 mg/kg)
Aflatoxin G2	Not Detected	0.1 ppm (0.1 mg/kg)

Table 4. Aflatoxin Assay Test

Table 3 and 4 shows the drug is free from any form of contamination which ensures the proper hygiene is maintained. Total Viable Aerobic Count (TVAC) profiles checked across fungal and bacterial plating matrices were also absent ensuring the safety profile and therapeutic benefits well preserved.

Test for Heavy Metals

Table 5 compiles the results of heavy metal analysis by ICP OES (Inductively Coupled Plasma Optical Emission Spectrometry) technique.

Heavy metal analysed	Identified value
Arsenic (Ar)	BDL
Lead (Pb)	BDL
Cadmium (Cd)	BDL
Mercury (Hg)	BDL

Table 5. Heavy Metal Analysis – ICPOES

The analysis of heavy metals such as arsenic, mercury, cadmium, lead demonstrated that the formulation is safe for therapeutic usage. Therefore, ensuring the safety, purity and quality of the standardized SSN formulation.

Test For Pesticide Residues

Pesticide Chemical Class Checked	Representative Compounds Tracked	Residue Level Detected	AYUSH Regulatory Limit
I. Organochlorine Pesticides	Alpha, Beta, Gamma, Delta BHC, DDT, Endosulfan	BQL (Below Quantification Limit)	0.1 to 1.0 mg/kg
II. Organophosphorus Class	Malathion, Chlorpyrifos, Dichlorvos	BQL	0.2 to 1.0 mg/kg

III. Organocarbamate Group	Carbofuran	BQL	0.1 mg/kg
IV. Synthetic Pyrethroids	Cypermethrin	BQL	1.0 mg/kg

Table 6. Test For Pesticide Residues

Thus, the raw drugs collected during medicine preparation were purified properly which shows that the drug SSN is free from any pesticide residues and hence ensuring the quality of the drug.

Conclusion

This study serves as a groundwork for future research works. The drug Soothag Sanniku Nei has been evaluated for its safety, purity and quality. Further study is needed to understand the formulation at molecular level and to elucidate its pharmacological profile.

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