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QUALITY AND SAFETY EVALUATION OF VELLULLI NEI AS PER SIDDHA LITERATURE

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ABSTRACT

Vellulli Nei is a classical Siddha polyherbal medicated ghee preparation indicated for the management of Kunma Vali, a condition comparable to dyspepsia and upper gastrointestinal discomfort. The present study aimed to evaluate the quality, safety, and phytochemical characteristics of Vellulli Nei prepared according to Siddha literature. Physicochemical, phytochemical, biochemical, heavy metal, pesticide residue, sterility, specific pathogen and aflatoxin analyses were performed following PLIM and AYUSH guidelines. The formulation exhibited acceptable physicochemical characteristics, including viscosity (61.89), refractive index (1.44), iodine value (114.68 mg I_2/g), saponification value (170.58 mg KOH/g), acid value (0.87 mg KOH/g), and peroxide value (4.23 mEq/kg). Phytochemical screening revealed the presence of flavonoids, glycosides, steroids, and protein Heavy metals, microbial contaminants, pesticide residues, specific pathogens, and aflatoxins were absent or below detectable limits. These findings confirm the quality, safety, and potential therapeutic value of Vellulli Nei for internal administration.

KEYWORDS: Vellulli Nei, Siddha Medicine, Quality Evaluation, Safety Assessment.

INTRODUCTION

Siddha medicine is one of the oldest traditional systems of healthcare, utilizing herbal, mineral, and animal-derived substances for disease management. Vellulli Nei is a classical lipid-based Siddha formulation described in Agasthiyar Irandayiram Part I & II[1] and traditionally prescribed for Kunma Vali, a gastrointestinal disorder characterized by epigastric pain, bloating, nausea, and indigestion.[6] safety evaluation of traditional formulations are essential to ensure quality, reproducibility, and scientific validation. The present study evaluates the physicochemical properties, phytochemical profile, microbial quality, and safety parameters of Vellulli Nei prepared according to classical Siddha methods.

MATERIALS AND METHODS

Ingredients

- Allium sativum (Vellulli) – 140 g
- Piper longum (Thippili) – 8.75 g
- Indhuppu – 8.75 g
- River water – 1.2 L
- Cow's ghee – 650 mL
- Goat's milk – 325 mL

Vellai poondu
Fig.no 1,

Thippilli
Fig.no 2,

indhuppu
Fig.no 3,

Aatru neer
Fig.no 4

Goat's milk
Fig.no 5

Cow's ghee
Fig.no 6

Preparation

Fig.no 6,

Fig.no 7

Soaking In The Lemon Juice And After Dry It

Removed Skin of Vellulli
Fig.no 7

Evoporate the Moisture By Heating
Fig.no 8

Filtered For 7 time
Fig.no 9

Filtered for 7 Times Through Pure cloth

Fig.no 10

Dissolve Indhuppu In Viniger
Fig.no 11,

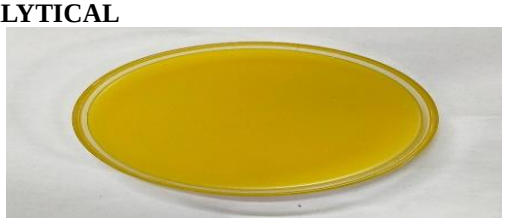
Filter and Let It
Fig.no 12

Solidify To Purified
Fig.no 13

As in siddha literature, take the *vellulli* and peel it outer layer, quickly boil them in water. Strain the water, then boiled *vellulli* add powder *thippili* and *induppu* grained them with goat's milk and make a paste. Added ghee with paste and stirring with a spatula. place it on stove and heat slowly it until reach the ghee consistency. Then cool it and stored.[4]
DOSAGE - **3** ¾ *Varaganedai* [15 gm]
ADJUVENT - cow's milk
SHELF LIFE – 6 months

Analytical Evaluation
The prepared formulation was subjected to:
1. Physicochemical analysis
2. Phytochemical screening
3. Biochemical analysis
4. Sterility testing
5. Specific pathogen testing
6. Pesticide residue analysis
7. Aflatoxin estimation
8. Heavy metal analysis

RESULTS
1. PHYSICOCHEMICAL ANALYTICAL



Figures: 14

Table:1

State	**Liquid**
Nature	Viscous
Odor	Mild
Touch / Consistency	Greasy
Flow Property	Free Flowing
Appearance	Yellowish

Table: 2

S. No	**Parameter**	**VN**
1	Viscosity at 50^{o}C (Pa s)	61.89
2	Refractive index	1.44
3	Weight per ml (gm/ml)	0.88

4	Iodine value (mg I_2/g)	114.68
5	Saponification Value (mg of KOH to saponify 1gm of fat)	170.58
6	Acid Value mg KOH/g	0.87
7	Peroxidase Value m Eq/kg	4.23

Fig no 15.

2. Phytochemical Screening

Table 3: (+) Indicates Positive and (-) Indicates Negative.

1.	ALKALOIDS	-
2	FLAVANOIDS	+
3	GLYCOSIDES	+
4	STEROIDS	+
5	TRITERPENOIDS	-
6	COUMARIN	-
7	PHENOL	-
8	TANIN	-
9	SAPONINS	-
10	PROTEIN	+
11	SUGAR	-
12	ANTHOCYANIN	-
13	BETACYANIN	-

3. BIOCHEMICAL ANALYTICAL

Test for Acid Radicals.

Specific Radical	**Test Report**
Test for carbonates	Positive- Indicates Presence
Test for chlorides	Negative -Indicates Absence
Test for sulfates	Positive- Indicates Presence
Test for sulphides	Negative -Indicates Absence
Test for phosphates	Negative - Indicates Absence
Test for Fluoride and Oxalate	Negative - Indicates Absence
Test for Borates	Negative - Indicates Absence
Test for Nitrates	Negative - Indicates Absence
Test For Basic Radicals	
Specific Radical	**Test Report**
Test for Lead	Negative - Indicates Absence
Test for Arsenic	Negative - Indicates Absence
Test for Mercury	Negative - Indicates Absence
Test for Copper	Negative - Indicates Absence
Test for Ferric	Negative - Indicates Absence
Test for Ferrous	Negative - Indicates Absence
Test for Zinc	Negative - Indicates Absence
Test for Silver	Negative - Indicates Absence
Test for Magnesium	Negative - Indicates Absence

4. STERILITY TEST: [POUR PLATE METHOD]

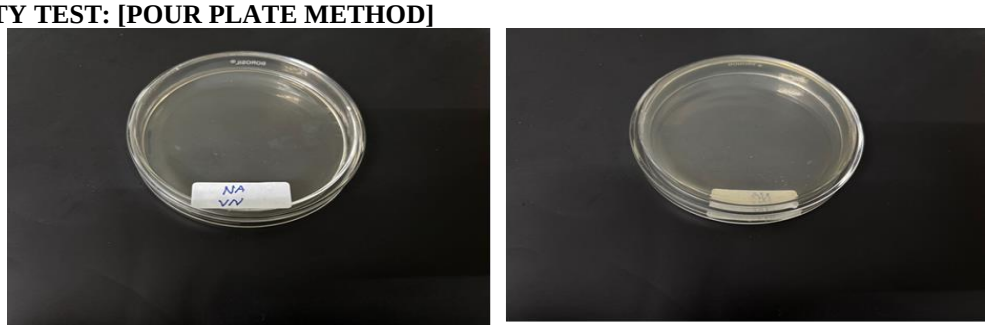


Fig no 16.

OBSERVATION

No growth was observed after incubation period reveals the absence of specific pathogen
No growth / colonies was observed in *vellulli nei*, it ensuring safe of drug.

Table: 4

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^5CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^3CFU/g	

5. SPECIFIC PATHOGEN TEST

Culture plate with E-coli (EC) specific medium

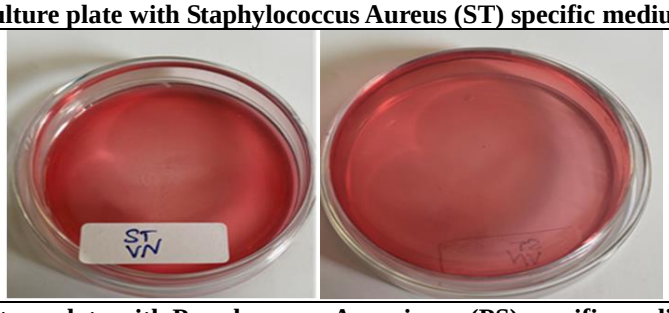
Culture plate with, Salmonella (SA) specific medium

Fig no 18, **Fig no 19**

Culture plate specific medium, Staphylococcus Aureus (ST)

Fig no 21 **Fig no 22**

Culture plate with Staphylococcus Aureus (ST) specific medium



Culture plate with Pseudomonas Aeruginosa (PS) specific medium

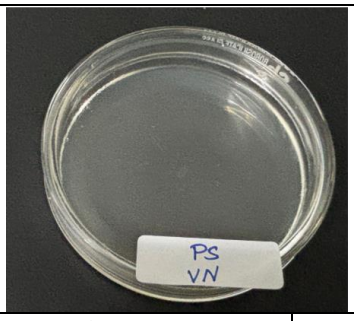


Fig no 23

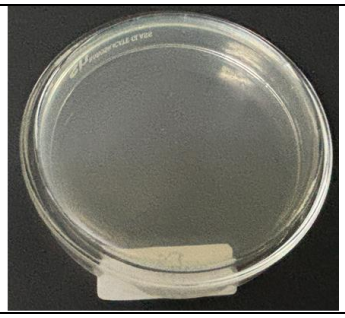


Fig no 24

Observation
No growth was observed after incubation period. Reveals the absence of specific pathogen
No growth / colonies were observed in *vellulli nei*.

Table: 5

Organism	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

6. PESTICIDE RESIDUE ANALYTICAL
Table: 6

Pesticide Residue I .Organo Chlorine Pesticides	Sample VN	AYUSH Limit (mg/kg)
Alpha BHC	BQL	0.1mg/kg
Beta BHC	BQL	0.1mg/kg
Gamma BHC	BQL	0.1mg/kg
Delta BHC	BQL	0.1mg/kg
DDT	BQL	1mg/kg
Endosulphan	BQL	3mg/kg
II. Organo Phosphorus Pesticides		
Malathion	BQL	1mg/kg
Chlorpyriphos	BQL	0.2 mg/kg
Dichlorovos	BQL	1mg/kg
III. Organo carbamates		
Carbofuran	BQL	0.1mg/kg
III.Pyrethroid		
Cypermethrin	BQL	1mg/kg

BQL- Below Quantification Limit
The results showed that there were no traces of pesticides residues such as Organo chlorine, Organo phosphorus, Organo carbamates and pyrethroids in the vellulli nei.

7. AFLATOXIN ANALYSIS.
Table:7

Aflatoxin	Sample VN	AYUSH Specification Limit
B1	Not Detected - Absent	0.5 ppm (0.5mg/kg)
B2	Not Detected - Absent	0.1 ppm (0.1mg/kg)
G1	Not Detected - Absent	0.5 ppm (0.5mg/kg)
G2	Not Detected - Absent	0.1 ppm (0.1mg/kg)

The results shown that there were no spots were being identified in the vellulli nei loaded on TLC plates when compare to the standard which indicates that the sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1 and Aflatoxin G2.[7]

8. HEAVY METAL ANALYTICAL

Table: 8

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis	Maximum Limit
Lead	217.0 nm	Below detection limit	10 ppm
Arsenic	193.7 nm	Below detection limit	3 ppm
Cadmium	228.8 nm	Below detection limit	0.3 ppm
Mercury	253.7 nm	Below detecion limit	1 ppm

DISCUSSION

The physicochemical parameters indicate that Vellulli Nei possesses desirable quality characteristics and stability. Low acid and peroxide values suggest minimal rancidity and good shelf stability. The presence of flavonoids, glycosides, steroids, and proteins supports the traditional therapeutic use of the formulation in gastrointestinal disorders.

Safety assessment demonstrated complete compliance with AYUSH standards. Heavy metals were below detection limits, pathogenic microorganisms were absent, and no pesticide residues or aflatoxins were detected, confirming the formulation's safety for internal use**.**

CONCLUSION

The present study establishes that Vellulli Nei is safe Siddha formulation with acceptable physicochemical characteristics, a distinct phytochemical profile, The absence of heavy metals, microbial contamination, pesticide residues, and aflatoxins confirms its safety. These findings support the traditional use of Vellulli Nei in gastrointestinal disorders and provide scientific evidence for its quality assurance and therapeutic potential.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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