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Preparation, Quality control and Standardization of a Destructive Distillate *Swasakasa Nei* (SKN), A Traditional Siddha Herbal Pharmaceutic for *Swasakasam* (Bronchial Asthma)

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ABSTRACT: Standardization is essential to ensure the quality and reliability of traditional medicines. This study aimed to collect, authenticate and purification of raw materials, preparation of *Swasakasa Nei* (SKN) according to SOP, and Quality evaluation and Standardization procedures following Pharmacopoeial Laboratory of Indian Medicine (PLIM) guidelines. SKN, prepared as *Kuzhithylam*, is used to treat Swasakasam (Bronchial Asthma) in the Siddha system of medicine. The organoleptic characters of *Swasakasa Nei* reveal that SKN was a black, thick semisolid with a smoky odour, greasy consistency, and free-flowing nature drug. Physicochemical analysis showed values for Saponification Value (202.19), Iodine Value (30), Acid Value (7.25%), Peroxide Value (0.58%), Refractive Index (1.462), Specific Gravity (0.9131 g/ml), Loss on Drying (34.17%), Total Fatty Matter (60.18%), Free Fatty Acids (1.06%), and Unsaponifiable Matter (0.98%). The congealing point was 19°C, with no mineral oil and definite oxidation on rancidity. HPTLC fingerprint analysis revealed multiple prominent peaks at various wavelengths. Microbial contamination tests showed no specific microbes, and aflatoxin assays confirmed SKN was free from Aflatoxins B1, B2, G1, and G2. Pesticide residue analysis detected no organochlorine, organophosphorus, or pyrethroids, and heavy metal analysis showed no trace elements or heavy metals. These standards affirm the authenticity, genuineness, and safety of SKN, contributing to its scientific validation.

1. INTRODUCTION

India has numerous traditional medical systems such as Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa-Rigpa and Homoeopathy (Ayush). The Siddha system, primarily prevalent in the southern region of India, notably Tamil Nadu, is often called Tamil medicine. Siddha medicine promotes human well-being and emphasizes natural remedies derived from herbs, metals, secondary minerals, marine products, and the animal kingdom (Siva, 2022, 2023; Subbarayappa, 2001). Siddha medicines are divided into two categories based on their application: Internal and External. Internal medicines, administered orally, are further classified into 32 categories based on their form, preparation methods, and shelf life. External medicines and therapies encompass various drug forms and applications such as nasal, eye, and ear drops, as well as procedures like leech application, a total of 32 in number (Thiyagarajan, 2009).

Tailam, a medicated oil, is utilized both internally and externally. It's prepared by boiling herbal decoctions, juices, and pastes with oils for a specific duration, then filtered. Its potency lasts for one year. Ney involves blending herb extracts with cow's Ghee through boiling to extract fat-soluble components, ensuring thorough integration (Thiyagarajan, 2009). Ney, derived from seeds, creepers, barks, and herbs, refers to oils/Ghee in Siddha medicine, with a shelf life ranging from 6 months to 1 year. Twelve types of medicinal oils are categorized by extraction methods such as boiling, melting, distillation, calcination, solar exposure, earth, wood, rock, soaking in

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water, vapor, flame, and specific processing. These oils are administered via five methods: *Muṭi ney* (scalp oil), *Kuṭi Ney* (internal oil), *Piṭi Ney* (massage oil), *Tulai Ney* (orificial oil), and *Cilai ney* (skin/wound oil) for various therapeutic applications (Thiyagarajan, 2009).

Puṭa ney or *Kulittailam* is prepared through calcination or destructive distillation method that involves crushing constituent drugs and placing them in an earthen pot with perforated holes at the bottom. Iron wires are drawn through these holes and tied together, with the pot sealed and placed in a pit over a collecting vessel. Cow dung cakes are arranged around the pot and set on fire. After cooling, the setup is disassembled, and the oil collected in the vessel is used further (Thiyagarajan, 2009). "*Swasakasa Nei*" was also prepared as Kulittailam.

Standardization ensures the quality and reliability of traditional medicines, which is crucial as their global popularity rises. Variances in raw material collection due to geography, seasons, and procedures can affect medicine quality. Siddha classical texts emphasize the importance of selecting and purifying raw drugs, following the correct processes to complete the medicine, using traditional testing methods for finished products, and using proper preservation techniques. Authentication and adequate processing of raw materials yield high-quality drugs (Rathinamala & Moonandi, 2014). It involves all manufacturing and quality control measures for reproducible quality. Standards quantify the parameters that reflect material quality and efficacy. Quality control extends from raw material collection and drug preparation to patient use, not just a laboratory procedure (Revathy & Moonandi, 2014).

Standardization is crucial for widespread adoption, thorough documentation, reproducibility, large-scale industrial production, prevention of adulteration and contamination, assessment of both raw material and final product quality, estimation of active ingredient quantities, and ensuring consistent batch-to-batch quality of finished products Revathy and Moonandi (2014).

An endeavour was undertaken to explore the standardization process of *Swasakasa Nei* (SKN), a Siddha herbal remedy used for Bronchial asthma. This present study was carried out with the following objectives,

- Collection, Authentication and Purification of raw drug materials.
- Preparation of the drug SKN as per standard operating procedures.
- Assess the quality and Standardization of SKN through modern techniques like organoleptic assessment, physicochemical analysis, HPTLC fingerprinting, heavy metal testing, microbial load determination, specific pathogen testing, pesticide residue and aflatoxin analysis as per Pharmacopeial Laboratory of Indian Medicine (PLIM) guidelines (Lohar, 2008; Ministry of AYUSH, 2018).

2. MATERIALS AND METHODS

Swasakasa Nei had been selected from the classical Siddha sastric text as *Cikiccā rattina tīpam ennum vaittiyanūl* (Kannusamipillai, 2007).

2.1. Ingredients in the *Swasakasa Nei* (SKN)

Ingredients of the *Swasakasa Nei* are listed in Table 1.

2.2. Source and collection of raw drug materials

Piramʹmataṇṭu root and *Vellerukku* leaves were gathered from wastelands, cultivated fields, and roadsides in Kallakurichi, Thirupathur, and Coimbatore Districts. *Pacu ney* (Cow's Ghee) was procured from a reputable ghee company like the Aavin store in Chennai, India.

2.3. Authentication of raw drug materials

The Botanist and Head of Gunapadam, Department of National Institute of Siddha, Chennai -47, India identified and authenticated raw drug materials. The authentication certificate numbers are NISMB4752021 on 26/07/2021 and Gun/Aut/028/21 on 06/07/2021.

2.4. Purification of raw drug materials

The *Piramʹmataṇṭu* root was thoroughly rinsed under fresh running water until all traces of mud and impurities were removed. As for the *Vellerukku* leaves, they were gently wiped with a clean cloth on both sides instead of washing them. Butter was heated in a mud pot until the water content evaporated, and then it was strained through a filter as purified Ghee (Kannusamipillai, 2007).

2.5. Standard operating procedure for preparation of SKN

In the initial step, several holes were created at the base of a mud pot, and iron wires were attached to allow oil collection into a vessel. Next, 60 to 80 *Vellerukku* leaves were coated with cow's Ghee on both sides, while *Piramʹmataṇṭu* root was cut into small pieces and similarly coated. These prepared leaves and roots were layered within the mud pot until filled. The pot's opening was sealed with a mud pan and cloth-clay mixture, with a porcelain vessel placed below to collect the drained oil. Cow dung cakes were placed above the porcelain vessel and subjected to an incineration process (*Puṭam*), whereby heat facilitated oil drainage into the vessel, as illustrated in Figure 1 (Kannusamipillai, 2007).

2.6. Quality evaluation and Standardization procedures

Standardization is a tool in the quality control process. As a preliminary work, the parameters mentioned in the Pharmacopeial Laboratory of Indian Medicine for medicated Ghee were studied as follows,

2.6.1 Organoleptic characters

Colour, odour, taste, size, shape and special features such as touch, texture, etc.

Table 1
Ingredients of *Swasakasa Nei* (SKN).

S. No	Tamil Name	Scientific Name	Parts used	Quantity
1.	*Piramˈmataṇṭu*	*Argemone mexicana* Linn	Root	78.75 grams (2 $\frac{1}{4}$ *palam*)
2.	*Vellerukku*	*Calotropis procera* Linn	Riped leaf	60-80 Numbers
3.	*Pacu ney*	Cow's Ghee	Purified Ghee	Required quantity

Figure 1. Standard operating procedure for preparation of SKN. (a) Pierced Mud pot with iron wires, (b) Roots of *Argemone mexicana*. Linn, (c) Dried *Argemone* Roots coated by cow's Ghee, (d) Leaves of *Calotropis procera*. Linn, (e) Arranged alternative layers of roots and leaves within a mud pot, (f) Sealed mud pot by mud pan and covered with layers of cow dung cakes, (g) Processes of Incineration (*Puṭam*), (h) Collection of oil (*Kulittailam*) in a clean vessel, (i) *Swasakasa Nei*.

2.6.2 Solubility profiles

A solubility study was conducted based on methods mentioned in the Pharmacopeial Laboratory of Indian Medicine.

2.6.3 Physicochemical Parameters

Rancidity test (Kreis test), Specific gravity, pH value, Moisture content (Loss on drying), Congealing range, Mineral oil (Holde's test), Iodine value (Iodine Monochloride Method), Saponification value, Unsaponifiable matter, Refractive index (Abbe's refractometer), Acid value, and Peroxide value were evaluated (Lohar, 2008; Ministry of AYUSH, 2018).

2.6.4 HPTLC Fingerprint Analysis:

The high-performance thin-layer chromatographic fingerprint of SKN was evaluated following the method outlined by Ganesh et al. (2023) with slight adjustments.

2.6.5 Microbial Contamination Test:

Total viable aerobic bacterial and fungal counts for *Escherichia coli*, *Salmonella*, *Staphylococcus aureus*, and Pseudomonas aeruginosa were determined by following Ratajczak et al. (2015) method with slight modifications.

2.6.6 Aflatoxins (B1, B2, G1, G2) Evaluation:

We used HPLC with a fluorescence detector (HPLC-FLD) (Aliakbarzadeh et al., 2023; Jeyaraj et al., 2022). Aflatoxins (ng/g) were calculated by Aflatoxins (ng/g) = Conc. from linearity ng/mL x dilution factor.

2.6.7 Pesticide Residue Analysis:

Determined using Gas Chromatography-Mass Spectrometry (GCMS) and Liquid Chromatography Mass Spectrometry (LCMS) (Balkan & Karaağaçlı, 2023).

2.6.8 *Heavy Metals Analysis:*

The levels of heavy metals, including lead, cadmium, arsenic, and mercury, in SKN were measured using an Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES) instrument (Gomez et al., 2007).

3. RESULTS

3.1. Organoleptic characters

While examining the organoleptic characteristics of SKN, it was revealed that it was a thick black, semisolid material with a Smokey odour and free-flowing, with a greasy consistency while touching. The inferences were tabulated in Table 2.

Table 2
Organoleptic characters of *Swasakasa Nei*.

S. No	Organoleptic characters	Observations
1.	Description	Colored thick semisolid material
2.	Odour	Smoky odour
3.	Touch	Greasy
4.	Flow property	Free-flowing
5.	Appearance and colour	Black and Brown

3.2. Solubility profiles

SKN is a ghee-based medicine. So, it was well soluble in chloroform, ethanol, and ethyl acetate. But insoluble in water. The inferences were tabulated in Table 3.

Table 3
Solubility profiles of *Swasakasa Nei.*

S. No.	Solvent Used	Solubility / Dispersibility
1.	Chloroform	Soluble
2.	Ethanol	Soluble
3.	Water	Insoluble
4.	Ethyl acetate	Soluble

3.3. Physicochemical Parameters

The analysis of the physicochemical parameters of SKN determines that the values of Saponification Value, Iodine value, Acid Value, Peroxide Value, Refractive index, Specific gravity (gm/ml), Loss on drying, Total fatty matter (% by mass), Free fatty acids (% by mass) and Unsaponifiable matter (% by mass) are such as 202.19, 30, 7.25%, 0.58%, 1.462, 0.9131, 34.17%, 60.18%, 1.06%, and 0.98% respectively. The congealing point was 19°, mineral oil was absent, and the radoxidity was oxidized. The observed results were tabulated in Table 4.

3.4. HPTLC fingerprint analysis

HPTLC fingerprint analysis of the SKN reveals that the presence of various prominent peaks (Figure 2) at 245 nm and 366 nm of wavelengths corresponds to the presence of versatile phytocomponents.

3.5. Microbial contamination test

Microbial contamination test shows the absence of microbes like E.coli, Salmonella, S.aureus, and P.aeruginosa in the SKN. The observed results were tabulated in Table 5.

3.6. Evaluation of Aflatoxins (ppm)

The results of the aflatoxin assay reveal that SKN was free from Aflatoxins B1, B2, G1, and G2. Values of aflatoxins were present below the limit of quantification. The observed results were tabulated in Table 6.

3.7. Evaluation of Pesticide Residues (ppm)

The analysis of Pesticide Residues reveals that SKN contains no traces of organochlorine, organophosphorus, or pyrethroids. Values of Pesticide Residues present in the SKN were below the detection limit. The observed results are tabulated in Table 7.

3.8. Heavy metals analysis (ppm)

The heavy metals analysis reveals that SKN had no trace of elements and heavy metals like Lead, Cadmium, Arsenic and Mercury. Which were present below the limit of quantification. The observed results were tabulated in Table 8.

4. DISCUSSION

In this study, various appropriate techniques were employed to assess SKN's quality. The ingredients of SKN were authenticated using visual inspection, organoleptic characteristics, taxonomical methods, and morphological examination. This approach helps to prevent drug adulteration.

The organoleptic properties of SKN, such as colour, odour, taste, touch, and texture, correspond to the raw ingredients used in the preparation of the medicated Ghee. The SKN was black-coloured, thick semisolid material with a smoky odour and free flowing in nature, greasy like consistency while touch. SKN is a ghee-based medicine. So, it was well-soluble with chloroform, ethanol, and ethyl acetate. But insoluble in water.

The analysis of physicochemical parameters of SKN includes the saponification value, which enables comparison of the average fatty acid chain length. Long-chain fatty acids in fats exhibit a low saponification value due to fewer carboxylic functional groups per unit mass than short-chain fatty acids (Kamaliya et al., 2020). The saponification value of SKN was found to be 202.19. A saponification value above the normal range suggests the presence of lower molecular weight saturated fatty acids (Pal & Mishra, 2018).

Iodine values determine the level of unsaturation in Ghee; a higher iodine value indicates greater unsaturation in the Ghee. Increased unsaturation elevates the potential for absorption and atmospheric oxidation, leading to rancidity. The iodine value of SKN was 30, suggesting minimal rancidity in this formulation. Ghee with a higher iodine value is less stable and more susceptible to oxidation and free radical production. High iodine value ghee is prone to oxidation and polymerization, resulting in rancidity, reduced shelf life, and

Table 4
Physicochemical Parameters of *Swasakasa Nei*.

S. No	Chemical Parameters	Inst. used	Method	Result
1.	Saponification Value	Chemically	API	202.19
2.	Iodine value	Chemically	API	30
3.	Acid Value	Chemically	API	7.25%
4.	Peroxide Value	Chemically	API	0.58%
5.	Refractive index	Refractometer	API	1.462
6.	Mineral Oil	Chemically	API	Absent
7.	Specific gravity (gm/ml)	Chemically	API	0.9131
8.	Loss on drying	Hot air oven	API	34.17%
9.	Total fatty matter (%by mass)	Chemically	API	60.18%
10.	Free fatty acids (%by mass)	Chemically	API	1.06%
11.	Un saponifiable matter (%by mass)	Chemically	API	0.98%
12.	Congealing point	Chemically	API	19°
13.	Rancidity	Chemically	API	Oxidized

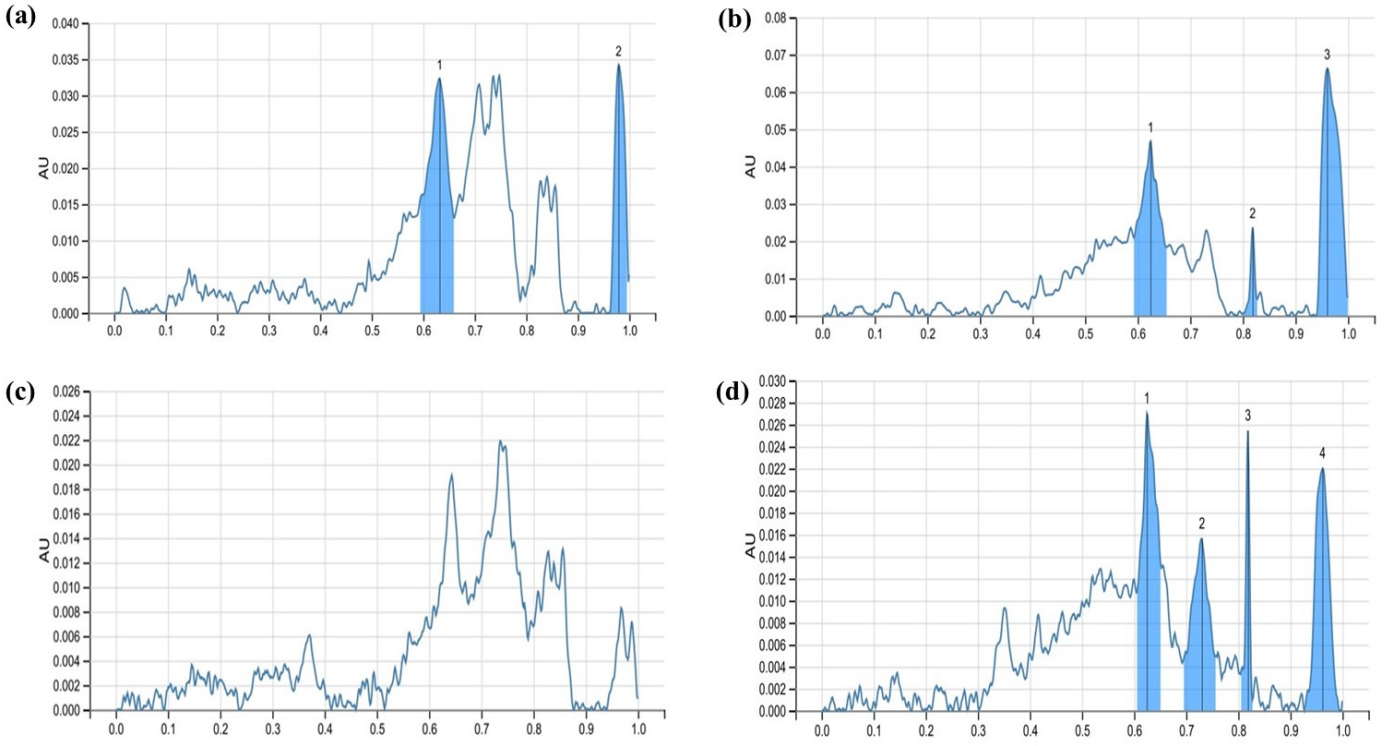

Figure 2. HPTLC fingerprinting of *Swasakasa Nei* show different peaks of phytoconstituents at various wavelengths. (a) Track 1 at 245 nm, (b) Track 2 at 245 nm, (c) Track 1 at 366 nm, (d) Track 2 at 366 nm.

Table 5
Microbial contamination test of *Swasakasa Nei*.

S. No.	Test parameters	Inst. Used	Method	Requirement	Result
1.	Total viable aerobic count (cfu/gm)	Microbiological	API	Max.-100000	<10
2.	Total fungal count (cfu/gm)	Microbiological	API	Max.-1000	<10
3.	E.coli/gm	Microbiological	API	Absent	Absent
4.	Salmonella/gm	Microbiological	API	Absent	Absent
5.	S.aureus/gm	Microbiological	API	Absent	Absent
6.	P.aeruginosa/gm	Microbiological	API	Absent	Absent

Table 6
Aflatoxins (ppm) evaluation of *Swasakasa Nei*.

S. No.	Test parameters	Inst. Used	Method	Requirement	Result
1.	Aflatoxin B1 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.5	BLQ (LOQ:0.0005)
2.	Aflatoxin B2 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005)
3.	Aflatoxin G1 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.5	BLQ (LOQ:0.0005)
4.	Aflatoxin G2 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005)

Table 7
Pesticide Residue (ppm) evaluation of *Swasakasa Nei*.

S. No	Test Parameter	Inst. Used	Method	Result
1.	Endosulfan	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
2.	Permethrin	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
3.	Chlorpyrifos	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
4.	Heptachlor (Sum of heptachlor and heptachlorepoxide)	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
5.	Aldrin	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
6.	Dichlorvos	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
7.	Malathion	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
8.	Parathion methyl	LCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
9.	Parathion Ethyl	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
10.	Dieldrin	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
11.	Delta methrin	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
12.	2-4'-DDT	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
13.	4-4'DDT	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
14.	Gamma HCH	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
15.	Beta HCH	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
16.	4-4'DDD	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
17.	2-4'DDE	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
18.	2-4'DDD	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
19.	4-4'DDE	GCMSMS	IH/MS(Ref.API)	BDL(DL:0.005)
20.	Lindane	GCMSMS	API	BDL(DL:0.005)
21.	BHC Delta	GCMSMS	API	BDL(DL:0.005)
22.	Alachlor	GCMSMS	API	BDL(DL:0.005)
23.	Alpha BHC	GCMSMS	API	BDL(DL:0.005)
24.	Atrazine	GCMSMS	API	BDL(DL:0.005)
25.	Butachlor	LCMSMS	API	BDL(DL:0.005)
26.	Ethion	GCMSMS	API	BDL(DL:0.005)
27.	Phorate	LCMSMS	API	BDL(DL:0.005)
28.	EndosulfanI	GCMSMS	API	BDL(DL:0.005)
29.	EndosulfanII	GCMSMS	API	BDL(DL:0.005)
30.	EndosulfanIII	GCMSMS	API	BDL(DL:0.005)
31.	Isoproturon	LCMSMS	API	BDL(DL:0.005)

Table 8
Heavy metals Analysis (ppm) of *Swasakasa Nei*.

S. No.	Test parameters	Inst. Used	Method	Requirement	Result
1.	Lead (as Pb) (ppm)	ICP-OES	ITC/STP/F/INST/008	NMT-10	BLQ (LOQ:0.5)
2.	Arsenic (as As) (ppm)	ICP-OES	ITC/STP/F/INST/008	NMT-3	BLQ (LOQ:0.5)
3.	Mercury (as Hg) (ppm)	ICP-OES	ITC/STP/F/INST/008	NMT-1	BLQ (LOQ:0.5)
4.	Cadmium (as Cd) (ppm)	ICP-OES	ITC/STP/F/INST/008	NMT-0.300	BLQ (LOQ:0.25)

product stability (Pal & Mishra, 2018).

The acid value measures the quantity of fatty acids in SKN released from glycerides through hydrolysis caused by moisture, temperature, and/or the lipolytic enzyme lipase. This value indicates the product's rancidity and aids in determining the shelf life of the Ghee (Ministry of Health and Family Welfare, 2011). The acid value for SKN was 7.25%, indicating good stability of the finished product. A higher acid value would increase the likelihood of photooxidation and rancidity (Pal & Mishra, 2018).

Specific gravity indicates the presence of solute content in the solvent (Ministry of Health and Family Welfare, 2011). The value for SKN was found to be 0.9131 gm/ml. Which was closer to plain cow's Ghee, for which it was 0.9. The refractive index indicates the sample density compared to air and liquid media (Ministry of AYUSH, 2007) and the SKN value was 7.25%, which was within the limit. Peroxide Value, Loss on drying, Total fatty matter (% by mass), Free fatty acids (% by mass) and Unsaponifiable matter (% by mass) are such as 0.58%, 34.17%, 60.18%, 1.06%, and 0.98% respectively. The congealing point was 19° C, mineral oil was absent, and rancidity was definitely oxidized.

HPTLC fingerprint analysis of SKN revealed the presence of two prominent peaks, indicating two key phyto components, with Rf values ranging from 0.597 to 0.962 in track 1 at 245 nm. Three prominent peaks, indicating three key phyto components, had Rf values ranging from 0.593 to 0.940 in track 2 at 245 nm. No peaks were observed in track 1 at 366 nm. In track 2 at 366 nm, four prominent peaks indicated four key phyto components, with Rf values ranging from 0.604 to 0.928.

The microbial contamination test shows the absence of specific microbes like *E.coli*, *Salmonella*, *S.aureus*, and *P.aeruginosa* in the SKN test drug. The results of the aflatoxin assay reveal that test drug SKN was free from Aflatoxin B1, B2, G1, and G2. Values of aflatoxins are Below the limit of quantification. The analysis of Pesticide Residues reveals that test drug SKN contains no traces of organochlorine, organophosphorus, or pyrethroids. Values of pesticide residues are below the detection limit. The heavy metals analysis reveals that test drug SKN has no trace of elements, and heavy metals such as lead, calcium, arsenic, and mercury are below the limit of quantification.

5. CONCLUSION

Quality control analysis is a major and essential step in preparing Traditional medicine. The quality of the raw drugs materials and drugs affects the safety and efficacy of medicinal products. So, quality control is essential to follow in each step, from authentication to the final product development, as it will pave the way to standardisation of traditional drugs. The study reveals that sufficient quality control measures were followed to prepare SKN. Organoleptic characters, Physicochemical, HPTLC fingerprinting, Microbial contamination test, Aflatoxin assay, Pesticide Residues analysis and Heavy metals analysis. These standards exhibit authenticity, genuineness and safety of the final product. So, this study is a step forward in the scientific validation of SKN. It reveals that *Swasakasa Nei* (SKN) is safer to consume and more effective.

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CONFLICTS OF INTEREST

None.

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AUTHOR CONTRIBUTIONS

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