Standardization and Quality Control of *Sanjeewanie Kameshwari Rasayanaya*

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ABSTRACT

Modaka is a special preparation in *Bhaisajya Kalpana*, prepared by grinding powdered ingredients with bases such as bee honey and ghee. Among the various *Modaka* formulations, *Kameshwari Modaka* is well known for its rejuvenative and aphrodisiac properties and is marketed in Sri Lanka as *Sanjeewani Kameshwari Rasayanaya* (SKR). The present study aimed to evaluate the safety and quality of SKR using a comprehensive set of analytical methods. SKR was prepared according to the Sri Lankan Ayurveda Pharmacopeia at the *Sanjeewani* Ayurveda Drug Company, *Embilipitiya*. Quality and safety assessments included physicochemical analysis (loss on drying, ash values, total sugar, free fatty acids), microbiological and aflatoxin screening, heavy metal detection using microwave digestion, and phytochemical as well as chromatographic profiling (TLC and HPTLC) of the dichloromethane extract. Physically, SKR exhibited loss on drying (3.6%) and total ash (2.8%), both within standard limits. Microbiological evaluation revealed acceptable values, with aerobic plate count (1.9×10^4), yeast and mold (<100), *Staphylococcus aureus* (<10), *Escherichia coli* and *Salmonella* spp. absent, and *Pseudomonas aeruginosa* (<100). Toxicological assessment confirmed the absence of lead, cadmium, arsenic, mercury, aflatoxins (B1, B2, G1, G2 and total), and synthetic dyes. Total sugar and free fatty acids were 27.7% and 2.0% respectively. Phytochemical screening of the dichloromethane extract indicated the presence of alkaloids, tannins, saponins, flavonoids, steroids, cardiac glycosides, terpenoids, and carbohydrates, while proteins were absent. HPTLC fingerprinting (Ethyl acetate: Dichloromethane: Cyclohexane 0.1:3.4:1.5) revealed six peaks with R_f values 0.01, 0.38, 0.53, 0.66, 0.69, and 0.85, establishing a reproducible profile for the formulation. Overall, SKR complied with established quality and safety standards, supporting its acceptance as a standardized Ayurveda drug.

Keywords: Aphrodisiac, *Kameshwari Modaka*, *Sanjeewani*, Rejuvenation, Safety

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Introduction

Ayurveda, the timeless science of life, provides a holistic approach to health and wellness, encapsulating a comprehensive understanding of medicinal formulations through *Bhaisajya Kalpana*. *Modaka* is a special preparation mentioned in *Bhaisajya Kalpana* that involves grinding powdered ingredients with bases like bee honey and ghee (Department of Ayurveda, 1961). This preparation is known by several synonyms, including *Gutika*, *Vati*, *Modaka*, *Vatika*, *Pindi*, *Guda* or *Varthi* (Department of Ayurveda, 1961). *Kameshwari Modakaya* is mentioned as the eighth formulation in the Sri Lankan Ayurveda Pharmacopeia under *Modaka Kalpana* and renowned for its rejuvenative, relaxing and aphrodisiac properties among *modaka* preparations (Department of Ayurveda, 1961). *Kameshwari Modakaya* prepared according to Sri Lankan Ayurveda Pharmacopeia is commercially available as *Sanjeewani Kameshwari Rasayanaya* (SKR). This study focuses on the standardization and quality control of the marketed product SKR, to ensure its safety, efficacy and consistency. SKR includes 25% of Cannabis (*Bhanga*) seeds and leaves tempered with ghee and 75% of 22 herbal ingredients (Table 01) from the total weight along with rock salt (*saindhava lavana*), sugar (*sharkara*), ghee (*ghrita*) and bee honey (*madhu*). In Ayurveda drug formulations, cannabis leaves and seeds are recommended to be used after being subjected to purification process (*Shodhana*). According to Sri Lanka Ayurveda Pharmacopoeia, Cannabis seeds and leaves should be soaked in water for 4-5 hours, then drained, and naturally dried (Perera, 2025). Thereafter, they should be fried in cow's ghee and used in drug preparations. Ghee is having a detoxification effect on cannabis (Abeysinghe, 1997). In this study also purification method described in Ayurveda Pharmacopeia for cannabis seeds and leaves was followed.

Moreover, SKR has three principal therapeutic actions as rejuvenative, relaxant and aphrodisiac (Department of Ayurveda, 1961). As a rejuvenative drug, it improves body strength, immunity and appetite, is good for digestive disorders, regulates healthy blood sugar levels, acts as a nervine tonic and enhances memory and concentration. As a relaxant it controls stress and good for disturbed sleep, depression and anxiety. SKR enhances sexual strength and stamina, improves the concentration of sperms both qualitatively and quantitatively due to its aphrodisiac properties.

Table 1: Herbal ingredients of *Sanjeewani Kameshwari Rasayanaya*

Botanical name	Family	Sri Lankan Name	Sanskrit name	Used part
Cannabis sativa L.	Cannabaceae	*Kansa*	*Bhanga*	Seeds, leaves
Coriandrum sativum L.	Apiaceae	*Koththamalli*	*Dhanyaka*	Seeds
Terminalia chebula Retz.	Combretaceae	*Aralu*	*Haritaki*	Fruit cover
Terminalia bellirica (Gaertn.) Roxb.	Combretaceae	*Bulu*	*Vibhitaki*	Fruit cover
Phyllanthus emblica L.	Euphorbiaceae	*Nelli*	*Amalaki*	Fruit
Acorus calamus L.	Araceae	*Wada kaha*	*Vacha*	Stem
Saussurea lappa (Decne.) Sch.Bip.	Asteraceae	*Suwada kottam*	*Kushta*	Stem
Trachyspermum roxburghianum DC.	Apiaceae	*Heen Asamodagam*	*Yawanika*	Seeds
Aegopodium podagraria L.	Apiaceae	*Maha asamodagam*	*Ajamoda*	Seeds
Glycyrrhiza glabra L.	Fabaceae	*Welmee*	*Yashtimadhu*	Stem
Nigella sativa L.	Ranunculaceae	*Kaluduru*	*Kalajaji*	Seeds
Cuminum cyminum L.	Apiaceae	*Sududuru*	*Ajaji*	Seeds
Cinnamomum zeylanicum Blume.	Lauraceae	*Kurundu*	*Thwak*	Stem bark
Elettaria cardamomum L. Maton.	Zingiberaceae	*Enasal*	*Ela*	Seeds

Cinnamomum tamala Buch.-Ham.	Lauraceae	*Tejapathra*	*Tejapathra*	Leaves
Zingiber officinale Roscoe.	Zingiberaceae	*Inguru*	*Shunti*	Rhizome
Piper nigrum L.	Piperaceae	*Gammiris*	*Maricha*	Seeds
Piper longum L.	Piperaceae	*Tippili*	*Pippali*	Seeds
Myrica esculenta Buch-Ham	Myricaceae	*Katphala*	*Katphala*	Bark
Pistacha chinensis Bunge	Anacardiaceae	*Karkataka Shrungi*	*Karkataka Shrungi*	Gall
Kaempferia galanga L.	Zingiberaceae	*Inguru piyali*	*Shatee*	Rhizome
Abies webbiana (Wall. Ex D. Don) Lindl.	Pinaceae	*Thalis pathuru*	*Thalisa patra*	Leaves
Mesua ferrea L.	Calophyllaceae	*Nelum renu*	*Nagakeshara*	Stamens

Since the demand for health-related products is growing continuously in the global market, there is a growing demand for standardization in order to make products work effectively (Kalpana et al., 2022). The standardization process must be implemented starting from the selection of raw materials all the way to the production of the final product. Quality, safety and efficacy are three main aspects of standardization (Silva, 2006). Ensuring the safety and efficacy of herbal products, ensuring a proper supply, preventing adulteration and implementing strict quality control measures in both raw materials and finished goods will go a long way toward maintaining integrity and growth within the herbal product industry. The primary aim of this research study was to prepare SKR according to authentic texts and to analyze its quality and safety (Wang et al., 2023). The quality and safety evaluation process of SKR consisted of a thorough analysis of the product, covering a range of parameters including organoleptic, physico-chemical, toxicological, microbiological and chemical parameters.

Materials and Method

Collection and authentication of raw materials

All the ingredients used for SKR except cannabis were purchased from the local market in Colombo, Sri Lanka and authenticated by the Department of Ayurveda Pharmacology and Pharmaceutics, Faculty of Indigenous Medicine, University of Colombo. Cannabis seeds and leaves were purchased and authenticated by the Ayurveda Drug Cooperation, *Nawinna*, Sri Lanka.

Preparation of *Sanjeewani Kameshwari Rasayanaya*

Three batches of SKR were prepared and one sample from each batch was selected randomly for the study. The drug was prepared according to Sri Lankan Ayurveda Pharmacopeia following standard operating procedures at the *Sanjeewani* Ayurveda Drug Company, *Embilipitiya*. First, all the herbal ingredients (Table 01) except cannabis were taken. The contaminants of the raw materials were removed manually, washed with water and then dried in the electric dryer. Then all these herbal ingredients and rock salt were powdered and roasted on mild fire. Equal amounts of all the powdered ingredients (5g each) were mixed together and kept aside. *Bhanga* seeds and leaves were fried in *ghrita* and powdered separately. An equivalent weight of *bhanga* seeds and leaves powder (115g), equal to the total weight of the previously prepared herbal powder mixture, was taken. All the above powders were mixed using a mixing machine. Then this mixture was mixed with *sharkara* (460g), which is equivalent to twice the weight of the mixture. After that, *madhu* and *ghrita* were added as required and ground to achieve the *modaka* consistency (Figure 01). Finally, fried *thila* (sesame seeds) and *karpoora* (camphor) were added (5g each) to enhance the fragrance (Department of Ayurveda, 1961).The prepared SKR was filled into the sterile containers.

1 (a) Drying the ingredients

1 (b) Powdering the ingredients

1 (c) Frying the herbal mixture

1 (d) Cannabis fried in ghee

1 (e) Grind the mixture to gain *modaka* consistency

Figure 1: Preparation of SKR

Physico-chemical analysis

Parameters such as, total ash, loss on drying at 105^{0}C, total sugar, free fatty acids and coloring matter were done in triplicate for SKR and the average was taken. Standard procedures were followed for each parameter.

Total ash: Accurately weighed 4g of SKR was taken in a silica crucible and was ignited in a muffle furnace at 550^{0}C for 5-6 hours till carbon free white ash was obtained. The total ash value was calculated with reference to the air-dried sample following the standard procedure described in British pharmacopeia (BPC, 2018).

Loss on drying at 105^{0}C: Accurately weighed 2g of SKR was taken in a moisture dish and was heated in a hot air oven at 105^{0}C till constant weight was obtained. The percentage moisture content of the sample was calculated with reference to the air-dried sample following the standard procedure described in British pharmacopeia (BPC, 2018).

Total sugar: Total sugar content of SKR was determined using Lane and Eynon titration method (Lane and Eynon, 1923). A sample solution made by dissolving SKR in distilled water was taken into a burette. Ten milliliters of Fehling's reagent (A+B) was taken into a conical flask. Then approximately 20ml of the prepared sample solution in the burette was added to the flask. The mixture was heated over a boiling water bath for 2–3 minutes and then 2-3 drops of methylene blue indicator was added to the flask while heating is continued. Then the sample solution was added drop wise into the flask while boiling, until the blue color disappears, indicating the endpoint.

Free fatty acids: Free fatty acid in SKR was determined according to the method described in SLS 313: part 2/section 6 of 2009. Accurately weighed 5g of SKR was taken into a conical flask and mixed with 50ml of solvent mixture (ethanol: diethyl ether 1:1, neutralized with 0.1M NaOH solution using phenolphthalein as indicator). About 2-3 drops of phenolphthalein was added to the flask and titrated against the 0.1M NaOH until a light pink end point was obtained. The volume of NaOH used was recorded and calculated the free fatty acid content as oleic acid.

Coloring matter: Paper chromatography technique was used to separate and identify any colouring matter (Mutwkel *et al,* 2022). A small volume of the sample SKR was applied on the baseline of the chromatography paper using a capillary tube. The paper was suspended in a chromatography chamber containing the solvent system. The solvent was allowed to travel up the paper. After development, the solvent front was marked and the paper was dried. Separated compounds were visualized under UV light and their R_f values were calculated. The presence or absence of distinct spots corresponding to synthetic dyes on the chromatography paper was observed.

Heavy metal analysis

Heavy metal analysis for Lead (Pb), Cadmium (Cd), Arsenic (As), Mercury (Hg) was performed using microwave digestion followed by Inductively Coupled Plasma Mass Spectrometry (ICP-MS) (Julshamn et al., 2013). Approximately 0.5g of SKR was accurately weighed and digested using a microwave digestion system. The digestion process utilized concentrated nitric acid (HNO_3) and hydrogen peroxide (H_2O_2) in a closed vessel under controlled temperature and pressure conditions to ensure complete decomposition of the sample matrix. After digestion, the samples were diluted to a fixed volume with distilled water and analyzed using ICP-MS. Standard solutions were used to prepare calibration curves for lead, cadmium, arsenic and mercury. Quality control was ensured through the analysis of blank samples and standard reference materials. The limit of determination for each heavy metal was 0.05 mg/kg. Results were expressed in mg/kg based on the dry weight of the sample.

Aflatoxin analysis

Aflatoxin B1, B2, G1, G2 and Total aflatoxin were analyzed using liquid chromatography - tandem mass spectrometry (LC-MS/MS) with the limit of determination as 0.8µg/kg (Runsheng *et al,* 2014).

Microbiological analysis

Aerobic plate count: The determination of aerobic plate count was performed according to ISO 4833-1:2013 method. The results were expressed as Colony Forming Units (CFU/g) per gram of the sample.

Escherichia coli: The detection of *E. coli* was performed using the ISO 7251:2005 method. The results were expressed in Most Probabale Number per gram (MPN/g).

Staphylococcus aureus: The detection of *Staphylococcus aureus* was performed using the ISO 6888-1:2021 method. The results were expressed as Colony Forming Units (CFU/g) per gram of the sample.

Yeast and mold count: The determination of yeasts and molds was carried out following ISO 21527-2:2008 method. The results were expressed as Colony Forming Units (CFU) per gram of the sample.

Salmonella spp.: The determination of *Salmonella* sp. was performed using the ISO 6579-1:2017 method. Suspected colonies were counted per 25g of sample.

Pseudomonas aeruginosa: The detection of *Pseudomonas aeruginosa* was conducted according to the ISO 13720:2010 method. The results were expressed as Colony Forming Units (CFU) per gram of the sample.

Preparation of the dichloromethane extract of SKR

The SKR extract was prepared by mixing 50g of the SKR with 100ml of dichloromethane for 24 hours in the shaker at 140rpm speed, followed by concentration using rotary evaporator at 40^0C.

Qualitative phytochemical analysis

Alkaloids, tannins, saponins, flavonoids, terpenoids, steroids, cardiac glycosides, carbohydrates and proteins were analyzed qualitatively in the dichloromethane extract of SKR. The procedures followed for each phytochemical are as follows (Harbone, 1998).

Alkaloids:

i. Mayer's reagent test - Two drops of the reagent was added to 2ml of extract, mixed well and observed for cream color precipitate.
ii. Wagner's reagent test - Two drops of the reagent was added to 2ml of extract, mixed well and observed for reddish color precipitate.

iii. Picric acid test - Two drops of the reagent was added to 2ml of extract, mixed well and observed for yellowish color precipitate.

Tannins:

i. $Fecl_3$ Test - Five drops of $Fecl_3$ were added to 2ml of extract, mixed well and observed for blackish green precipitate.
ii. Lead acetate test - Three drops of lead acetate solution was added to 5ml of extract, mixed well and observed for yellow precipitate.

Saponins:

Foam test - Five milliliters of extract was mixed with 2.5ml of distilled water, shaken vigorously and kept for 10 minutes. The mixture was observed for stable foam of honey comb appearance.

Flavonoids:

i. Ammonia test - Five milliliters of dil. Ammonia solution was added to 5ml of extract followed by the addition of con. H_2SO_4. It was observed for a yellow color solution.
ii. Shinoda test - Five milliliters of extract was added to a test tube with pieces of Magnesium and 3 drops of con. HCl and heated. The solution was observed for a reddish orange color.

Terpenoids:

iii. Salkowski test - Five milliliters of extract was mixed with 2ml of Chloroform and 3ml of con. H_2SO_4 was added along the sides of the test tube. The solution was observed for a reddish orange color.

Steroids:

Lieberman Burchard test - Two milliliters of Acetic anhydride and 2ml of con.H_2SO_4 were added to 2ml of extract and mixed well. The solution was observed for a dark bluish green color.

Cardiac glycosides:

Keller Kiliani's test - One milliliters of Glacial acetic acid was added to 3ml of extract and con.H_2SO_4 was introduced to the bottom of the tube. The solution was observed for a reddish brown ring at the interface of the two liquids.

Carbohydrates:

Benedict's test - Two milliliters of extract was mixed with 3ml of Benedict's reagent and boiled for 2 minutes. The solution was observed for a brick red precipitate.

Proteins:

Biuret test - Two milliliters of extract was mixed with 2ml of 1% NaOH and few drops of $CuSO_4$.

The solution was observed for a purple color.

Chromatographical analysis

Thin Layer Chromatography & High-Performance Thin Layer Chromatography was performed for the dichloromethane extract of SKR (WHO, 2001). Extract was spotted on a pre-coated silica gel 60G F254 aluminum plate using a capillary tube. Solvent system of Ethyl-acetate: Dicholomethane: Cyclohexane (0.1:3.4:1.5 v/v%) was used to obtain a clear separation of compounds. Developed TLC plate was visualized under UV radiation of 366 nm wavelength. The plate was scanned with the HPTLC scanner using winCATS software.

Results

Organoleptic Characteristics

Table 2: shows results from organoleptic analysis.

Table 2: Results of organoleptic analysis of SKR

Organoleptic Parameters	Result
Color	Dark brown
Odor	Characteristic
Taste	Sweet
Consistency	Paste like

Figure 2: Final appearance of SKR

Physico-chemical Analysis

Table 3: shows the results for the physico-chemical analysis of SKR.

Table 3: Results of physico-chemical analysis of SKR

Physical Parameters	Result (M±SD)
Loss on drying at 105^0C	2.80% ± 0.05%
Total ash	3.60% ± 0.15%
Total sugar	27.7% ± 0.20%
Free fatty acids	2.0% ± 0.10%
Coloring matter	No synthetic dyes

Heavy metal Analysis

Table 4: shows the results for the heavy metal analysis of SKR where the limit of detection is 0.05 mg/kg (AYUSH, 2008).

Table 4: Results of heavy metal analysis of SKR

Heavy metal	Result	Limit of detection mg/kg
Lead (Pb)	Not detected	0.05
Cadmium (Cd)	Not detected	0.05
Arsenic (As)	Not detected	0.05
Mercury (Hg)	Not detected	0.05

Aflatoxin Analysis

Table 5: shows the results for the aflatoxin analysis of SKR where limit of detection is 0.8 µg/kg.

Table 5: Results of aflatoxin analysis of SKR

Aflatoxin	Result	Limit of detection µg/kg
Aflatoxin B1	Not detected	0.8
Aflatoxin B2	Not detected	0.8
Aflatoxin G1	Not detected	0.8
Aflatoxin G2	Not detected	0.8
Total aflatoxin	Not detected	0.8

Microbiological Analysis

Table 6: shows the results for the microbiological analysis of SKR.

Table 6: Results of microbiological analysis of SKR

Parameter	Result	Permissible limits
Aerobic plate count	1.9×10^4 cfu/g	10^5/g
Escherichia coli	Not detected	Absent
Staphylococcus aureus	<10 cfu/g	Absent
Yeast and mold count	<100g cfu/g	10^3/g
Salmonella spp.	Absent in 25g	Absent
Pseudomonas aeruginosa	<100 cfu/g	Absent

<10 means 10^{-1} dilution contains no colonies

<100 means 10^{-1} dilution contains no colonies

Qualitative phytochemical analysis

Table 7: shows the results for the qualitative phytochemical analysis of SKR.
Table 7: Results of qualitative phytochemical analysis of SKR

Phytochemical	Result
Alkaloid	+
Tannins	++
Saponins	+
Flavonoids	++
Terpenoids	+
Steroids	++
Cardiac glycosides	+
Carbohydrates	++
Proteins	-

Chromatographical analysis

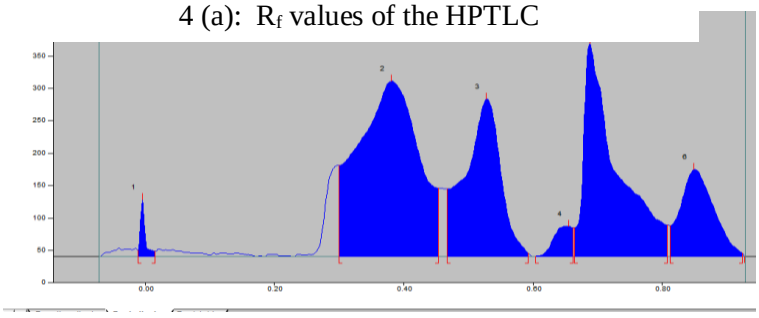
Figure 3: shows the Thin Layer Chromatogram of dichloromethane extract of SKR under 366nm UV light and figure 4 shows the HPTLC fingerprint profile of it.

Figure 3: Chromatogram of dichloromethane extract of SKR under 366nm UV light

Track 1, ID:

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	-0.01 Rf	9.8 AU	-0.00 Rf	88.0 AU	7.93 %	0.02 Rf	7.7 AU	537.9 AU	1.02 %
2	0.30 Rf	140.4 AU	0.38 Rf	270.5 AU	24.36 %	0.45 Rf	05.1 AU	20682.4 AU	39.36 %
3	0.47 Rf	104.0 AU	0.53 Rf	243.0 AU	21.89 %	0.59 Rf	5.2 AU	10890.9 AU	20.73 %
4	0.60 Rf	0.4 AU	0.66 Rf	46.5 AU	4.19 %	0.66 Rf	44.1 AU	1096.4 AU	2.09 %
5	0.66 Rf	44.3 AU	0.69 Rf	328.3 AU	29.57 %	0.81 Rf	48.8 AU	13698.3 AU	26.07 %
6	0.81 Rf	47.2 AU	0.85 Rf	134.0 AU	12.07 %	0.92 Rf	5.3 AU	5641.0 AU	10.74 %

4 (a): R_f values of the HPTLC



4 (b): Graphical interpretation of the peaks of HPTLC
Figure 04: HPTLC fingerprint profile of dichloromethane extract of SKR

Discussion

SKR was having a dark brown color, characteristic odor, sweet taste and a paste like consistency (Figure 2). Loss on drying (LOD) is a critical parameter in the quality control and stability assessment of herbal drugs. It refers to the loss of weight of a substance when subjected to drying at a specified temperature, usually 105°C. Loss on drying is used to determine the volatile components in a drug. Moisture in herbal drugs serves as a medium for the growth of microorganisms, including bacteria and fungi, which can lead to contamination, spoilage and degradation of the active compounds. Low moisture content prevents microbial growth and it is important for the stability of a herbal drug. Loss on drying at 105^0C of SKR was 2.8% which is below the standard limit of 10%. This indicates relatively low moisture content in the sample, which is a desirable attribute for herbal drugs. Ash values are used to determine the quality and purity of a drug. It refers to the residue left after a sample has been heated at a high temperature, typically around 600°C, until all organic matter has been burnt off. The remaining inorganic components, primarily minerals, constitute the ash value. Low ash values indicate more purity and quality while high ash values indicate contamination, substitution or adulteration of a drug. SKR has a total ash value of 3.6% which is below the standard limit of 4%. This result indicates that SKR has a relatively low inorganic content, which is a positive indication of its quality and purity.

Total sugar content is an important parameter for determining the nutritional composition and quality of a herbal drug. It refers to the total of all the naturally occurring sugars in a drug, including both reducing sugars (glucose and fructose) and non-reducing sugars (sucrose). Total sugar content is significant in determining the energy value, sweetness and potential impact on blood sugar levels when consumed. In Ayurveda formulations, sugars like jaggery, bee's honey and cane sugars are commonly used not only to improve the taste and palatability of the product but also to enhance the therapeutic efficacy. Total sugar content of SKR was found to be 27%, which falls within the standard range of 10% to 30% for a herbal preparation. Free fatty acids are fatty acids that are not bound to molecules such as triglycerides. They exist in their free form in a drug. It is an important indicator of the quality and stability of a herbal drug. The presence of a higher level of free fatty acids in a drug typically arises due to the hydrolysis of triglycerides, which occurs when fats or oils break down into glycerol and free fatty acids. This process can be influenced by factors like heat, light and the presence of water or enzymes. Higher free fatty acid levels can lead to unpleasant odors, flavors and deterioration of the product over time. In this

study, SKR is having relatively low free fatty acid content of 2.0, suggesting the high quality of the drug.

Addition of synthetic dyes, which is not traditionally part of Ayurveda, may sometimes be used in modern formulations. These dyes provide bright colors, but carry concerns regarding safety and regulatory approval, especially for long-term use. The absence of synthetic dyes in SKR ensures the use of natural ingredients. Furthermore, the absence of synthetic dyes may improve the product's appeal to consumers who are increasingly seeking natural, organic, and chemical-free alternatives in their healthcare products.

Heavy metal concentrations in the sample analyzed were below the limit of detection at 0.05 mg/kg, which implies that the samples are free from detectable levels of these toxic heavy metals like lead, arsenic, cadmium and mercury, hence complying with the safety standards on heavy metal content. The absence of detectable levels of these heavy metals may reflect good agricultural and manufacturing practices, ensuring minimal contamination from environmental sources. The presence of heavy metals is associated with neurotoxicity, nephrotoxicity and carcinogenicity (Saikat et al., 2022). The non-detectable status of heavy metals in SKR offers a better opportunity for Sri Lankan Ayurveda products to meet international safety standards, thus increasing their global acceptability and marketability.

Aflatoxin contamination in herbal products is a critical concern due to its toxic and carcinogenic properties. The absence of this harmful compound in SKR confirms its exceptional safety for administration.

Microbiological analysis is an important aspect of assessing the safety and quality of Ayurvedic formulations, as it ensures that the product is free from harmful microorganisms that may cause health risks. In this study, the microbiological analysis was conducted to evaluate the presence of microbial contamination, including bacteria, fungi, and yeast, which can proliferate in herbal formulations due to moisture or improper storage conditions. All the parameters tested under the microbiological analysis for SKR were below the permissible limits (AYUSH, 2008). This result indicated that SKR was free from pathogenic microorganisms, which is a positive outcome and suggests that the preparation has been appropriately processed and handled under hygienic conditions.

The dichloromethane extract of SKR was positive for alkaloids, tannins, saponins, flavonoids, steroids, cardiac glycosides, terpenoids and carbohydrates and negative for proteins. Previous research studies shows that phytochemicals like alkaloids, flavonoids, saponins, terpenoids and steroids are responsible for rejuvenative and aphrodisiac properties of a drug. (Saleem et al., 2020). Presence of these phytochemicals support vitality enhances energy, improve blood circulation and promote sexual health. Steroids and cardiac glycosides contribute to the regulation of hormones and cardiovascular health, further supporting physical endurance and overall wellness (Zhang, 2019). These phytochemicals work synergistically to improve the body's resilience, promote longevity and enhance sexual performance, making SKR a valuable drug for use in the aims of rejuvenation and vitality enhancement.

HPTLC fingerprint of SKR gave 6 peaks with R_f values 0.01, 0.38, 0.53, 0.66, 0.69 and 0.85. These R_f values can be used as a reference for identifying specific compounds in further studies or for quality control purposes. The HPTLC fingerprint profile provides a detailed graph of the compounds in the SKR extract, supporting its potential therapeutic applications by identifying key bioactive compounds. Overall, these chromatographical analyses confirm the presence of multiple phytochemicals, which may contribute to the rejuvenative and therapeutic properties of SKR.

Conclusion

The present study confirmed that Sanjeewani Kameshwari Rasayanaya (SKR) is a safe and high-quality Ayurvedic formulation prepared in accordance with traditional principles. Its physicochemical and phytochemical characteristics, together with microbiological and toxicological assessments, validate both its safety and therapeutic potential. The presence of bioactive phytoconstituents supports its traditional claims of rejuvenation, vitality enhancement, and aphrodisiac activity. Furthermore, the HPTLC fingerprint profile provides a scientific basis for quality control and standardization, ensuring consistency in future production. Overall, SKR holds promise not only as a valuable formulation in Ayurveda practice but also as a preparation with potential for wider acceptance in the global herbal market.

Conflict of interest

Not declared.

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