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Analytical Evaluation And Quality Control Parameters For Lipid Based Ayurvedic Formulations: A Comprehensive Review

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Abstract

Introduction:

In Ayurveda, oil and fat-based formulations, known as Sneha Kalpana, are extensively used for treating various ailments. These formulations often face quality degradation due to oxidation, leading to unpleasant odors and health risks. Therefore, establishing robust quality control parameters is crucial to ensure the safety, efficacy, and consistency of these formulations. This review focuses on the analytical techniques and tests employed for quality control of Ayurvedic lipid-based formulations.

Methods:

The review compiles and discusses various physical, chemical, and contaminant-related quality control parameters used to evaluate oil and fat-based Ayurvedic formulations. Methods such as refractive index measurement, congealing point, iodine value, acid value, peroxide value, saponification value, and fatty acid composition analysis are reviewed. Additionally, tests for contaminants like heavy metals, aflatoxins, and pesticide residues are covered. Analytical techniques, including HPTLC, HPLC,

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GC, and gas-liquid chromatography, are also explored for identifying and quantifying active compounds.

Results:

The review summarizes various tests critical for maintaining the quality of Ayurvedic oils and fats, such as the Baudouin test for sesame oil and the Polybromide test for mustard oil. It provides insights into the effects of oxidation on lipid-based formulations, including changes in fatty acid composition and the formation of secondary oxidation products, which affect product quality. The study also highlights the significance of analyzing contaminants and the importance of compliance with regulatory standards.

Discussion:

The study emphasizes the necessity of implementing rigorous quality control measures in the production of Ayurvedic oil-based formulations to ensure product consistency and safety. By adopting modern analytical techniques and expanding chemical parameters, the standardization of these formulations can be achieved. The integration of new quality control measures, including tests for secondary oxidation and active compounds, will contribute to improving the safety, efficacy, and global acceptance of Ayurvedic products.

Keywords- Sneha Kalpana, Ayurvedic medicine, Quality control, Sneha Paka, Tila Taila

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Introduction

Ayurveda, known as the "science of life," encompasses a diverse range of ingredients and practices within the traditional Indian system of medicine. These ingredients include botanicals, metals, minerals, animal products, gemstones, organic and non-organic poisons, and calcium compounds. Through specific pharmaceutical processes, these ingredients are transformed into various dosage forms, including liquid forms, solid forms, and semi-solid forms.[1] Among the wide array of Ayurvedic dosage forms, oil and fat-based formulations (Sneha Kalpana) hold significant importance. These formulations involve the processing of herbal juices, decoctions, and pastes with oils or fats. They are administered both internally and externally to address specific disease conditions, following precise dosing protocols.[2]

Fats and oils, key components of these formulations, consist of glycerol esters and fatty acids. While pure fats are colorless, odorless, and tasteless, lipid-soluble substances enhance their sensory properties. However, they are prone to oxidation, leading to rancidity and potential health risks. Factors like fatty acid composition, processing, heat, light, water content, metals, and antioxidants influence oxidation.[3] In Ayurveda, fats and oils are heated with herbs and liquids, stored long-term, and consumed. Quality control before, during, and after processing is essential to ensure safety, efficacy, and high standards.

In this comprehensive review, we aim to explore the quality control parameters applicable to fats and oil-based formulations in Ayurveda. We shed light on their significance and rationale for application in these products. By examining analytical evaluation and control parameters, we provide insights into the critical aspects of ensuring quality standards in Ayurvedic oils and lipid-based formulations.

Oil and Fat-based Formulations in Ayurveda (Sneha Kalpana)

Sneha Kalpana, a vital dosage form in Ayurveda, involves the processing of oils or fats with herbs. It can be subdivided into four distinct phases for a clearer understanding. The first phase is Kalka, where specific herbs are transformed into a paste. The second phase is Sneha, which incorporates oil or fat, or sometimes both. The third phase is Drava, involving the addition of liquid

media such as juices, herbal decoctions, infusions, milk, curd, gruel water, buttermilk, meat soup, or water. The fourth phase is Gandha, which includes fragrant substances like saffron, camphor, clove, cinnamon bark and leaves, cardamom, vetiver, leaves of specified plants as indicated in the text. Phases I, II, and III are combined in specific proportions (generally 1:4:16 for Phase I:II:III) and heated over mild to moderate heat until specific process completion characteristics are achieved. The mixture is then filtered, and if fragrancing is required, it is performed on the filtered oil/fat. After another round of filtration, the formulation is ready for use. [2]

Sneha Kalpana formulations provide a versatile approach to treating various ailments, used both externally and internally via oral intake, Basti (medicated enema), Nasya (nasal application), and massage. These time-tested Ayurvedic preparations are renowned for their efficacy in enhancing health and well-being.

Lipids used in Ayurveda as base in Sneha Kalpana:

Ayurveda utilizes various oils and fats from both vegetable and animal sources. These include sesame oil, castor oil, coconut oil, mustard oil, linseed oil, Karanja oil, radish oil, Indian beech oil, drumstick oil, walnut oil, pistachio oil, bael oil, and black mustard oil, as mentioned in the text. In terms of fats, ghee, butter, clarified butter, animal fats, milk fat, curd fat, muscle fats, and bone marrows are indicated and used. Among these, sesame oil is highly regarded, while ghee is considered the best among all fats and oils.[4] In practice, sesame oil, ghee, coconut oil, and mustard oil are the most commonly used.

Quality assessment and control parameters for Lipids and Sneha formulations:

A. Identity and purity test-

Quality assessment of fats and oils starts with identification and purity tests, which include detailed descriptions of their organoleptic features like color, odor, appearance, feel, clarity, and identity. Specific tests are performed to verify the identity and purity. Comprehensive summary of these tests, serving to confirm oil identity and detect any potential adulteration are given below:

1. **Baudouin test (test for sesame oil)-** It detects sesame oil based on the reaction between phenols and furfurals in an acidic solution. [5] A pink or red color in the acid layer confirms sesame oil presence. [6]

2. **Polybromide test for Mustard oil-** Identifies fatty acids with three or more non-conjugated double bonds using bromine. The formation of a precipitate confirms their presence, making it more reliable for fatty acid detection than glycerides.[7]
3. **Argemone oil test-** Mustard oil is often adulterated with argemone oil. It is detected via TLC/HPTLC. Alkaloids (sanguinarine and dihydrosanguinarine) fluoresce yellow-orange under UV light, confirming contamination.[8]
4. **Test for castor oil-** The method detects the presence of triricinolein, the main triglyceride component of castor oil, using TLC/HPTLC. The presence of castor oil appears as a distinct spot at an Rf value of ~0.25.[9]
5. **Test for presence of palm oil [Palmolein]-** Palm oil is very commonly used for adulteration in many vegetable oils. This test Uses the cloud point method, where palmolein crystallizes at ~10°C. Gradual cooling and stirring determine the temperature at which cloudiness appears, indicating palm oil presence.[10]
6. **Test for presence oil animal fat-** To detect animal fat, fat crystals should be examined microscopically. Animal fats like beef tallow and lard have unique crystalline structures visible under a microscope. Fat samples are dissolved, recrystallized, and observed under a microscope.[11]
7. **Mineral oil test-** Mineral oil is a mixture of colorless, odorless, and light alkanes derived from petroleum. Its presence in edible oils is undesirable as it can contaminate the oils and impact their quality and safety for consumption. The test Uses Holde's Test (turbidity formation in hot water) and TLC/HPTLC (faster spot movement due to non-polarity) to detect mineral oil adulteration in edible oils. [12,13]
8. **Cotton seed oil test-** Based on the reaction of cyclopropenoid fatty acids with sulfur in carbon disulfide, producing a red color, confirming the presence of cottonseed oil. [14]

B. PHYSICAL CHARACTERISTICS:

1. **Refractive index**

   The refractive index [RI] measures light bending when passing between substances. While typically determined relative to air rather than vacuum, RI is characteristic for each oil type and influenced by factors like unsaturation, oxidation, and heat treatment. RI increases with oxidation and unsaturation levels. [15,16] Typically measured using Abbe's refractometer with sodium light's D-line (λ = 589.3 nm) as the reference.[17]

2. **Wt per ml & Specific gravity**

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The mass per unit volume of fats and oils is measured to convert volume to mass or vice versa. It requires measuring the mass of a certain volume at a specified temperature using a calibrated pycnometer/RD bottle. This parameter is applicable to fats and oils which does not deposit crystals at determination temperature. Mass per unit volume is expressed in g/ml or Kg/L and is similar to specific gravity. Specific gravity is determined at fixed temperatures [25 °C and 60 °C], while mass per unit volume allows flexibility in temperature selection [25, 40, 50 or 60°C, and if required higher temperature]. API recommends conducting both tests at 25 °C, while AOCS provides different methods.[18-20] The composition, saturation levels, oxidation, and polymerization of fats can affect their mass per unit volume, especially when processed with herbs. [21,22]

3. Congealing point

Congealing point is the temperature at which a fat solidifies, indicating its resistance to flow. It applies to fats and oils that solidify within the temperature range of 24-45°C, based on their triglyceride composition. It is an important indicator of purity and is determined by the mixture of the liquid and solid phases.[23] Titer point is a similar test specific to fatty acid mixtures from saponified fat or oil samples, reflecting their compositions.[24] Congealing point is unique to different fats and plays a role in determining storage conditions.

4. Smoke point determination

The smoke point, also known as the burning point, is the temperature at which oil produces bluish smoke under specific conditions.[25] Factors like oil volume, container size, air currents, light source, and FFA content affect the smoke point. Higher FFA leads to lower smoke points, but FFA alone is an unreliable indicator of heat resistance.[26,27] Determining the smoke point involves gradually heating the oil and observing continuous bluish smoke.[35] Sesame oil, with a smoke point of around 180°C, is favored in Ayurvedic cooking and formulations. Its favorable characteristics make it suitable for heating and cooking in Ayurvedic Sneha Paka preparations.[21]

5. Flash point determination

The flash point is the lowest temperature at which a liquid can produce an ignitable mixture in the air near its surface. It is determined by applying a test flame to the sample under specific conditions. The sample

is heated slowly with stirring, and a small test flame is introduced at intervals until the vapor above the sample ignites momentarily. The Pensky Marten [closed cup] method is commonly used for flash point testing.[28] It is essential for assessing the suitability and safety of oils during handling, transport, and processing. Determining the flash point enables informed decisions, ensuring product quality, and preventing accidents and fires.[29]

6. Optical rotation

The optical rotation test Evaluates fat and oil purity by measuring light rotation due to chiral compounds. Using a polarimeter with a sodium lamp, samples dissolved in chloroform are analyzed to detect changes in color, concentration, and processing effects.[30]

7. **Viscosity**

Viscosity greatly influences fats and oils, impacting flow and functionality across various uses. The Brookfield viscometer, a common tool, gauges viscosity through torque on a rotating spindle within the sample. Analyzing torque and calibrating with reference fluids reveals viscosity. Temperature, shear rate, and preparation influence it, demanding controlled conditions. Reference values assess results, affirming fats and oils' quality and suitability for distinct applications.[31]

8. Determination of color

Color measurement is pivotal in the oils and fats industry, assessing color preferences during refining and processing like heating, cooking, and infusion. This involves comparing oils with Lovibond glasses. Color is determined using red and yellow slides in a specified cell. A glass cell is filled, placed in the tintometer, and color adjusted until a match occurs. This technique ensures accurate color evaluation, aiding quality control and desired visual traits for various applications.[32]

C. CHEMICAL CHARACTERISTICS AND PARAMETERS:

1. Saponification Value

Saponification is the process of converting fat or oil into soap and alcohol through the action of aqueous alkali. The saponification value [SV] provides insights into the properties of the oils involved. A higher SV indicates a lower average length of fatty acids, a lighter mean molecular weight of triglycerides, and vice versa. SV is determined by measuring the amount of alkali required to saponify a specific quantity of the test sample. This is expressed as the number of mg

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of potassium hydroxide [KOH] needed to neutralize the fatty acids resulting from the complete hydrolysis of the sample. [33] As time passes, the fatty acids undergo decomposition, resulting in a shorter average length and higher SV for oils. An increasing SV suggests oil deterioration.[34].

2. Unsaponified matter

Unsaponified matter refers to substances that remain soluble in fats and oils after saponification, are insoluble in water, but can be dissolved in test solvents like Light Petroleum or diethyl ether. These substances include natural lipids such as sterols, aliphatic alcohols, pigments, vitamins, hydrocarbons, and non-volatile foreign organic matter at 100°C. Diethyl ether is commonly used as a solvent to determine unsaponified matter.

In Ayurveda, herbs are cooked with oils, and their active components dissolve in the oils. Analyzing unsaponified matter helps understand herb solubility. The process involves saponifying the sample with alkali [KOH] and dissolving it in organic solvents like ether or hexane as per recommended standards.[32,33] Determining unsaponified matter provides valuable insights into the composition and properties of oils and fats, aiding their application in Ayurvedic preparations and other fields.

3. Iodine value

The iodine value [IV] measures unsaturation in fats and oils by counting double bonds in triglycerides. It indicates melting point and oxidative stability linked to unsaturation. Higher IV means more unsaturation and higher oxidation susceptibility, while lower IV suggests oxidation of unsaturated bonds in fatty acids.[15,34-36] To determine IV, iodine uptake is measured per 100 parts of the sample. Iodometry involves adding an iodine solution, and groups like -C=C- bonds react, reducing the color strength. The required iodine amount maintains the yellow/brown color, revealing iodine-sensitive groups.[37] Methods include monochloride, pyridine bromide (API), and cyclohexane acetic acid (AOCS) which ensure accurate assessment of unsaturation, aiding quality evaluation and determining oxidative stability in fats and oils.[37,38]

4. Acid Value (AV)/ Free fatty acid (FFA)

Free fatty acids (FFA) or acid value (AV) are key indicators of lipid quality, affecting sensory and physicochemical properties. Higher

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AV suggests extensive hydrolysis, often caused by lipase activity, high temperatures, hydrolysis, and oxidation. FFA speeds up hydroperoxide decomposition, leading to secondary oxidation and unpleasant tastes.[39] Titrimetric and potentiometric methods are used to used acidity in such samples (ISO). [40] AV represents the amount of potassium hydroxide [KOH] needed to neutralize free acids per g of the sample.[41]

Measuring free fatty acids is crucial for assessing Ayurvedic oil and fat quality. It evaluates hydrolysis and lipid degradation in traditional formulations. Monitoring FFA levels ensures freshness, potency, and therapeutic properties. Controlling acidity maintains sensory characteristics and prevents rancidity.

5. Peroxide value

The peroxide value [PV] measures the initial oxidation and rancidity in fats and oils. It indicates the presence of peroxide and hydroperoxide compounds formed during primary oxidation. PV is expressed as milliequivalents [meq] of active oxygen per 1000 g of substance. The iodometric titration methods are used for determination of PV.[30,42] PV is commonly used as a chemical method to assess the oxidative deterioration of oils. This test provides insights into the extent of the initial oxidation stage and the development of flavor associated with the oxidation of fats and oils. It is applicable for peroxide values ranging from 0 to 30 meq of active oxygen per kg. This method is used to determine the primary oxidation of such samples

6. **Water content**

The presence of water content in fats and oils can be very critical. In the Ayurvedic Sneha Paka processing oils/Ghee are processed with herbal juice, decoction, milk, or water. Water content in the final product (Siddha Sneha) decides the process completion and quality of the product as well.[43]

Water acts as a barrier against the reaction of fatty acids and oxygen when present in higher quantities. However, when the water content is reduced, oxidation of fats and oils occurs at a faster rate, inducing the hydrolysis of ester bonds and making oxygen more effective results in the formation of various fatty acids and their undesirable breakdown products, leading to off-flavors.[44,45]

Checking water content in Ayurvedic oils and ghee is vital. Karl Fischer titration is commonly used for this purpose. The allowable moisture limit

in edible oils is usually below 0.2% w/w.[46] Strict control of water content ensures stability, shelf life, and quality of Ayurvedic preparations, preventing rancidity.

7. Para anisidine value

The p-anisidine value is a key parameter for assessing secondary oxidation in oils and fats. It measures the oxidation history, mainly involving aldehydes and ketones. The reaction with para anisidine produces a measurable product at 350 nm. This test is applicable to both volatile and non-volatile oils and is particularly sensitive to unsaturated volatile aldehydes compared to saturated volatile aldehydes. Therefore, it serves as a reliable method for assessing secondary oxidation products.[47] By analyzing this value, the extent of secondary oxidation and the potential development of off-flavors and odors can be determined, aiding in quality control and shelf life assessment.

8. Totox value

Totox is the total oxidation value, calculated by adding the p-anisidine value to twice the peroxide value. It provides an overall assessment of the deterioration and oxidation in fats and oils. A lower Totox value indicates higher oil quality.[48]

9. Thiobarbituric acid reactive substances [TBARS]

TBARS are byproducts of fat and oil oxidation. The TBARS assay detects lipid oxidation by measuring malondialdehyde [MDA], a breakdown product of unsaturated fatty acids. In this assay, TBA reacts with MDA, forming a red-colored product measured at 532-535 nm. The TBARS number represents MDA content in mg per kg. However, not all lipid oxidation generates MDA, which can affect TBARS data accuracy.[49] Spectrophotometric methods are employed in the TBARS assay to assess lipid oxidation, providing valuable information on quality, stability, and shelf life of fats and oils.[50]

10. Sterol and cholesterol compositions

Analyzing sterol and cholesterol composition in fats and oils is crucial for assessing their quality and authenticity. Gas chromatography (GC) accurately separates and quantifies sterols, while reversed-phase HPLC is used for cholesterol analysis.[51,52] The determination of total sterol and cholesterol content provides valuable insights into the nutritional value, potential health benefits, and possible adulteration of the fat or oil sample.

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11. Total ester value

Total ester value is a critical parameter for measuring esterified fatty acids in oils and fats. Esters are common lipids formed from the reaction between an alcohol and an acid. It reflects the degree of esterification, which affects product quality and stability. Calculated as the difference between saponification value and acid value, higher ester values indicate greater ester content and lower molecular weight fatty acids.[53] Determining the total ester value involves lipid extraction, ester hydrolysis, and titration with a standardized base like NaOH.[54] This process helps assess purity, authenticity, and shelf life, with higher esterification levels indicating reduced susceptibility to oxidation and rancidity.

12. Rancidity test

Rancidity refers to the unpleasant odor and taste that develops in edible fats and oils due to oxidative or hydrolytic degradation. As stored oils age, they can undergo oxidation and become rancid, with aldehydes contributing to the rancid flavor. The Kries test and UV absorption measurements are commonly used to assess rancidity.[55-56]. UV absorption measurements detect the presence of oxidized fatty acids with conjugated double bonds, with different absorption peaks for dienes and trienes. UV absorption is useful for comparing relative changes in oil oxidation but not for quantifying the extent of oxidation.[57]

13. Hexaneal Tests

Hexaneal tests, also known as hexane value tests, are employed to quantify the hexane-soluble material content in fats and oils. Hexane serves as a solvent during lipid extraction from edible fats and oils, and the hexaneal test gauges the solubility of lipids in hexane. This test is widely utilized to evaluate the quality and purity of fats and oils, as well as to detect impurities or contaminants. In the context of Ayurvedic oils and Ghee, the hexaneal test aids in determining the portion of drugs dissolved in oils, distinct from non-lipid components.[58]

14. Differential Scanning Calorimetry [DSC]

Differential Scanning Calorimetry [DSC] analyzes thermal properties and predicts oxidative stability and shelf life of fats and oils. By detecting heat flow during controlled temperature changes, DSC assesses an oil's susceptibility to oxidation, aiding in quality evaluation and selection of oils with better stability.[59] DSC also helps determine the shelf life of oils,

informing storage and packaging strategies.[60]

15. Determination of presence of unsaturated Fatty acid in Oil and Fats [Bellier test]

The Bellier test is a qualitative method used to detect unsaturated fatty acids in fats and oils. This test relies on the observation of insoluble precipitates formed when unsaturated fatty acids react with specific chemicals. Each oil has its unique precipitation temperature for oils containing long-chain saturated fatty acids.[61]

16. Rancimat test/Oxidative stability index

The Rancimat test measures the oxidative stability of fats and oils by determining the induction time for volatile oxidation products to form. It relies on changes in conductivity caused by volatile organic acids. This test is important for assessing shelf life and quality, as longer induction times indicate greater resistance to oxidation.[62]

In the Rancimat test, airflow is passed through a fat or oil sample at a constant temperature [50-220 °C], causing oxidation and the formation of volatile compounds. These compounds, including formic acid, are carried by the airflow and absorbed into a measuring solution [distilled water], where conductivity is monitored. A significant increase in conductivity signals the end of the induction period, indicating the stability of fats and oils against oxidation. Longer induction times suggest greater resistance to oxidative processes, which is important for assessing shelf life, quality, and suitability for different applications and storage conditions.[63] The Rancimat method offers efficient analysis of oils and fats, correlating with sensory and analytical methods, ensuring the production of stable and high-quality lipid-based products.

D. COMPOSITIONS AND CONSTITUENTS:

1. Fatty acid composition

The fatty acid composition of fats and oils plays a significant role in their nutritional and functional properties. analyzed by converting fatty acids into methyl esters via esterification (using boron trifluoride or methanol-alkali). Gas-liquid chromatography (GLC) with a flame ionization detector (FID) separates and quantifies them. Comparing elution patterns with standards identifies fatty acids.[64,65] Alternative esterification methods suit neutral oils (acid value <2), providing an effective means to determine fatty acid profiles and understand composition changes caused by

processing, heating, cooking, or the addition of other ingredients.[66]

2. **Determination of total polar compounds**:

The determination of total polar compounds is crucial for assessing the degradation of fats and oils during heating, cooking, or frying. These processes can lead to the formation of polar components, including monoglycerides, diglycerides, and free fatty acids. Polar compounds in fats and oils, both unused and processed, are analyzed using silica gel column chromatography. Polar components elute first, followed by non-polar ones. Further analysis via UV-Vis spectrophotometry or gas chromatography determines their properties.[67]

The polar fraction of Ayurvedic oils and fats may contain the active biological ingredients. Assessing the polar components is crucial for evaluating quality, determining active ingredient concentration, and gaining insights into the formulation and effectiveness of Ayurvedic products.

3. **Oil Soluble extractive value**

Lohakar et al. devised a method to determine the oil soluble extractive value of processed herbs in Sesame oil using a 90% v/v aqueous methanol solvent. They found that this solvent was effective in extracting the desired components. The procedure involved adding 100 ml of 90% v/v aqueous methanol to 50 ml of the medicated oil in a conical flask, stirring it for an hour with a magnetic stirrer, and then storing the mixture in a deep freezer at −20°C for 2 days to solidify the oils. The top methanol layer was filtered, yielding the methanol extract for further experiments, including extractive value calculation and TLC profiling. This method provides a reliable approach for extracting the oil soluble components of herbs within Sesame oil, facilitating subsequent analysis and evaluation.[68]

4. **Fingerprinting through TLC/HPTLC**

Fingerprinting Ayurvedic oils and fat-based products using TLC and HPTLC is crucial for ensuring quality and authenticity. TLC separates and identifies compounds in complex mixtures, providing specific fingerprints for different oils and fats. HPTLC offers improved resolution and sensitivity, making it useful for analyzing minor components and impurities. These fingerprinting techniques play a vital role in authenticating Ayurvedic oils and fat-based products, detecting adulteration, identifying specific botanical ingredients, and assessing overall

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product quality. The generated fingerprints serve as reference standards for quality control and aid in the development of standardized formulations.[69]

5. Active compounds identification and quantification

Identification and quantification of active compounds in Ayurvedic oils and ghee-based products are vital for quality and efficacy. HPTLC, HPLC, and GC are employed for this purpose. HPTLC separates and visualizes polyphenols, alkaloids, flavonoids, and terpenoids. HPLC quantifies markers like curcumin and boswellic acids. GC analyzes volatile compounds such as essential oils and fatty acids in ghee. These techniques ensure consistency and potency, contributing to quality control and formulation. By standardizing the identification and quantification of active compounds, these methods contribute to quality control, formulation, authentication, and therapeutic effectiveness of Ayurvedic oils and ghee-based products.[65,69]

E. CONTAMINANTS:

In addition to other tests, the analysis of heavy metals is conducted to detect potential contamination that may arise during the production, processing, packaging, and storage of these products. Heavy metals such as lead, cadmium, mercury, and arsenic have the potential to contaminate fats and oils, and their consumption in high concentrations can lead to health risks, including long-term accumulation in the body and adverse effects on human health. These heavy metals are also known to catalyze and accelerate the oxidation process of oils and fats. Furthermore, the presence of water along with heavy metals can significantly hasten the oxidation process,[70] which is particularly relevant in Ayurvedic oils and fats, as certain oils undergo processing with arsenic and lead compounds.[71] Therefore, heavy metal analysis becomes a crucial parameter in conjunction with other quality parameters for ensuring product safety. The analysis typically involves sample preparation followed by instrumental techniques such as atomic absorption spectroscopy [AAS], inductively coupled plasma mass spectrometry [ICP-MS] for quantifying the specific heavy metals present in the formulation[72].

The presence of contaminants like aflatoxins and pesticide residues is a concern in vegetable-based oils. Aflatoxins, specifically types B1, B2, G1, and G2, are commonly analyzed

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using HPTLC and Enzyme-Linked Immunosorbent Assay [ELISA].[73] Pesticide residue testing includes various types such as organochlorine, organophosphorus, carbamate, pyrethroid, and herbicides, with limits set by different countries.[74] Gas chromatography [GC] is typically employed for this analysis.[75] Microbial load testing ensures fats and oils' safety by detecting bacteria, yeast, and mold. Total viable count (TVC) measures overall microbes, while specific tests identify pathogens or spoilage organisms. Ensuring the absence or controlled levels of these contaminants is essential for maintaining the quality and safety of vegetable-based oils.[76]

Discussion

Quality control plays a vital role in ensuring the safety and effectiveness of pharmaceutical products. The standardization of quality control parameters is essential for producing safe and effective pharmaceuticals consistently. Various techniques are employed to assess and control the quality of raw materials, during the manufacturing process, and in finished products. These techniques can be regulated to establish the necessary quality standards. In the context of oils and fats, which comprise triglycerides formed by esterifying glycerol with fatty acids, maintaining quality is influenced by various factors such as saturation levels, time, temperature, storage conditions, light exposure, water content, and the presence of heavy metals. During the initial stages of oxidation, unsaturated fatty acids react with oxygen, resulting in the formation of primary oxidation products such as hydroperoxides and free fatty acids. Hydroperoxides, being highly reactive, undergo further chemical reactions leading to the generation of secondary oxidation products, including aldehydes and ketones. These secondary oxidation products are responsible for the rancid odor associated with deteriorated oils and fats. [77]

To determine the quality of raw and processed lipids, several physical and chemical characteristics can be employed. Developing standardized methods through scientific processes is essential for assessing and ensuring the quality of these lipids. The Government of India has established standards for various lipid formulations such as Ghee, sesame oil, mustard oil, castor oil, and specific preparations like Changeri Ghrita, Mahakalyanaka Ghrita, Chandanadi Taila, Jatyadi Taila, and

Narayan Tail through BIS and API.[78,74] These standards primarily focus on physical and chemical parameters. However, it is crucial to expand these parameters to include tests like p-anisidine value, rancimat test, TBRAS, and others to assess secondary oxidation. Additionally, adopting a marker-based approach for both raw materials and finished products, along with establishing standardized fingerprints for all prepared formulations, will further enhance the standardization of product quality.

While some progress has been made in developing fingerprints for formulations like Shadbindu Taila, Anu Taila, Kalyanaka Ghrita, and Dhatryadi Ghrita,[75,76,79,80] it is imperative to implement these parameters in manufacturing practices to consistently deliver safe and effective products. Moreover, there is a need to explore the area of oil/fat soluble extractive values in Ayurveda Sneha paka, which refers to the amount of active compound transferred from the raw material to the final product and the extent to which the active component undergoes modification. Limited research has been conducted in this direction, making it an open field for further exploration. Understanding these values will contribute to comprehending the mechanism of action of Ayurvedic drugs under different conditions. Analytical techniques, such as chromatography, spectroscopy, and mass spectrometry, are commonly employed for quality assessment. Stability testing is also crucial to determine shelf life and storage conditions.

Conclusion:

Quality control in Ayurvedic medicine ensures safety, efficacy, and consistency. Expanding chemical parameters, adopting marker-based approaches, and integrating modern analytical techniques enhance standardization. Compliance with regulations and stability testing further improve quality, promoting wider acceptance of Ayurveda.

Conflict of interest- Nil

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