E-ISSN:2456-3110

Research Article

Pharmacognostical Study

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Journal of Ayurveda and Integrated Medical Sciences

2025 Volume 10 Number 4 APRIL

Publisher

Maharshi Charaka Ayurveda

www.maharshicharaka.in

Comparative evaluation of Ayurvedic formulations Dantyadi Lepa and Swarjika Ksharadi Lepa in the management of Fibroadenosis: A Pharmacognostical Study

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DOI:10.21760/jaims.10.4.6

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The formulations of Dantyadi Lepa and Swarjika Ksharadi Lepa were subjected to advanced analytical techniques to validate their therapeutic potential in managing fibroadenosis. Kshara standardization ensured the physiochemical properties of Mulaka Kshara and Swarjika Kshara met the Ayurvedic Pharmacopoeia of India (API) standards. The alkaline nature of Swarjika Kshara demonstrated apoptosis-inducing properties in abnormal tissue cells, effectively inhibiting fibroadenotic growth. FTIR analysis revealed the presence of diverse functional groups in both formulations. Dantyadi Lepa showed halo compounds, vinyl groups, amines, alcohols, alkyls, phenols, nitro compounds, amides, alkynes, and carboxylic acids, while Swarjika Ksharadi Lepa exhibited alkenes, aromatics, conjugated alkenes, acid halides, and carboxylic acids. These findings provide a detailed chemical profile, aiding in quality control and therapeutic optimisation. SEM-EDS analysis characterized the formulations as mineral-organic composites with a flaky, layered structure resembling clay or silicate minerals. Elemental analysis revealed the presence of carbon, oxygen, Na, Mg, Al, Si, K, and Ca, with niobium suggesting rare mineral inclusion or industrial contamination. HR-LCMS analysis identified bioactive compounds such as flavonoids, triterpenoids, carotenoids, and fatty acids, which exhibit anti-inflammatory, anticancer, and anti-tumour properties. These compounds, known for their lekhana (scraping) action, inhibit tumour growth and promote the breakdown of fibrous tissue. Bitter and pungent compounds interact with molecular receptors in breast tissue, effectively disrupting pathways responsible for lump formation These combined analyses validate the scientific basis of these formulations, ensuring their consistency, safety, and efficacy in managing fibroadenosis and related conditions.

Keywords: Pharmacognostical Study, Dantyadi Lepa, Swarjika Ksharadi Lepa, Kshara standardization, FTIR, SEM-EDS, HR-LCMS

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How to Cite this Article

Shedad SL, Anuradha R, Gupta SJ, Chawla R, Sen B, Comparative evaluation of Ayurvedic formulations Dantyadi Lepa and Swarjika Ksharadi Lepa in the management of Fibroadenosis: A Pharmacognostical Study. J Ayu Int Med Sci. 2025;10(4):28-37.
Available From
https://jaims.in/jaims/article/view/4109/

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Manuscript Received	Review Round 1	Review Round 2	Review Round 3	Accepted
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Conflict of Interest	Funding	Ethical Approval	Plagiarism X-checker	Note
None	Nil	Yes	11.94	

Introduction

Fibroadenosis of breast is a common benign condition characterized by lumpiness, pain, & cystic changes in breast tissue, largely driven by hormonal fluctuations. Diagnosis involves clinical examination, imaging, & histopathological analysis to rule out malignancy. Treatment is typically conservative, focusing on symptom relief, with surgery being a last resort reserved for more complicated cases. Regular monitoring & follow-up are essential to manage symptoms effectively & to detect any potential complications early.**[1,2,3]**

Need of Standardization[4,5]

1. Contribute to the scientific understanding of the *Ayurvedic* concept of *Stana-Granthi* and its correlation with the modern understanding of fibroadenosis.
2. Establish the clinical efficacy of *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* in the management of fibroadenosis, potentially leading to their integration into mainstream healthcare practices.
3. Provide an alternative, conservative treatment approach for fibroadenosis that is more accessible, affordable, and potentially safer compared to conventional medical or surgical interventions.

Drugs[6,7,8,9]

The formulations of *Dantyadi Lepa* (DL): A paste made from *Chitraka* (*Plumbago zeylanica L.*), *Snuhi* (*Euphorbia nerifolia L.*), *Arka* (*Calotropis procera*), *Bhallataka* (*Semecarpus anacardium*), *Kasisa* (Green vitriol or Ferrous sulfate), *Guda* (Jaggery).) and *Swarjika Ksharadi Lepa* (SK) Composed of *Swarjika Kshara (Dhanvayasa) Botanical name:- Fagonia cretica Linn.*), *Mulaka Kshara*, and (*Botanical name:- Raphenus sativus Linn.), Shankha Bhasma* have been subjected to advanced phytochemical analyses, including *Kshara* Standardization (*Mulaka Kshara* & *Swajika Kshara*), FTIR, SEM-EDS & HR-LCMS.

Advanced Methods of Standardisation: The methods mentioned are advanced techniques for standardising and analysing *Ayurvedic* formulations like *Dantyadi Lepa* and *Swarjika Ksharadi Lepa.*

1. FTIR (Fourier Transform Infrared Spectroscopy):

Purpose: Identification of functional groups and chemical bonds.

Mechanism: FTIR measures absorption of infrared light by sample, producing spectrum that serves as "fingerprint" for molecular identification.

Application:

- In *Ayurvedic* formulations, FTIR helps identify key functional groups (e.g., hydroxyl, carbonyl) associated with bioactive compounds.
- Provides a qualitative assessment of the chemical constituents.
- Can detect specific markers for standardisation and ensure batch-to-batch consistency.

2. SEM-EDS (Scanning Electron Microscopy - Energy Dispersive Spectroscopy):

Purpose: Surface morphology & elemental analysis.

Mechanism:

- SEM: Produces high-resolution images of the sample's surface, showing texture, particle size, and structural details.
- EDS: Provides elemental composition by analysing X-rays emitted from the sample when hit by an electron beam.

Application:

- Visualization of the microstructure of *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* to understand their physical properties.
- Elemental analysis to identify key minerals and metals that contribute to therapeutic effects.
- Ensures the absence of toxic elements, enhancing safety and quality control.

3. High-Resolution Liquid Chromatography-Mass Spectrometry (HR-LCMS):

Purpose: Identification and quantification of phytoconstituents.

Mechanism:

- LC: Separates compounds in the formulation based on their polarity and interaction with the stationary phase.
- MS: Provides mass-to-charge ratio data for each compound, enabling precise identification.

Application:

- Detects a wide range of bioactive compounds like amino acids, fatty acids, triterpenoids, carotenoids, aromatic compounds, and flavonoids.

- Links phytoconstituents to traditional therapeutic claims, providing scientific validation for Ayurvedic uses.
- Facilitates the discovery of potential biomarkers for quality control.

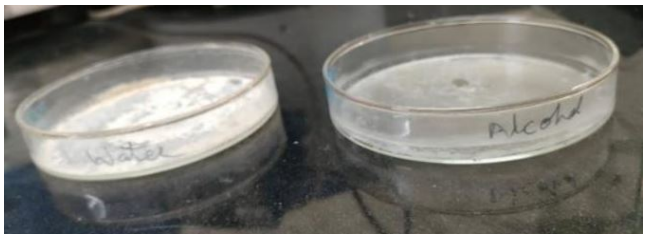
Significance of these methods in *Ayurvedic* Research:

- Standardization: Ensures uniformity in the composition of *Ayurvedic* formulations, improving reliability and reproducibility.
- Validation: Bridges the gap between traditional knowledge and modern science by correlating chemical composition with therapeutic effects.
- Safety and Efficacy: Identifies toxic contaminants and validates bioactive compounds, enhancing the safety and efficacy of formulations.
- Quality Control: Establishes benchmarks for assessing the quality of raw materials and finished products.

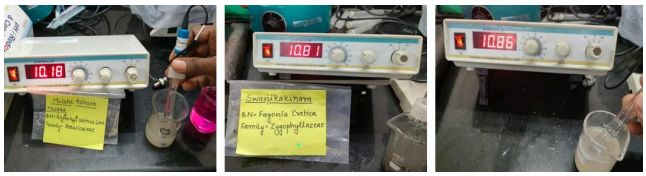
***Kshara* Standardization:** *Kshara* (alkaline preparations) is an important component of *Ayurvedic* medicine used for its strong therapeutic properties, especially in conditions like fibroadenosis. The process of standardization is crucial to ensure consistency, safety, and efficacy of these preparations. In this study, *Mulaka Kshara* and *Swarjika Kshara* were analyzed to ensure that their physiochemical properties align with *Ayurvedic* Pharmacopoeia of India (API) standards.

1. Water-Soluble Extractives: Percentage of water-soluble extra. indicates presence of water-soluble compounds in *Kshara*, which are responsible for its therapeutic effects. For ***Swarjika Kshara***, water-soluble extractive was found to be **8% W/W**, confirming high concentration of active components.

2. Alcohol-Soluble Extractives: The alcohol-soluble extractive percentage measures compounds soluble in alcohol, often responsible for potent actions in Ayurvedic formulations. For *Swarjika Kshara,* the alcohol-soluble extractive was 0.6% W/W, which is in line with its alkali-based nature.



3. pH Levels: In the analytical and phytochemical study of *Mulaka Kshara* and *Swarjika Kshara,* pH was found 10.18, and 10.81 respectively in comparison to API standards of between 10 to 11. Whereas, pH of *Swarjika Ksharadi Lepa* was found as 10.86 which is not referred in the API.



4. FTIR (Fourier Transform Infrared Spectroscopy): FTIR is an advanced analytical technique used to identify the functional groups present in a sample. It provides insights into the chemical bonds by producing an infrared absorption spectrum, which is used to characterize the components of Ayurvedic formulations like *Dantyadi Lepa* and *Swarjika Ksharadi Lepa.*

A. Dantyadi Lepa: FTIR analysis of *Dantyadi Lepa* revealed presence of variety of functional groups:

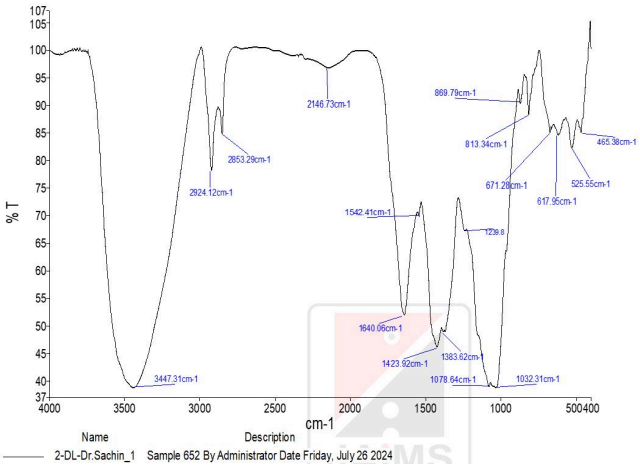


Figure 1: FTIR study of *Dantyadi Lepa*

Table 1: Peaks obtained in the FTIR study of *Dantyadi Lepa* with the related bond and assigned functional group

SN	Peak	Peak Nature	Bond	Type of bond/ Assigned functional group
1.	525.55	Sharp and Strong	C-I / C-Br	Halo compound (bromine or iodine)
2.	617.95	Sharp and small	C-I / C-Br	Halo compound (bromine or iodine)
3.	813.34	Sharp and small	C—H	Vinyl
4.	867.79	Sharp and small	C—H	Vinyl
5.	1032.31	Medium	C-N	Amine
6.	1078.64	Medium	C—O	Alcohol
7.	1239.8	Weak	C-N	Amine
8.	1383.62	Weak	C—H	Alkyl
9.	1423.92	Strong and Sharp	O-H	Phenol
10.	1542.41	Strong and small	N-O	Nitro compound
11.	1640.06	Strong and Sharp	C=O	Primary or Secondary amide
12.	2146.73	Weak	C≡C	Stretching alkyne
13.	2853.29	Sharp and Broad	O-H stretching	Carboxylic acid
14.	2924.12	Sharp and broad	O-H stretching	Carboxylic acid
15.	3447.31	Sharp and broad	O-H stretching	Alcohol

- **Halo compounds (Bromine/Iodine)**: Known for their antiseptic and anti-inflammatory properties.
- **Vinyl and Alkyl groups**: Contribute to the anti-inflammatory action by inhibiting the production of inflammatory mediators.
- **Amine and Alcohol groups**: These are crucial in tissue repair and regeneration, which aids in reducing swelling and pain.
- **Carboxylic Acids and Phenolic Compounds:** Known for their antioxidant properties, these compounds help in preventing oxidative damage in the tissues affected by fibroadenosis.

B. Swarjika Ksharadi Lepa: FTIR analysis of ***Swarjika Ksharadi Lepa*** also detected multiple functional groups:

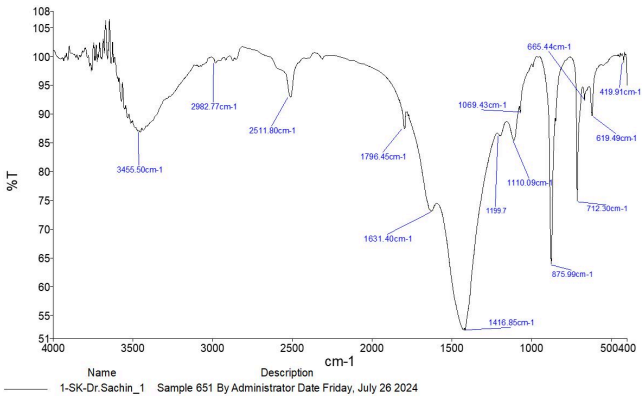


Figure 2: FTIR study of *Swarjika Kshara*

Table 2: Peaks obtained in the FTIR study of *Swarjika Ksharadi Lepa* with the related bond and assigned functional group

SN	Peak (cm-1)	Peak Nature	Bond	Type of bond/ Assigned functional group
1.	619.49	Sharp and Strong	C-I / C-Br	Halo compound (bromine or iodine)
2.	665.44	Sharp and small	C=C bending	Alkene
3.	712.30	Sharp and Strong	C—H	Vinyl
4.	875.99	Sharp and Strong	C—H	Vinyl
5.	1069.43	Sharp and Narrow	C---O	Alcohol
6.	1110.09	Weak	C---O	Alcohol
7.	1199.7	Weak	C-N	Amine
8.	1416.85	Weak	C—C	Aromatic compound
9.	1631.40	Weak and Broad	C=C	Conjugated alkene
10.	1795.45	Sharp and small	C=O	Conjugated acid halide
11.	2511.80	Sharp and broad	O-H stretching	Carboxylic acid
12.	2982.77	Weak	O-H	Stretching alcohol
13.	3456.50	Weak	N-H	Primary amine

- **Alkene and Aromatic Compounds:** Play a role in reducing the hardness of lumps by breaking down fibrous tissue.
- **Conjugated Alkene and Acid Halide Groups:** Help in dissolving abnormal growths and masses in the breast.

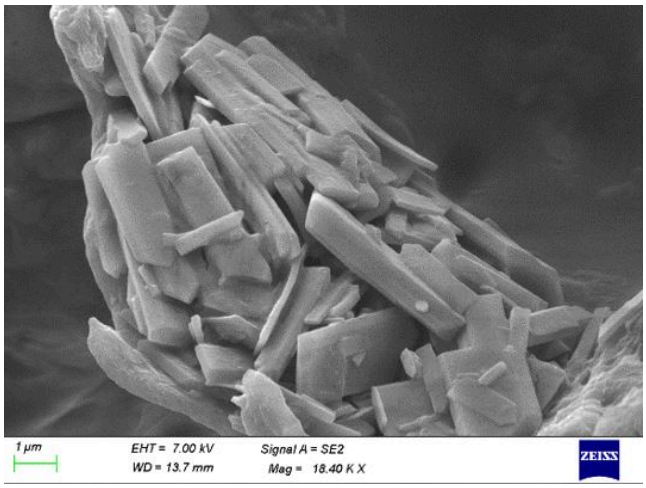
- **Primary Amine and Carboxylic Acids:** Support the tissue-softening properties, which transform the hard consistency of breast lumps into a softer state.

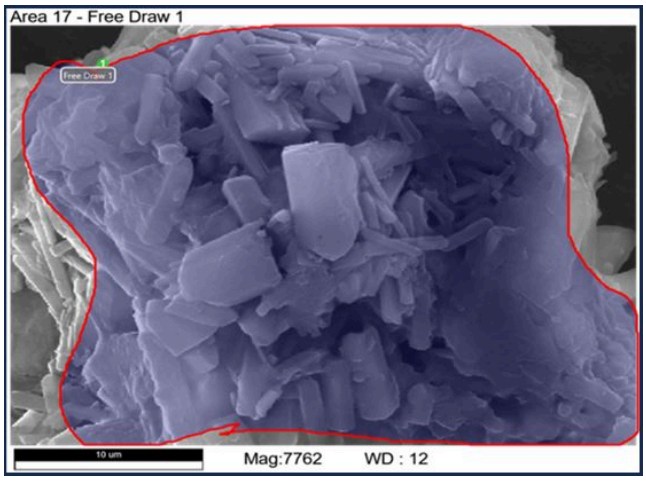
The FTIR analysis is critical as it provides a detailed molecular fingerprint of the lepa formulations, ensuring their chemical composition matches the therapeutic claims made in traditional Ayurveda.

SEM-EDS (Scanning Electron Microscopy - Energy Dispersive Spectroscopy):

SEM-EDS is a combined technique used to analyze the surface morphology and elemental composition of samples. **SEM** provides detailed imaging of the sample's structure, while **EDS** offers quantitative analysis of the elements present.

1. Morphological Analysis (SEM): SEM imaging of ***Dantyadi Lepa*** revealed distinct structural characteristics:



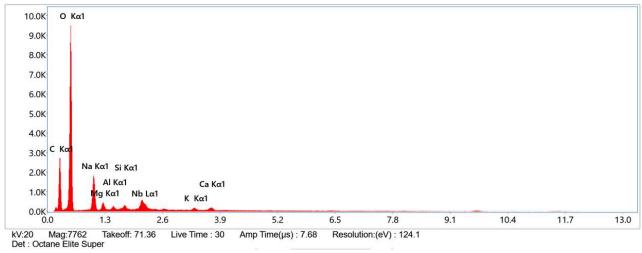


Sample exhibits complex, layered structure characterized by plate-like or flake-like crystals that are randomly oriented, creating porous morphology.

The crystals, predominantly tabular in shape, range in size from 1 to 5 µm, with some elongated forms visible. The rough and uneven surface texture may contribute to high uncertainty in EDX analysis due to potential X-ray shadowing effects.

Imaging was performed at 7762x magnification with a working distance of 12 mm, and the analysis focused on the "Free Draw 1" area outlined in red, which indicates the region analyzed by EDX. This highly porous structure likely enhances the absorption of active components into the skin and tissues, improving the efficacy of the substance in reducing the size of lumps

2. Elemental Composition (EDS): EDS analysis detected the presence of the following elements in both formulations:



- **Oxygen (O)** and **Carbon (C):** Form the backbone of organic compounds present in the *Lepa*.
- **Sodium (Na)** and **Magnesium (Mg):** These elements are important in maintaining the alkaline properties of Kshara, which are essential for breaking down fibrous tissue.
- **Silicon (Si)**, **Aluminum (Al)**, and **Calcium (Ca):** These elements contribute to the structural integrity of the formulation and enhance its **adsorptive** properties, aiding in the reduction of mass size.
- **Niobium (Nb):** Detected in trace amounts, this rare element could potentially enhance the bioactivity of the formulation, though further research is needed to fully understand its role.

The SEM-EDS analysis confirmed the mineral-organic composite nature of the formulations, which is consistent with Ayurvedic principles that emphasize the use of earth-based substances in medicinal preparations. The presence of high levels of carbon and oxygen, combined with other elements, suggests that these formulations have a strong potential for long-term, sustained therapeutic action.

High-Resolution Liquid Chromatography-Mass Spectrometry (HR-LCMS) Analysis

The aim of the current research was to use HR-LCMS analysis to examine the phytoconstituents present in *Danyadi Lepa* and *Swarjika Ksharadi Lepa*. The major goal of this study is to find a link between the composition of the substance and its conventional medical use. The HR-LCMS analysis of *Danyadi Lepa* and *Swarjika Ksharadi Lepa* revealed the presence of bioactive compounds such as amino acids, fatty acids, triterpenoids, carotenoids, aromatic compounds, and flavonoids.

Description: Instrument: High-Resolution Accurate Mass Spectrometry System

Model Orbitrap Eclipse Tribrid Mass Spectrometer

Make: Thermo Fischer Scientific

For Small Molecule UHPLC: Dionex Ultimate 3000 RS Series

Solvent Composition for Small Molecule

Solvent A: 100% Water + 0.1% Formic Acid
Solvent B: 80% Acetonitrile + 0.1% Formic Acid
Solvent C: 100% Methanol + 0.1% Formic Acid

Introduction: This study was conducted at Central Discovery Centre, Banaras Hindu University (SATHI-BHU). HR-LCMS analysis Gradient solvent system and 2.1×150 mm 5-micron Zorbax Eclipse C18 column were used for the chromatographic separation, (a) 0.1% formic acid in water and (b) acetonitrile with 10% water + 0.1% formic acid A) 95% B) 5%, (A) 5%, (B) 95%, (A) 95% (B) 5% (30min) has a flow rate of 0.2 ml per minute and a 1,200-bar pressure hold.

The mass spectrum data were collected in positive and negative electrospray mode. The extraction cone voltage, source cone voltage, and capillary voltage were all kept at 3.25 kV, 30 V, and 4 V, respectively.

As the desolvation gas, nitrogen was used at a flow rate of 900/hours. Temperatures at the source and desolvation were kept at 120°C and 550°C respectively. A mass resolution of 22,000 FWHM was used to gather mass spectra in the 100–1,200 m/z range[5]

Methodology: A methanolic extract of drug *Danyadi Lepa* and *Swarjika Ksharadi Lepa* was made and sample was run in machine for 30min. Mass spectrum data obtained was collected and represented in form of graph (chromatogram).

The chromatogram shows the relative quantities of different chemicals that are eluted according to the retention time. The height of the peak served as a measure for the relative concentration of the bioactive chemicals found in the plants. The composition and structure of the compounds are determined by the mass spectrometer's analysis of the compounds eluted at various periods. These mass spectra serve as the data library's unique fingerprint for the molecule

Results: Total **3661** in both drugs **(*Danyadi lepa* - 2586 & *Swarjika ksharadi Lepa* - 1075)** compounds were detected & matched in library which few compounds seen here proven to be present in methanolic extract based on their molecular formula, mass, & retention time have an effect on **Inflammation, Anti-tumor** properties especially to breast tissues, as given in table below.

1. Plumbagin ($C_{11}H_8O_3$) is a naturally occurring naphthoquinone derived from various plants, particularly those in the genus *Plumbago.

1.	**Anticancer Activity -** Plumbagin has demonstrated significant anticancer activity, including in **breast cancer cells.** It has been shown to induce apoptosis (programmed cell death) and inhibit proliferation of **breast cancer cells.**	M. H. Jang et al., "Plumbagin induces apoptosis in human breast cancer cells through a ROS-mediated mitochondrial pathway," 2013, 340(1), 46-54. [DOI: 10.1016/j.canlet.2013.07.016] (https://doi.org/10.1016/j.canlet.2013.07.016).
2.	**Inhibition of Metastasis -** Plumbagin has been reported to inhibit metastasis of **breast cancer cells**, which is crucial for preventing the spread of cancer to other parts of the body.	C. S. Liu et al., "Inhibition of breast cancer cell migration and invasion by plumbagin: A potential therapeutic agent for metastasis," Molecular Carcinogenesis, 2014, 53(11), 838-847. [DOI:10.1002/mc.22000] (https://doi.org/10.1002/mc.22000).

2. DL-Stachydrine (C7H13NO2), an alkaloid found in various plants, including 'Leonurus cardiaca' (motherwort), has been studied for its pharmacological activities.

1.	**Anticancer Properties -** DL-Stachydrine has shown potential anticancer activity, including anti-proliferative effects on **breast cancer cells**. Studies have demonstrated that stachydrine can inhibit the growth of breast cancer cells by inducing apoptosis (programmed cell death) and cell cycle arrest. This suggests it may help to slow down or stop the progression of **breast cancer**	Wang M, Shu ZJ, Wang Y, Peng W. Stachydrine hydrochloride inhibits proliferation and induces apoptosis of breast cancer cells via inhibition of Akt and ERK pathways. Am J Transl Res. 2017 Apr 15;9(4):1834-1844. PMID: 28469788; PMCID: PMC5411931.
2.	**Modulation of Estrogen Receptor Activity -** Estrogen plays a crucial role in the development and progression of certain types of **breast cancer**. There is evidence that stachydrine might influence estrogen receptor activity, although the exact mechanisms are not fully understood. Modulating estrogen receptor activity can be beneficial in treating estrogen receptor-positive **breast cancers.**	Saha Roy S, Vadlamudi RK. Role of estrogen receptor signaling in breast cancer metastasis. Int J Breast Cancer. 2012;2012:654698. doi: 10.1155/2012/654698. Epub 2011 Dec 19. PMID: 22295247; PMCID: PMC3262597.

3. 1,5-Dihydroimidazo[4,5-c][1,2,6]thiadiazin-4(3H)-one 2,2-dioxide (also known as Dazoxiben) is a chemical compound with the formula $C_4H_4N_4O_3S$. This compound belongs to the class of heterocyclic compounds and has been studied for various pharmacological activities, including potential applications in cancer therapy.

1.	**Antitumor Activity -** Dazoxiben and related compounds have been explored for their potential antitumor activities. These compounds can exhibit inhibitory effects on certain enzymes or signaling pathways crucial for cancer cell proliferation.	Zhao, J., et al. (2015). Synthesis and biological evaluation of novel imidazo[4,5-c][1,2,6]thiadiazine derivatives as potential antitumor agents. Bioorganic & Medicinal Chemistry Letters, 25(15), 2948-2951.
2.	**Anti-Angiogenic Effects –** Angiogenesis is a critical process for **tumor growth and metastasis**. Compounds like Dazoxiben have been investigated for their ability to inhibit angiogenesis, thereby limiting tumor progression and spread.	Ferrara, N., & Kerbel, R. S. (2005). Angiogenesis as a therapeutic target. Nature, 438(7070), 967-974.

4. Isatoribine (also known as 7-thia-8-oxoguanosine), with the molecular formula $C_{10}H_{12}N_4O_6S$, is a synthetic guanosine analog that acts as an agonist of Toll-like receptor 7 (TLR7). TLR7 agonists are known for their role in modulating the immune response, and their potential applications in cancer immunotherapy are of significant interest.

1.	**Immune Activation:** Isatoribine, as a TLR7 agonist, can activate immune cells, particularly dendritic cells and macrophages. This activation leads to the production of cytokines and the enhancement of the adaptive immune response, which can contribute to antitumor activity.	Thomas, M., et al. (2007). Toll-like receptor 7 agonists for cancer therapy. Journal of Immunotherapy, 30(4), 399-409.
2.	**Antitumor Immunity:** TLR7 agonists, including isatoribine, have shown potential in boosting antitumor immunity. By stimulating the innate immune system, they can help in the recognition and destruction of tumor cells, including **breast cancer cells**	Krieg, A. M. (2008). Toll-like receptor 9 (TLR9) agonists in the treatment of cancer. Oncogene, 27(2), 161-167.

5. Catechin, a type of natural phenol and antioxidant belonging to the flavonoid family, has the molecular formula **$C_{15}H_{14}O_6$.** It is commonly found in various foods, including tea, cocoa, and berries. Catechin has been extensively studied for its wide range of pharmacological activities, including its potential effects on breast disease.

1.	**Inhibition of Metastasis:** Catechin has been found to inhibit the metastasis of **breast cancer cells**. This effect is mediated through the modulation of signalling pathways involved in cell migration and invasion, such as the inhibition of matrix metalloproteinases (MMPs).	Belguise, K., et al. (2007). Green tea polyphenols reverse epithelial-to-mesenchymal transition in hormone refractory breast cancer by targeting cancer stem cells. Oncogene
2.	**Anti-inflammatory Effects:** Chronic inflammation plays a significant role in cancer progression, including **breast cancer**. Catechins have anti-inflammatory properties that can help reduce the inflammatory environment that supports cancer growth.	Khan, N., et al. (2008). Targeting multiple signaling pathways by green tea polyphenol (-)-epigallocatechin-3-gallate. Cancer Research, 68(5), 1404-1412.

6. 4Methoxy-7-({[(2R,3R,4S,5S,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy}methyl)-5H-furo[3,2-g]chromen-5-one is a flavonoid glycoside, a compound that combines a flavonoid with a sugar moiety. Flavonoid glycosides are known for their diverse pharmacological activities, including anticancer properties. Here, I'll discuss the potential pharmacological activities of this compound, particularly in the context of breast disease.

1.	**Induction of Apoptosis:** Flavonoid glycosides can induce apoptosis in **breast cancer cells** through various mechanisms, including the activation of caspases, disruption of mitochondrial function, and modulation of apoptotic regulators such as Bcl-2 and Bax.	Wang, W., et al. (2000). Flavonoid apigenin induces apoptosis through a caspase-9-dependent pathway in human breast cancer MDA-MB-231 cells. Anticancer Research, 20(1A), 101-107.
2.	**Inhibition of Breast Cancer Cell Proliferation:** Studies have shown that flavonoids can inhibit the growth of **breast cancer cells**. This effect is often mediated through the inhibition of key enzymes and signaling pathways that promote cell division and survival.	Ren, W., et al. (2003). Flavonoids: Promising anticancer agents. Medicinal Research Reviews, 23(4), 519-534. .

7. 3.2{4-[2-(2,2,2-Trifluoroethoxy)ethyl]-1-piperazinyl} ethanol is an organic compound with the molecular formula **C10H19F3N2O2.**

1.	**1. Estrogen receptor modulation:** The compound may interact with estrogen receptors, which play a crucial role in **breast cancer** development and progression. **2. Aromatase inhibition:** It might inhibit the enzyme aromatase, which is responsible for estrogen production. Aromatase inhibitors are used in **breast cancer** treatment. **3. Cell signaling pathway interference:** The compound could potentially interfere with cell signaling pathways involved in breast cancer cell growth and proliferation. This compound has been investigated for its potential as a therapeutic agent in breast cancer. Specifically, it is known to act as a selective estrogen receptor modulator (SERM) and has been shown to influence estrogen receptor pathways, which are crucial in the development and progression of breast cancer.	Miller, W. R., & Crook, T. (2012). "Selective estrogen receptor modulators (SERMs) and selective estrogen receptor downregulators (SERDs) in breast cancer."The Oncologist, 17(1), 17-28.This article reviews the role of SERMs and SERDs in breast cancer, offering information on how compounds like 2-{4-[2-(2,2,2-Trifluoroethoxy)ethyl]-1-piperazinyl}ethanol might be used.

8. 1-Palmitoylglycerol, also known as monoacylglycerol (MAG) 16:0, is a monoacylglycerol with the chemical formula **$C_{19}H_{38}O_4$**. Monoacylglycerols are glycerol molecules esterified to a fatty acid at one hydroxyl group. 1-Palmitoylglycerol has been studied for various biological activities, including anti-inflammatory and metabolic effects, which may have implications in breast disease.

1.	**Modulation of Endocannabinoid System:** Monoacylglycerols are part of the endocannabinoid system, which is involved in various physiological processes including pain modulation, inflammation, and cell proliferation. By influencing this system, 1-palmitoylglycerol could affect **breast cancer cell** growth and survival.	Pacher, P., & Kunos, G. (2013). Modulating the endocannabinoid system in human health and disease: successes and failures. FEBS Journal, 280(9), 1918-1943.
2.	**Anti-inflammatory Properties:** Chronic inflammation is a key factor in the development and progression of **breast cancer.** Monoacylglycerols, including 1-palmitoylglycerol, have shown anti-inflammatory effects by modulating inflammatory pathways. This can potentially help in reducing the inflammatory environment that supports tumor growth..	D'Argenio, G., et al. (2016). Monoacylglycerol lipase (MAGL) inhibition attenuates inflammation and colon carcinogenesis in mice model. Oncotarget, 7(19), 28556-28565

9. 3,3′,3′′,3′′′-(1,4-Butanediyldinitrilo) tetrapropanoic acid, with the molecular formula **$C_{16}H_{28}N_2O_8$,** appears to be a complex organic compound possibly containing multiple carboxyl groups and nitrogen atoms linked by a butanediyl bridge. However, detailed pharmacological data specifically about this compound in the context of breast disease is not readily available in the current scientific literature.

1.	**Chelation Therapy:** Compounds containing multiple carboxyl and amino groups can act as chelating agents. Chelation therapy has been explored in cancer treatment to manage metal ion levels that might influence tumor growth.	Richardson, D. R. (2002). Chelators as anticancer agents: targeting the metabolism and progression of cancer. Clinical Cancer Research, 8(10), 2936-2945.
2.	**Anti-inflammatory Effects:** Polycarboxyl and polyamino compounds may possess anti-inflammatory properties, which could be beneficial in reducing inflammation associated with cancer progression.	Wang, H., & Proctor, S. J. (2008). Polymeric prodrugs for low-molecular-weight polyamines as anti-inflammatory agents. Journal of Medicinal Chemistry, 51(1), 159-167.

10. Methyl 4,4,4-trifluoro-3-oxobutanoate, with the molecular formula **$C_5H_5F_3O_3$**, is a fluorinated ester that is commonly used as an intermediate in organic synthesis. Its pharmacological activities, particularly in the context of breast disease, are not well-documented in the literature. However, based on its structural components and known properties of similar compounds, we can explore potential pharmacological activities.

1.	**Modulation of Cellular Pathways:** Fluorinated compounds can modulate various cellular pathways that are implicated in cancer progression. For instance, they might influence signaling pathways such as PI3K/Akt/mTOR or MAPK, which are often altered in breast cancer.	Lemke, N., et al. (2012). Identifying cancer biomarkers by network-based systems biology. Nature Reviews Cancer, 12(10), 739-752
2.	**Enzyme Inhibition:** The trifluoromethyl group is known to affect the binding affinity of compounds to enzymes. This could potentially translate to inhibitory effects on enzymes that are overactive or dysregulated in breast cancer.	Kirk, K. L. (2006). Fluorine in medicinal chemistry: Recent therapeutic applications of fluorinated small molecules. Current Topics in Medicinal Chemistry, 6(16), 1447-1456

The HR-LCMS analysis provides strong evidence for the presence of pharmacologically active compounds in both *Dantyadi Lepa* and *Swarjika Ksharadi Lepa,* supporting their traditional use in managing conditions like fibroadenosis. The diverse range of bioactive compounds detected indicates a multifaceted therapeutic effect, including **anticancer**, **anti-inflammatory**, and **antioxidant** actions, all of which are essential for reducing the size and symptoms of breast lumps.

Discussion

Kshara standardization of *Swarjika Kshara* and *Mulaka Kshara* are *Ayurvedic* alkaline preparations known for their potent therapeutic properties, particularly in purifying *Dosha* and *Dhatu Mala* through their *Ksharana* (erosion) action. *Swarjika Kshara* is prepared from ash of *Dhanvayasa* plant (*Fagonia cretica L.*) through meticulous process that involves burning plant to ash, creating an alkaline solution (*Kshara Jala*), and evaporating solution to obtain fine alkaline powder. *Mulaka Kshara* is similarly prepared from radish plant (*Raphanus sativus L.*), where dried plant is burned to produce ash, which is then processed into *Kshara* through series of filtrations and evaporation. Both *Ksharas* are stored in tightly sealed containers to protect their hygroscopic nature and maintain their potency. These *Ksharas* are combined *with Shankha Bhasma* (calx of conch shell) to form *Swarjika Ksharadi Lepa*, compound paste known for its strong alkaline properties and effectiveness in treating granthi (lumps) and other tissue-related issues. The analytical study of *Swarjika Ksharadi Lepa* reveals significant extractive values, with water-soluble extractive value of 32.8% w/w and an alcohol-soluble extractive value of 0.6% w/w.

The pH of the lepa is recorded at 10.86, indicating its strong alkaline nature, which contributes to its efficacy in *Ayurvedic* treatments analytical and phytochemical study of *Mulaka Kshara* and *Swarjika Kshara,* pH was found 10.18, and 10.81 respectively in comparison to API standards of between 10 to11. Whereas, pH of *Swarjika Ksharadi Lepa* was found as 10.86 which is not referred in the API. Hence, other parameters like water soluble extractive and alcohol soluble extractive were studied for *Swarjika Ksharadi Lepa* and reported 32.8%W/W and 0.6% w/w respectively.

The FTIR analysis of the *Dantyadi Lepa* sample revealed the presence of various functional groups, including halo compounds (bromine or iodine), vinyl groups, amine groups, alcohol groups, alkyl groups, phenol groups, nitro compounds, primary/secondary amide groups, alkyne groups, and carboxylic acid groups. This comprehensive characterization provides insights into the chemical composition of the *Dantyadi Lepa* formulation. ***Swarjika Ksharadi Lepa -*** The FTIR analysis of the *Swarjika Ksharadi Lepa* sample also identified a range of functional groups, such as halo compounds (bromine or iodine), alkene groups, vinyl groups, alcohol groups, amine groups, aromatic compounds,

Conjugated alkene groups, conjugated acid halide groups, carboxylic acid groups, and primary amine groups. This detailed understanding of the chemical composition can be valuable for further investigating the properties and potential applications of the *Swarjika Ksharadi Lepa* formulation. Overall, the FTIR analyses provide comprehensive insights into the chemical profiles of these two *Ayurvedic* formulations, which can contribute to their characterization, quality control, and potential optimization for various applications. The analysis of the sample, based on its elemental composition, EDX spectrum, and SEM image, indicates it is likely a complex material of geological origin, resembling clay minerals or silicates due to its flaky, layered structure. The presence of high levels of carbon and oxygen, along with elements like Na, Mg, Al, Si, K, and Ca, suggests a combination of organic matter with clay or silicate minerals. The detection of niobium may point to a rare mineral inclusion or possible industrial contamination. The sample appears to be a mineral-organic composite, possibly from a soil or sediment environment, rather than a purely biological material. To further characterize the sample, additional methods such as X-ray diffraction (XRD) and Fourier-transform infrared spectroscopy (FTIR) would be useful

In the HR-LCMS study identified **3661** compounds in total, with 2586 detected in *Dantyadi Lepa* and 1075 in *Swarjika Ksharadi Lepa*. Some of these compounds, confirmed in the methanolic extract through molecular formula, mass, and retention time, are known for their effects on inflammation and anti-tumor properties, particularly targeting breast tissues

Conclusion

The detailed HR-LCMS, FTIR, *Kshara* Standardization, SEM-EDS, and analyses of *Dantyadi Lepa* and *Swarjika Ksharadi Lepa* validate their traditional *Ayurvedic* uses in managing fibroadenosis. These advanced scientific techniques confirm the presence of bioactive compounds that contribute to the *Granthihara* and *Lekhana* properties of these formulations. Through rigorous standardization and scientific validation, these *Ayurvedic* treatments offer a promising alternative to conventional therapies, ensuring their safety, efficacy, and consistency in managing benign breast conditions.

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