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THERAPEUTIC POTENTIAL OF FLEXINECK SOFT GEL CAPSULES: A GC-MS BASED EVALUATION OF BIOACTIVE COMPOUNDS

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ABSTRACT

Cervical spondylosis is a degenerative condition affecting the cervical spine, intervertebral discs, and vertebrae, resulting in pain, stiffness, and neurological symptoms. Conventional treatments, such as NSAIDs, muscle relaxants, and corticosteroids, carry long-term adverse effects, highlighting the need for alternative therapeutic options. Flexineck soft gel capsules, developed by Sitaram Ayurveda, offer a herbal remedy for cervical spondylosis and related musculoskeletal disorders. This study utilizes Gas Chromatography-Mass Spectrometry (GC- MS) to analyze the bioactive compounds in Flexineck, identifying key phytochemicals with anti-inflammatory, analgesic, and antiarthritic properties. The presence of β-Caryophyllene, γ- Sitosterol, and other active constituents suggests potential efficacy in managing cervical spondylosis. These compounds exhibit significant anti-inflammatory, analgesic, antiarthritic, and antinociceptive effects, contributing to symptom relief. This research highlights Flexineck's therapeutic potential as a natural alternative to conventional treatments and underscores the role of GC-MS in validating the efficacy and safety of herbal formulations.

KEYWORDS: Cervical spondylosis, GCMS, Flexineck, Anti-inflammatory.

INTRODUCTION

Cervical spondylosis is an age-related degenerative condition that affects the cervical spine, intervertebral discs, and vertebrae. It commonly manifests as pain, stiffness, and neurological symptoms due to nerve compression, often leading to significant morbidity and a reduced quality of life. Studies indicate that approximately 95% of individuals aged 65 and above ibit signs of cervical spondylosis, though many remain asymptomatic.[1] Current treatment options primarily involve the use of NSAIDs, muscle relaxants, and corticosteroids to alleviate pain and inflammation. However, long-term use of these medications can result in adverse health effects, while surgical interventions are often expensive and complex. Given these challenges, there is a growing demand for herbal alternatives that provide effective symptom relief with minimal side effects.[2]

Flexineck soft gel capsules, launched by Sitaram Ayurveda Pvt. Ltd., offer a promising herbal solution for managing cervical spondylosis, both with and without radiculopathy. These capsules contain a blend of medicinal herbs known for their anti-inflammatory, analgesic, and musculoskeletal-supporting properties. They are formulated to address ditions such as fibromyalgia of the neck, stiffness of the head and neck, and musculoskeletal disorders affecting the upper body.

To validate the pharmacological properties and therapeutic efficacy of Flexineck soft gel capsules, this study employs Gas Chromatography-Mass Spectrometry (GC-MS). GC-MS is a powerful analytical tool used to identify and quantify bioactive compounds in complex formulations.[3] In the context of cervical spondylosis treatment, GC-MS analysis can help determine the presence of key phytochemicals with anti-inflammatory, analgesic, and musculoskeletal-supportive properties.[4] Additionally, it aids in ensuring the safety of the formulation by detecting potential contaminants or toxic substances.

This research aims to provide a comprehensive GC-MS analysis of Flexineck soft gel capsules, identifying the key bioactive constituents responsible for their therapeutic action. By understanding the chemical composition and biological activity of these compounds, this study contributes to the growing body of evidence supporting the use of herbal formulations as viable alternatives to conventional treatments for cervical spondylosis.[5]

MATERIALS AND METHODS

Ingredients & Formulation

Each Flexineck soft gel capsule is formulated using a combination of potent herbal ingredients, processed according to traditional Ayurvedic methods. The raw materials are carefully sourced, authenticated, and subjected to stringent quality control measures before being used in the preparation. The list of ingredients, their botanical names, parts used, and quantities are provided in Table 1.

Table 1: Composition of Flexineck soft gel capsule.

Ingredients	Botanical name	Parts used	Quantity
Bala	*Sida cordifolia*	Root	540mg
Masha	*Vigna mungo*	Seed	540mg
Prasarini	*Merremia tridentata*	Whole plant	540mg
Erandam	*Ricinus communis*	Root	135mg
Shundi	*Zingiber officinale*	Rhizome	135mg
Lasunam	*Allium sativum*	Bulb	135mg
Rasna	*Alpinia galanga*	Rhizome	135mg
Aswagandha	*Withania somnifera*	Root	42mg
Bala	*Sida cordifolia*	Root	42mg
Gokshura	*Tribulus terrestris*	Fruit	42mg
Guggulu	*Commiphora mukul*	Exudate	42mg
Prasarini	*Merremia tridentata*	Whole plant	42mg
Punarnava	*Boerhavia diffusa*	Root	42mg
Rasna	*Alpinia galanga*	Rhizome	42mg
Saindhava	*Rock salt*	As such	42mg
Sathavari	*Asparagus racemosa*	Root Tuber	42mg
Pippali	*Piper longum*	Fruit	14 mg
Maricha	*Piper nigrum*	Fruit	14 mg
Sundi	*Zingiber officinale*	Rhizome	14 mg
Vidarikhandha	*Pueraria tuberosa*	Root Tuber	42mg
VarahiKhandha	*Dioscorea bulbifera*	Root Tuber	42mg
Kshira	*Cow's milk*	As such	3ml
Thila taila	*Sesame oil*	As such	1ml

Method of preparation

The general method of oil preparation (Samanya Taila Paaka) was employed in the formulation of the oil used in Flexineck, which was subsequently encapsulated in soft gel capsules. The process involved the extraction of bioactive compounds through the traditional Taila Paaka method, ensuring optimal retention of medicinal properties.

Preparation Process

1. Selection of Ingredients

- Medicinal herbs with known therapeutic effects were selected based on classical Ayurvedic principles.
- The raw materials were authenticated and subjected to quality control before use.

2. Oil Infusion

- Sesame oil was used as a carrier medium.
- The herbal extracts were infused in the oil through controlled heating and stirring to ensure the uniform dispersion of active constituents.

3. Filtration and Storage

- After the desired consistency and concentration were achieved, the oil was filtered to remove solid residues.
- The prepared oil was stored in airtight containers under controlled conditions to prevent oxidation and degradation.

4. Encapsulation

- The prepared oil was encapsulated in soft gel capsules following industry- standard encapsulation techniques.
- Encapsulated oils underwent mandatory analytical tests before and after the process to ensure quality compliance and efficacy.

GC-MS analysis

The Gas Chromatography-Mass Spectrometry (GC-MS) analysis was conducted to determine the chemical composition of Flexineck oil and evaluate its efficacy and safety.

Sample Preparation

- The oil sample was extracted using hexane as a solvent.
- The extracted solution was filtered using a Nylon syringe filter (13 mm, 0.2 µm pore size)**.**
- The filtered sample was then transferred into a vial for injection into the GC-MS system**.**

Instrumentation

- GC Model: 7890A GC with 5975C triple-axis detector

- Column Specification:
- Type: DB-5MS
- Length: 30 m
- Diameter: 0.250 mm
- Film thickness: 0.25 µm

Chromatographic Conditions

- Injection Volume: 2 µL (splitless mode)
- Carrier Gas: Helium **(**99.9995% purity**)** at a flow rate of 1 mL/min
- Ionization Mode: Electron Impact **(**EI**)** at 70 eV
- Injector Temperature**:** 300°C (constant)

Table 2: Column Oven Temperature Program.

Oven	Rate °C/min	Value °C/min	Hold Time
Initial		100	1
Ramp 1	10	200	0
Ramp 2	20	300	10

Mass Spectral Database Used for Identification

- National Institute of Standards and Technology (NIST-08 Spectral Data)
- Comparison of obtained spectral configurations with reference spectra

RESULTS

Analysis and Identification of Bioactive Compounds

The GC-MS analysis identified various bioactive compounds present in Flexineck oil, along with their chemical formula, area percentage, primary, and secondary pharmacological actions. The identified compounds are listed in the table below.

Table 3: Primary and Secondary action of bioactive compounds identified through GCMS.

Sl. No.	Constituent	Chemical formula	Area (%)	Primary Action	Secondary Action
1.	δ-Elemene[6]	C15H24	0.872	Anti-inflammatory, Antimicrobial	Apotosis Inducer
2.	Copaene[7]	C15H24	1.859	Anti-inflammatory, Antimicrobial	Antioxidant, Neuroprotective potential, Anticancer
3.	β- Caryophyllen[8,9]	C15H24	5.112	Analgesic, Anti-inflammatory & Anti-nociceptive	Neuroprotective, Anti-anxiety, Gastroprotective

4.	β-Cedrene[10]	C15H24	0.694	Analgesic and Anti-inflammatory properties	Neuroprotective, Antimicrobial, Relaxant
5.	Butan-2-one, 4-(3-hydroxy- 2-Methoxypheny[11]	C11H14O3	2.945	Anti-inflammatory, Antioxidant	Antithrombotic, Antimicrobial, Anxiolytic
6.	n- Hexadecanoic acid[12]	C16H32O2	23.692	Anti-inflammatory, for the treatment of rheumatic symptoms	Neuroprotective, Wound healing support
7.	9,12-Octadecadieno ic acid (Z,Z)[13,14]	C18H32O2	25.697	Anti-inflammatory & anti-arthritic	Anti-cancer, antihistaminic, hypocholesterolemi c & Antibacterial activity
8.	Stigmastan- 3,5-diene[15,16]	C29H48	13.578	Analgesic and anti- inflammatory	Antimicrobial activity
9.	γ- Sitosterol[17,18]	C29H50O	25.553	Anti-inflammatory	Antihyperglycemic activity

Chromatogram

The GC-MS chromatogram generated from the analysis highlights the retention times and relative abundance of identified bioactive compounds. The peaks obtained correspond to different constituents in the Flexineck oil, confirming the presence of key therapeutic agents responsible for its efficacy in pain relief and inflammation management.

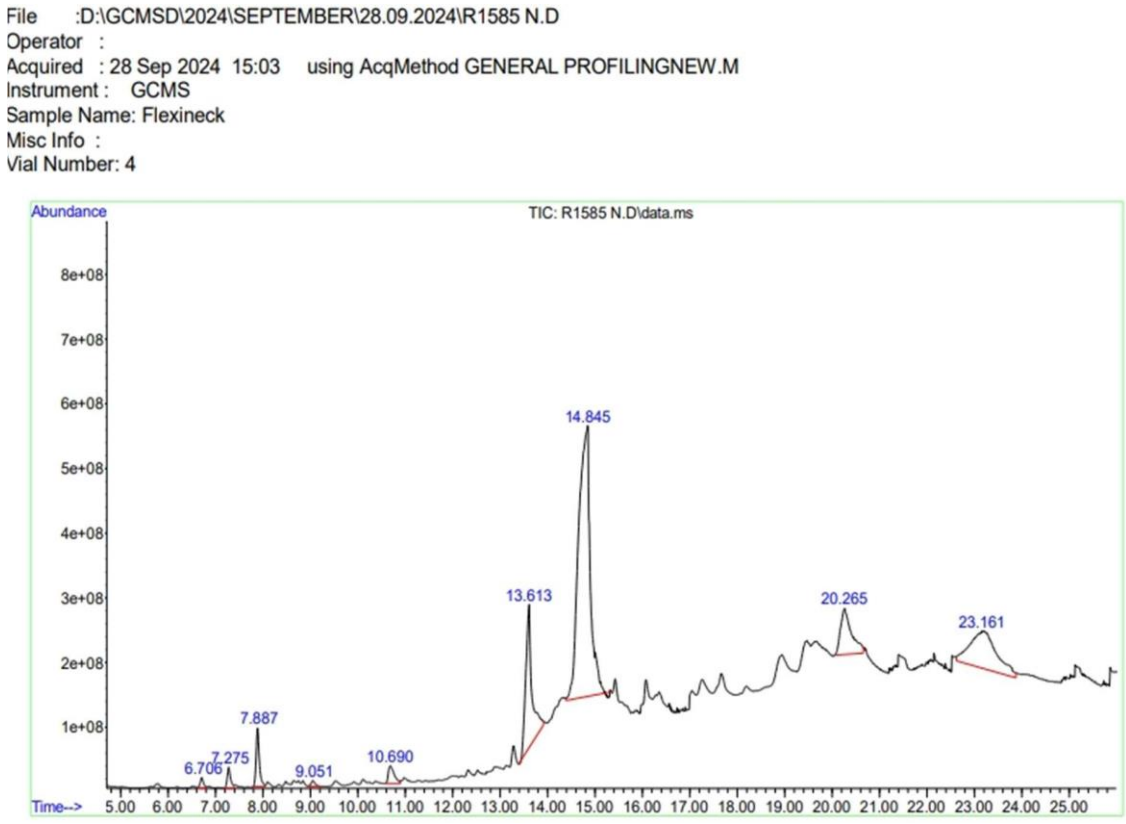

Fig. 1: GCMS chromatogram of Flexineck.

DISCUSSION

Identification of Bioactive Compounds in Flexineck Soft Gel Capsule

The present study aimed to identify the bioactive compounds present in Flexineck Soft Gel Capsule using Gas Chromatography-Mass Spectroscopy (GC-MS). This analysis provides a deeper understanding of the phytochemical composition and its potential therapeutic nefits in managing conditions such as cervical spondylosis (with or without radiculopathy), fibromyalgia of the neck, stiffness of the head and neck, musculoskeletal disorders affecting the upper body, and neurological disorders leading to neck pain.

The active constituents, their retention times (RT), and concentration (peak area %) are presented in Table 3 and Fig 1. The analysis confirmed the presence of nine ioactive phytochemical compounds in Flexineck Soft Gel Capsule. Six out of the nine compounds (β-Caryophyllene, β-Cedrene, n-Hexadecanoic acid, 9,12-Octadecadienoic acid (Z,Z), Stigmastan-3,5-diene, and γ-Sitosterol) have potent anti-inflammatory effects, which is crucial for reducing pain, swelling, and stiffness in conditions like cervical spondylosis and musculoskeletal disorders. Three compounds (β-Caryophyllene, β-Cedrene, and Stigmastan-3,5-diene) show significant pain-relieving properties, making them beneficial for chronic pain management. n-Hexadecanoic acid and 9,12-Octadecadienoic acid (Z,Z) exhibit anti-arthritic effects, which can help in managing joint degeneration and stiffness. Copaene, β-Caryophyllene, β-Cedrene, and n-Hexadecanoic acid have neuroprotective potential, which may help in repairing damaged nerves and improving nerve conduction in radiculopathy and neuropathic pain. The presence of Copaene, δ-Elemene, Butan-2-one, and Stigmastan-3,5-diene enhances the antioxidant and antimicrobial activity, helping to protect against infections and cellular damage.

These compounds contribute significantly to the therapeutic properties of the formulation, making it a potent natural remedy for conditions like cervical spondylosis, fibromyalgia of the neck, musculoskeletal disorders, and neurological issues leading to neck pain. By targeting inflammation, pain, and degenerative changes in musculoskeletal structures, the active compounds contribute to overall symptom relief and improved patient well-being.

Mode of Action of Flexineck Soft Gel Capsule

The therapeutic effect of the Flexineck Soft Gel Capsule is determined by the Ayurvedic principles of Rasa (taste), Guna (properties), Veerya (potency), Vipaka (post-digestive effect), and Doshagnatha (action on Doshas). The composition of the capsule is a blend of

ingredients with Vata-Kapha pacifying properties, supporting muscle and joint health while addressing inflammatory conditions.

Pharmacological Properties of Ingredients

A comprehensive analysis of the key ingredients is presented in the table below.

Table 4: Pharmacological properties of Flexineck ingredients.

INGREDIENTS	RASA	GUNA	VEERYA	VIPAKA	DOSHAKARMA
Bala	Madhura,	Laghu, Snigdha, Pichila	Sheeta	Madhura	Vata-pitta hara
Masha	Madhura,	Guru, Sara, Snigdha, Sramsana, Tarpana	Usna	Madhura	Vata-kapha hara
Prasarani	Tikta	Guru, Sara	Usna	Katu	Kapha-vata hara
Eranda	Madhura, Katu, Kashaya	Snigdha, Teekshna, Sookshma,	Usna	Madhura	Kapha-vata hara
Sunti	Katu	Guru, Ruksha, Teekshna,	Usna	Madhura	Vata-kapha hara
Rasona	Madhura, Lavana, Katu, Tikta, Kashaya	Snigdha, Guru, Teekshna, Sara	Usna	Katu	Vata-kapha hara
Rasna	Tikta	Guru	Usna	Katu	Kapha-vata hara
Aswagandha	Katu, Tikta, Kashaya	Laghu , Snigdha	Usna	Madhura	Kapha-vata hara
Gokshura	Madhura	Guru, Snigdha	Sheeta	Madhura	Tridoshahara
Punarnava	Madhura	Laghu, Ruksha	Usna	Katu	Kapha-vata hara
Saindava	Lavana, Madhura,	Virsya, Hridya, Laghu	Anushna	Madhura	Tridoshahara
Sathavari	Madurai	Guru, Snigdha	Sheeta	Madhura	Vata-pitta hara
Pippali	Katu	Laghu, Teekshna	Usna	Madhura	Vata-kapha hara
Maricha	Katu	Laghu, Teekshna, sukshma	Usna	Katu	Kapha-vata hara
Varahikhanda	Madura	Laghu, Snigdha	Usna	Katu	Kapha-vata hara, Pittakara

Vidarikhanda	Madura	Guru, Snigdha	Sheeta	Madhura	Vata-pitta hara,
Guggulu purified	Tikta, Katu	Laghu, Ruksha, Vishada, Sookshma	Usna	Katu	Tridoshahara
Thila thaila	Madhura, Kashaya, Tikta	Guru, Snigdha	Usna	Madhura	Vatahara
Ksheera	Madhura,	Guru, Snigdha, Pichila, Slakshna	Sheeta	Madhura	Vata-pitta hara, Kaphakara

Most of the ingredients in the formulation possess Madhura Rasa (sweet taste), Guru (heavy) and Snigdha (unctuous) Guna, Usna (hot) Veerya, and Vata-Kapha pacifying properties. Madhura Rasa, Guru, and Snigdha Guna are known for their nourishing effects, aiding in the nourishment of Dhatus (body tissues), particularly Asthi Dhatu (bones) and Mamsa Dhatu (muscles), thereby strengthening musculoskeletal structures.

The presence of Ksheera (milk) and Tila Thaila (sesame oil) further enhances the nourishing and rejuvenating effects as both are Brihmana (nourishing) in nature. The inclusion of herbs such as Ashwagandha, Masha, Shatavari, Varahi Kanda, and Vidarikanda supports muscle strengthening. Herbs like Bala, Gokshura, and Punarnava possess anti-inflammatory properties, reducing acute inflammation and contributing to pain management. Rasona, Pippali, Maricha, and Sunti help in enhancing digestion and ensuring proper absorption of the active phytochemicals. The combination of these herbs makes Flexineck Soft Gel Capsule a perfect blend of Brihmana (nourishing), Shothahara (anti-inflammatory), and Pachana (digestive- enhancing) medications, making it an ideal formulation for degenerative conditions associated with pain and inflammation.

CONCLUSION

The utilization of GC-MS analysis in researching medicinal formulations for the treatment of conditions such as cervical spondylosis provides critical insights into the therapeutic potential of Flexineck Soft Gel Capsules. This study validates the presence of bioactive compounds with proven anti-inflammatory, analgesic, antiarthritic, and antinociceptive activities, supporting the efficacy of the formulation in musculoskeletal and neurological disorders.

By elucidating the active components, their pharmacological properties, and their therapeutic

effects, this study highlights the potential of Flexineck Soft Gel Capsules as a natural alternative to conventional treatments. Additionally, this analysis ensures a better understanding of the formulation's safety profile, reinforcing the need for further exploration of herbal therapies as complementary or alternative treatment options to modern pharmacotherapy. The findings encourage further scientific validation of Ayurvedic formulations, ensuring their efficacy, safety, and potential integration into mainstream medical practice.

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