INNOVATIVE FORMULATION AND PACKAGING OF MEDICATED AROMA INHALERS USING TULSI OIL

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ABSTRACT

Present inhalers are vaporizers producing only local effect therefore there is a need of special aroma-inhalers which may promote better body mind and spiritual health. Aroma inhalers uses aromatic essential oil which improves mental and emotional wellbeing. This concept utilize principle of aroma therapy which is based on total wellbeing for taking care of related problem. Now-a-days there are lot off infectious out brakes therefore there is a need to strengthen our immune power and take care of different infectious out brake. Medicated aroma-inhaler may help in this regards and also take care of infection. To enhance health and wellbeing, aromatherapy uses natural organic extracts from natural sources. In this formulation we utilizes different types of ingredients like Pudina crystals, Camphor, Methyl salicylate, Eucalyptus oil, Tulsi oil, Garlic oil, Clove oil and Rose oil to create a beneficial synergistic mixture.

Keywords :
Aromatherapy, essential oils, health, stress relief, Mood disorder
1. INTRODUCTION

Today's population is becoming more and more focused on consuming foods that are naturally occurring and require less processing [1]. These features are perceived by the consumers as synonymous with health and are determining factors for food acceptance [2]. The World Health Organization, in a report published in 2015, estimated that each year about 600 million cases (almost 1 in 10 people in the world) of foodborne illnesses and 420,000 associated deaths occur globally [3]. Food spoilage is a metabolic process that causes foods to be undesirable or unacceptable for human consumption due to changes in sensory characteristics. Spoiled foods may be safe to eat, i.e. they may not cause illness because there are no pathogens or a toxin present, but changes in texture, smell, taste, or appearance cause them to be rejected [4].

The study on aromatherapy and aroma inhalers as a kind of treatment for a range of medical conditions is thoroughly analyzed and summarized in this review article [A][B][C][D]

Aim And Objective

**Aim:** Innovative formulation and packaging of medicated aroma-inhalers using Tulsi oil

**Objective:**

To design aroma-inhalers which use to

- Boost immunity
- Treat headaches, migraines
- Reduce stress, agitation.

1.1. Aromatherapy:

The medicinal application of essential oils from herbs, blossoms, and other vegetation is known as aromatherapy. These essential oils can enter into the human system through the pores of the skin or sense of smell. Aromatherapy is the use of purified essential oils made from flowers, herbs, and other plant-based components for health benefits. In this supplemental approach, organic substances are employed to promote wellness. It's commonly called "essential oil treatment." [05] [06]

Aromatherapy derives from the term aroma, referring to odour or fragrance, and therapy, which means treatment. This type of care uses a gentle approach to address cardiac, physiological, and psychological issues. It enhances one's psychological and physical well-being. [06]
Essential oils (EOs) derived from fragrant plants are used in aromatherapy, an organic therapeutic approach. EOs and their constituents have a variety of pharmacological actions, with particular attention to how they might be utilized for treating psychological conditions including anxiety and depressive disorders. \[06\]

1.2. History of Aroma therapy:

Aromatherapy has been utilized by humans for thousands of years. Aromatic plant components were used in resins, balms, and oils by ancient societies in China, India, Egypt, and elsewhere. These natural chemicals had medicinal and religious functions. They were known to have physical as well as psychological advantages.

The Persians are credited with the invention of essential oil distillation in the 10th century, however the practice may have existed for much longer. In the 16th century, information about essential oil distillation was published in Germany. In the nineteenth century, French physicians recognised the therapeutic potential of essential oils. \[8\]

1.3. Types of aromatherapies:

1.4. Essential oils:

Essential oils are naturally occurring, strongly scented, volatile chemicals that are produced as secondary metabolites by aromatic plants. They have antibacterial, therapeutic, and aroma qualities, and their origins date back to the Arabs of the Middle Ages. They are employed as antibacterial, analgesic, sedative, anti-inflammatory, spasmolytic, and locally anesthetic treatments, as well as in food preservation and burial. Their methods of action are now more understood, especially when it comes to antimicrobials. Synthesized by all plant organs, essential oils are soluble in organic solvents, volatile, liquid, limpid, rarely colored, lipid-soluble, and retained in secretory cells with a density less than that of water. Essential oils originate from aromatic vegetation in temperate to warm Mediterranean and tropical countries. Essential oils may be extracted using a variety of techniques.
Table 1. Plants producing essential oil.

<table>
<thead>
<tr>
<th>Essential oils</th>
<th>Parts of the plant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bergamot, lemon, lime, sweet orange, tangerine, mandarin</td>
<td>Fruit peel</td>
</tr>
<tr>
<td>Cinnamon</td>
<td>Bark</td>
</tr>
<tr>
<td>Citronella, lemongrass, petitgrain, palmarosa, patchouli</td>
<td>Leaves</td>
</tr>
<tr>
<td>Geranium, lavender, rosemary, spike lavender</td>
<td>Entire plant</td>
</tr>
<tr>
<td>Ginger, vetiver</td>
<td>Roots</td>
</tr>
<tr>
<td>Jasmine, neroli (orange blossom), rose, ylang ylang</td>
<td>Flowers</td>
</tr>
</tbody>
</table>

1.5. Methods of extraction essential oil:

1. Soxhlet Extraction

2. Hydro-Distilation Extraction

3. Supercritical Carbon Dioxide Extraction

4. Hydrodiffusion
Figure 2: Extraction Method of essential oil

1.6. Classification of essential oils:

BASED ON AROMA: Another way to classify essential oils is by their scent or aroma. Citrus, herbaceous, medicinal/camphorous, floral, resinous, woody, earthy, minty, and spicy oils are the different categories into which oils can be classified:

1. **Citrus Oils**: This group includes essential oils with a pronounced citrusy taste. Citrus fruits and vegetables include bergamot, grapefruit, lemon, lime, etc.

2. **Herbaceous Oils**: Plant-based oils which are most helpful plants, contrary. One can remove these oils off herbs like Clary Sage, Melissa, Basil, and Hyssop. These kinds of herbs include peppermint and rosemary.

3. **Medicinal/Camphorous**: Oils that have a specific therapeutic function are called camphoraceous oils. Cajeput, Tea Tree, and other plants provide some of these essential oils, which have an earthy and mugwort-like, borneol-like scent. A delicious, dried plum-like backdrop blended with a rosemary-like taste.

4. **Flower Oils**: Oils derived from flowers or those that contain flowers. Under this category lies the essence of plants. Rose quartz, jasmine. Some examples are Chamomile, Lavender, and Rose species that provide these oils.

5. **Woody Oils**: Essential oils with woody scents or those derived from plant bark along with additional woody components are referred to as woody oils—Pine, sandalwood, berries of juniper, and cedar wood, among other things make oils of this type.

6. **Earthy Oils**: Essential oils with an earthy scent or those derived from the roots and other earthy portions of plants are referred to as earthy oils. Some of these oils are produced by Vitalis, Patchouli, Angelica, etc.

1.7. Drugs chemical compositions

Phytochemical studies have shown that oleanolic acid, ursolic acid, rosmarinic acid, eugenol, carvacrol, linalool, and β-caryophyllene are some of the main chemical constituents of Tulsi. Tulsi also contains eugenol methyl ester, caryophyllene, terpinene-4-ol, (+)-δ-cadinene, 3-carene, α-
humulene, citral, α-pinene, β-pinene, α-camphor, carvacrol, luteolin, methyl chavicol, limatrol, decyldehyde, cirsileneol, cirsimaritin, isothymusin, isothymonin, apigenin, and rosmarinic acid.

1.8. Function of essential oils

1. Immunomodulatory
2. Anti-Inflammatory
3. Antimicrobial Activity
4. Antistress Activity
5. Anti-Arthritis
6. Analgesic

1.9. Uses of Tulsi Essential oil:

1. Use in Pharmacology: Pharmacological studies have revealed that animals treated with tulsi extract were useful for both physical and chemical stress reliever. A leaf extract has been acts as stimulant to release of ACTH from pituitary cells in vitro [18]. The evidence shows that the non-toxic nature of the tulsi plant and its extract, makes an excellent example of an adaptogenic medicinal plant.

2. Use in Health Benefits: Basil or tulsi has been used in oral care, giving relief from respiratory disorders, fever, asthma, lung disorders, heart diseases and stress. It is undoubtedly the most excellent medicinal herb ever known. In India tulsi has worshipped since thousands of year for its endless miraculous, medicinal values and it protects from many infections. Tulsi leaves added to drinking water or foodstuff which is able purify it and also kills germs present in it.

3. Use As Healing Power: Tulsi has lot of medicinal characteristics and it can be used as a nerve tonic and sharpen memory. It encourage for the elimination of the catarrhal matter and phlegm from the bronchial tube. Leaves of tulsi make stronger the stomach and encourage copious perspiration.

4. Use in Coughs: Tulsi has important component of many Ayurvedic cough syrups and expectorants. It helps in bronchitis and asthma. It relieves from cold and flu after chewing of leaves.

5. Use in Throat Infection: Tulsi leaves taken in water boiled for few minutes and filter this extract is very beneficial in sore/painful throat and it is also use as gargle.

6. Use in Respiratory Disorder: Tulsi has been use for the treatment of respiratory disorder. Green leaves juice mixed with honey and ginger are very effective in bronchial asthma, cough, cold and influenza. If it is added with cloves and common salt also gives instant relief in influenza.
7. Use in Fever & Common Cold: Tulsi leaves are specific for many fevers in the rainy season; when malaria and dengue fever are widely prevalent. Tender leaves, boiled with tea, act as preventive against these diseases. In case of acute fevers, a decoction of the leaves boiled with powdered cardamom in half a litre of water and mixed with sugar and milk brings down the temperature.

8. Use in Kidney Stone: Tulsi has effect on the kidney to strengthen their functioning. Tulsi juice and honey can able remove renal stone in the kidney, if taken regularly for six months it will expel.

1.10. The Current condition regarding ADR and Toxicology:

Any unpleasant, unexpected, and occurring dosages used in humans for treatment, diagnosis, or prevention are referred to as adverse drug reactions (ADR) A medication may produce toxicity and adverse drug reactions (ADRs) if the dose at which it is taken causes the plasma drug concentration to exceed the bare minimum hazardous concentration. There are several obstacles in the way of drug discovery due to adverse reactions to medicines and medication-induced toxicity, which also increase healthcare expenses and danger to patient safety.

1.11. BRAIN-TARGETED NASAL DELIVERY BY EO OR VO:

Therapeutic drugs are delivered to brain tissue through odorous molecules by aromatic plant extracts breathed through the nose, which stimulate the olfactory system. By controlling brain chemistry, these neurotransmitters reduce symptoms of anxiety and sadness and enhance the quality of sleep. The olfactory epithelium of the nasal mucosa receives aromatic Odor molecules through the nose chamber, which are evoked by first-order neurons in the olfactory bulb.

The olfactory tract is formed by mitral cell axons and secondary neurons, with selective mitral cell axons reaching the ipsilateral olfactory bulb. The amygdala, entorhinal cortex, piriform cortex, and olfactory tubercle are among the key olfactory regions to which secondary neurons project after entering the olfactory striatum. Subsequently, these impulses reach the orbitofrontal cortex after partially reaching the hippocampus. As a link connecting the nervous system and the body's processes, the central olfactory region sends an extra olfactory signaling channel to the prefrontal cortex, releasing neurotransmitters like endorphins and serotonin.
2. MATERIAL AND METHODS:

2.1. Formulation:

Table 2. Formulation of Tulsi oil.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Ingredients</th>
<th>Quantity</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Pudina crystal</td>
<td>2.0 gm</td>
<td>Irritation</td>
</tr>
<tr>
<td>2.</td>
<td>camphor</td>
<td>2.0 gm</td>
<td>Cold sores</td>
</tr>
<tr>
<td>3.</td>
<td>Methyl salicylates</td>
<td>0.5 ml</td>
<td>Minor aches</td>
</tr>
<tr>
<td>4.</td>
<td>Eucalyptus Oil</td>
<td>0.4 ml</td>
<td>Nasal Congestions</td>
</tr>
<tr>
<td>5.</td>
<td>Tulsi oil</td>
<td>1 ml</td>
<td>Antipyretics</td>
</tr>
</tbody>
</table>

2.2. Procedure:

- Weigh each item by the formula.
- Place the tulsi oil, camphor, and pudina in a beaker.
- Gradually warm the mixture and add pudina crystals and Bhimsun Camphor, stir it.
- After letting it cool, slowly pour it onto a cotton roll.
- Cap the cotton in the container and let the solution slowly run down a cotton roll.
- To produce a particular effect, the vapour will saturate in a container intended for an inhaler.

2.3. Evaluation of essential oils (Methods):

2.2.1 Gas Chromatography-Mass Spectrometry (Gc-Ms)

2.2.2 Multidementionol Gas Chromatography (Mdgc)

2.2.2 Gc-Isotonic Ratio Mass Specterometry (Gc-Irms)

2.2.4 Vibrational Spectroscopy
Gas chromatography-Mass Spectroscopy Analysis (GC-MS): Gas chromatography is an old essential oil chemical profiling method. As all the chromatographic methods, it is based on the single compound separation from a complex matrix between two phases regarding their affinity between the phases, their shape, and mass. In GC, the mobile phase is a gas and the fixed phase is a solid at room temperature, but at a high temperature, this phase will be slightly melted but will remain fixed on the column. The mass spectrometer measures these heavy metals at nanograms levels, ensuring accurate and reliable oil analysis.

Multidimensional Gas Chromatography (MDGC): A well-known technique for enhancing GC separations is multidimensional gas chromatography or MDGC. With this method, the material is subjected to more than one separate chromatographic separation. This consecutive combination of two GC columns with varying selectivities makes up the MDGC apparatus. The modulator, or interface between the two columns, is essential to the MDGC process. Small portions of the eluting peaks from the main column (heartcuts) are continually accumulated and focused by the modulator, which then quickly and effectively introduces them to the additional column. When using the MDGC instrument, samples are often split into fractions based on changes in polarity in the additional dimension, using a smaller polar column, and by volatility in the initial dimension. For heartcuts from the first column to be introduced continuously and interference-free, the following separation must occur in a timely manner.

GC-Isotonic Ratio Mass Spectrometry (GC-IRMS): The introduction of chemical compounds to an EO or combining it with another natural extract, isotope ratio mass spectrometry (IRMS) is another effective method. Calculating the δ13C and δ2H isotope ratios unique to a chemical is possible with GC-C/P-IRMS (GC-combustion/pyrolysis-IRMS).

- Advantages: Exceptionally accurate, very successful in demonstrating the validity of EOs, and suitable for any kind of oil.
- Disadvantages: Costly, it requires an experienced operator. It needs databases, which are somewhat time-consuming to construct.

Vibrational Spectroscopy: One analytical technique that stands out in several domains is vibrational spectroscopy; it is flexible, simple, inexpensive, and quick. The investigation of different organic or chemical compounds is therefore frequently done using it.

- Advantages: Ecologically friendly, inexpensive, easy, and quick to use; it may be used to analyze liquid, semi-solid, and solid samples; it is also not harmful.
- Disadvantages: It is challenging to understand spectra due to their nature and the conditions of their surroundings.
2.4. Literature survey:

Table 3. Literature survey

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Title</th>
<th>Authors</th>
<th>Year</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Early Detection of adverse drug reaction and drug induce toxicity</td>
<td>Yang. Sand Kars.</td>
<td>2023</td>
</tr>
<tr>
<td>2</td>
<td>Extraction Process of Haridra and Tulsi Essential oil with their medicinal uses</td>
<td>Sharma, A, Dikshit, M, Jhunjhunwala, A And Som, A. K</td>
<td>2022</td>
</tr>
<tr>
<td>3</td>
<td>Advance drug reaction monitoring of anti-cancer drugs in haematology</td>
<td>Selvam, P, Rohhi, G</td>
<td>2021</td>
</tr>
<tr>
<td>4</td>
<td>A review paper on Tulsi plant (ocimum sanctum)</td>
<td>Bhadra. P and Sethi.L.</td>
<td>2020</td>
</tr>
<tr>
<td>5</td>
<td>In addition Anti-viral patch goggle patent</td>
<td>Rolf D</td>
<td>2020</td>
</tr>
<tr>
<td>6</td>
<td>Essential oil and their application</td>
<td>Harman,R.A,Ayepa,E,shittu,s,fometu and wang,J.</td>
<td>2019</td>
</tr>
<tr>
<td>7</td>
<td>Biological properties and chemical composition of essential oil from flowers and aerial parts of lavenders</td>
<td>Smigielski, k, pyrisinowska, R, stobiecka,A.</td>
<td>2018</td>
</tr>
<tr>
<td>8</td>
<td>Biosynthesis factories of essential</td>
<td>Rehman R, Asif hanif M</td>
<td>2016</td>
</tr>
<tr>
<td>10</td>
<td>Astatus review on medicinal properties of essential oils</td>
<td>Raut J S and karuppayil S M</td>
<td>2014</td>
</tr>
</tbody>
</table>

3. CONCLUSION:

From above reports and study, we can conclude that aromatherapy is natural and noninvasive gift of nature for humans. Its not only the disease symptoms which are eradicated but the whole body is rejuvenated by the use of aroma. Aromatherapy regulates the physiological, spiritual and psychological for new phase of life. This therapy is not only preventive but also can be used in the acute and chronic stages of diseases.
Pharmaceutical industries are trying for environmental friendly, alternative and natural medicine for disease associated with pathogens and metabolism. There may be a possibility of enhancing the rate of reaction and bioavailability of drugs from use of these essential oils.

If properly studied, these volatile oils may have the synergistic effect with the drugs used in the treatment of central nervous system disorder.

Essential oils in aromatherapy are mainly applied through inhalation. In this case, through the respiratory system or olfactory nerves they are able to optimize the mood or otherwise benefits the state of mind adversely affected by life factors and subsequent effects of the illnesses like anxiety, depression and stress, as well as physical disorder associated with immune system dysfunction.

ACKNOWLEDGEMENT:

I take this privilege and pleasure to acknowledge the contribution of many individuals who have been inspirational and supportive throughout my work and endowed me with great pleasure and a profound sense of gratitude, I express my most cordial and humble thank to my eminent guide Prof. Kshitij Varma, Department of medicinal chemistry for his constructive guidance.

I would like to express my sincere to Prof. Dr. R. S. Bhambar, Principle, MGV’S Pharmacy College, Panchvati, Nashik for providing the necessary facilities, I would like to extend my deep appreciation to all my group members without their support and coordination we would not have been able to complete this project.

I would like to make a very special reference to my parents and friends for supporting me in every step of my life.

I acknowledge with thanks, the valuable suggestions, criticism, and cooperation from colleagues.

REFERENCE:


antinociceptive interaction of Syzygium aromaticum or Rosmarinus officinalis coadministered with ketorolac in rats. *Biomedicine & Pharmacotherapy, 94*, pp.858-864.
