Preparation and Evaluation of Herbal Lip Balm

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INTRODUCTION:
Plants have been used to make cosmetics for a very long time. Traditional cosmetic uses for plants include scented skincare products and infusions, poultices, and other applications. Scientists have focused on plants over the past century to learn more about their safety and usefulness in the cosmetics industry. Vitamins, antioxidants, oils both essential and frequently abundant in herbal sources, and these substances have positive effects on the skin in terms of anti-aging, antioxidant, emollient activity, and other properties.¹ Lips, the visible body part at the mouth of humans and many animals, are soft, movable, and serve as the opening for food intake and in the articulation of sound and speech. Colouring lips is been practiced over years since the ancient period. Some synthetic lip colorant, cheap and easy to make and obtain, can harm the lip skin. Also, lips do not contain any oil gland and therefore need a hydration and protection in all seasons.² Due to the presence of hazardous synthetic excipients in cosmetics, there has been a great public concern regarding the use of organic sources.³ Lips do not have any oil glands; thus, it is really important to provide that extra moisture and protection throughout the day.⁴ Cosmeceuticals are the ingredients that have medicinal properties that benefits topical action and also provide protection against degenerative skin condition.⁵ Herbs and spices have been widely used both traditionally and commercially to increase the shelf-life and safety of foods.⁶

Safflower:
Safflower (Carthamus tinctorius L.) is one of the world’s oldest crops, highly branched, herbaceous, thistle like annual herb with yellow to red petals. It belongs to the family Asteraceae of the broad group Composites. The safflower is a warm temperature crop, cultivated over the greater parts of tropical Asia, Africa, Russia and China. It is commonly known as “Kardi” in Marathi and “Kussum” in Hindi. The safflower seeds contain oil (35-45%). The colour of flower varies from whitish yellow to red orange, the most common being deep yellow. Safflower flowers contain two pigments viz. red (carthamin) which is insoluble in water and yellow (carthamidin) which is soluble in water and mainly used as a material for dye and is currently being used as a natural food colorant. The alkaline extracts were used for dyeing silk, wool, cotton and paper, to make the pigment in the state of the precipitate and ancient Chinese manufactured and produced it as red paint for cosmetics.⁷ Many Chinese medicines are prepared by using dried flowers and extract of flowers. Now-a-days the medicinal uses of flowers in China have become known to the rest of the world. The extract of florets containing pigments are used in treatment of many illnesses such as menstrual problem, cardio vascular diseases pain and swelling associated with trauma. These medicinal preparations have been widely accepted which helps in increasing the demand for the safflower petals. The administration of 1% concentration of safflower petals exerted a positive influence on blood pressure and serum lipid profile of hypertensive and hyperlipdemic subjects.⁸
According to observations at the Kazakh Research Institute of Plant Protection and Quarantine, it has been found that individuals after two weeks of taking safflower tea showed a decrease in blood viscosity to normal, hypertensive pressure reduced, and low pressure returned to normal, so we can say that safflower tea affects blood pressure. At the same time, it was noted that this drug doesn’t have a negative effect for those who do not suffer from hypertension. In Europe, safflower is known mainly because of the fact that vegetable oil, which has found its wide application in the food industry is made from safflower. Many people don’t even suspect that this plant is able to cure numerous pathologies. This fact was the impetus for a close study of this tea. It made directly from the petals of this plant flowers. This tea is used, in most cases, as an amen, which tends to facilitate the general well-being of patients in the presence of these or other diseases of the gastrointestinal tract. A decoction of the flowers of this plant treats peptic ulcer, gastritis, jaundice, and enterocolitis. The seeds of this plant provide with a blood-purifying and laxative effect. It is believed that the greatest benefits of this tea are cleansing the liver and kidneys, increasing sweating and healing of damage to the intestinal walls. Safflower tea is also an intestinal antiseptic. It should be taken for quite a long time, until the skin is completely cleansed, and then periodically carry out cycles of its reception, which helps the proper bowel movement. It should be taken for quite a long time, until the skin is completely cleansed, and then periodically carry out cycles of its reception, which helps the proper bowel movement. There are several studies using of Safflower in ophthalmology practice. The neuroprotective properties of Honghua was examined, an extract of safflower used as an herbal medicine in China, in several experimental models of retinal ischemia. A phytochemical study of the aerial organs of the safflower tinctorial was carried out. A technique has been developed for quantitative analysis of the amount of flavonoids in the safflower flowers. When using the results of phytochemical studies, it can be argued that safflower is not only a promising oilseed crop, but also a potential domestic medicinal raw material. Thus, the safflower tinctorial cultivated in the territory of the Samara region is promising for further justification of its use in medicine and pharmacy.

**Lip balm:**

Lip balms are formulations applied onto the lips to prevent drying and protect against adverse environmental factors. The cosmetic literature reports scant data on this type of formulation, although references related to lipstick apply because it is a cosmetic form similar to lip balm (stick form). This similarity extends to include organoleptic and stability requirements, such as resistance to temperature variations, pleasant taste, innocuousness, smoothness during application, adherence and easy intentional removal. Lip balm should not be considered equivalent to the lip gloss, with the former being a product intended for use by both men and women. The main ingredients of lipstick are fatty acids, such as waxes, oils and butters, which provide consistency and work as emollients in the preparations. Among these, castor oil, beeswax, carnauba wax, candelilla wax, paraffin and cocoa butter are often used. Lipstick also contains additives, such as antioxidants, conservatives and fragrances, as well as dyes and pigment. There are however, a few significant differences between lipstick and lip balm, especially regarding functionality where lipstick is used to impart color to the lips whereas lip balm provides protection. Furthermore, lipstick formulations are of greater complexity due to a larger number of ingredients compared to lip balm formulations. To formulate lip balms, it is necessary to balance the concentration of the main ingredients including butters, oils and waxes, so that the final product presents an adequate fusion point of between 65 and 75 ºC. Depending on the proportion of wax, oils and pigments, the formulation will present different characteristics. A long-wearing product may be obtained...
by employing a high proportion of wax and pigment, while the opposite will produce a smoother lipstick or lip balm.\(^{(14)}\). Thus, contact of the product with the skin will not cause a sensation of friction or dryness, and should allow the forming of a homogeneous layer over the lips in order to protect the labial mucous susceptible to environmental factors such as UV radiation, dryness and pollution. The ingredients used in a formulation like lip balm can have an undesirable effect on softening and rupture points, characteristics independent of each other. Two distinct formulations can have the same fusion point but different consistencies. These flaws can demand significant effort from the formulator to remedy. A balance between the ingredients of the formula must be achieved in order for the formulation to have acceptable fusion, softening and rupture points.\(^{(14)}\) The technique used to manipulate the raw materials that comprise conventional lipstick is of extreme importance to the final result. Excluding the step of dye dispersion, which is not applicable to lip balm, the technique consists basically of mixing the solid fat components, which are heated until fusion, adding the liquid oils and then molding. The moderate mixture agitation allows the exit of any trapped air. This and other technical details, especially during the heating and molding phases, have a major impact on the final product. Signs of instability such as aeration, deformation and cracking may result from inadequate preparation.\(^{(15)}\)

**Types of lip balms:**

- The lip balms are divided into different types by their ingredients:
  - UV filter lip balm: This type of lip balm can be applied all the year round, especially in summer or when staying in a place with an increased solar activity.
  - Nourishing lip balm: This type works best in winters.
  - Moisturising lip balm: If you apply this type of lip balm in winter, your lips can be cracked because the balm is too quick to be absorbed. This type is better to used in summer.
  - Medicated lip balm: It should be applied with care. It acts as softening and antiseptic medication.

**Significance**

The primary purpose of lip balm is to provide an occlusive layer on the lip surface to seal moisture in the lips and protect them from external exposure. Dry air, cold temperature, and wind all have a drying effect on skin by drawing moisture away from the body.

- Organic lip balm is lightweight and made with only natural ingredients like beeswax, cocoa butter, and several vitamins and minerals.
- Tinted: Colorful lip balms combine lip balm benefits with color. It’s a great way to add to your lips while nourishing them. Some tinted lip balms are a good alternative to lipstick.
- Flavored: Flavored lip balm is a fun way to enjoy lip products with unique flavors alongside moisturizing components.
- Plumping: There’s also a lip balm similar to a lip plumping gloss or lipstick made to make your lips look fuller. But these may harm your lips because some contain irritants that temporarily cause your lips to swell. Be cautious when using these, and make sure you choose a good-quality product with other beneficial ingredients.

**Application of Lip Balm:**

Lip balms are formulations applied onto the lips to prevent drying and protect against adverse environmental factors. Numerous lip balms of chemical origin are currently available in the market from companies like The body shop, Nivea, Himalaya, Blistex, etc. The cosmetic literature reports...
limited data on this type of formulation, although references related to lipstick apply because it is a
cosmetic form similar to lip balm. This similarity extends to include organoleptic and stability
requirements such as resistance to temperature variations, pleasant taste, innocuousness, smoothness
during application, adherence and easy intentional removal.(16) Lip balm should not be considered
equivalent to the lip gloss, with the former being a product intended for use by both men and
women.(16,17) To formulate lip balms, it is necessary to balance the concentration of the main
ingredients including butters, oils and waxes and other excipientsMany people seek weekly facials,
daily skin scrubs, anti-aging lotions, and many other products to ensure they have healthy and glowing
skin. But with all the attention being given to healthy skin, lip care is largely forgotten. Natural lip
balms offer a natural way to maintain and promote healthy lip.(17) Lip balms are often eaten away by
the user and hence it is imperative that health regulators have a microscopic look at the ingredients that
go in to the lip balm.(18)

Advantages and Disadvantages of Natural Lip Balm

Advantages of natural lip balm :
A. Lip balms help to protect the natural health and beauty of the lips.
B. Sun block lip balms are proved to prevent ultraviolet rays from hurting the lips.
C. They are not gender specific products and both men and women can use them.
D. Lip balm products help to protect lips affected by cold sores, chapping and dryness
E. Contact of the product with the skin will not cause a sensation of friction or dryness, and should
allow the forming of a homogeneous layer over the lips in order to protect the labial mucous
susceptible to environmental factors such as UV radiation, dryness and pollution.
F. It refreshed, renewed and also addresses lip-related symptoms resulting from colds.
G. The use of natural lip cosmetic to treat the appearance of the face and condition of the skin

Disadvantages of natural lipbalm :
A. Lip balms made of low quality ingredients can harm the lips seriously. Such lip balms maythe lips insteadmoisturizing it.
B. Lip balm addiction is another disadvantage usually seen with the use of them
C. Compared to commercially-prepared lip balms, homemade lip balms tend to stay on the lips for a
shorter duration of time. Thus need to reapply often
D. Some companies manufacture lip balms considering only the beauty aspect, ignoring the health
benefits and soft character of the skin. Such products will gradually damage the natural color,
softness and glow of the lips.
E. The naturally derived colors and flavours are more difficult to obtain and also haveissues related to
stability in the products
F. Natural oils have other disadvantages such as greasier, comedogenic, and less spreadability.(20-23)

Objective:
The main objective of these system are as follows
1. To select the drug and excipients for moisturizing lips
2. To prepare dosage form as per moisturizing lipbalm
3. To optimize the process of formulation.
4. To evaluate and prepared moisturizing lip balm
5. To give best result with use of herbal plant

Literature review:
1. Baraiya Seema et. Al. 2022, Because they are more effective, easily available, and are believed to have less side effects, customers favoured herbal cosmetics. The personalised care category with the fastest growth is herbal preparations. Cosmetic treatments that contain physiologically active ingredients or components derived from plants are known as cosmetics, and they are the personal care product category that is growing the fastest. The gentle action, lower toxicity, and greater efficacy of herbs have led to an increase in their appeal in cosmetics during the past few years. A sizable market for herbal cosmetics was created by people's quest for appearance and beauty. The demand for herbal cosmetics and Cosmeceuticals has directly increased due to the desire to seem younger than one's actual age and to be attractive, youthful, engaging, and fair. Therefore, the use of herbal cosmetics and cosmeceuticals is disregarded in the evaluation.

2. Pande Ayu Naya Kasih Permatananda, 2021, Lip balm is defined as a cosmetic formulation that is applied to the lips to prevent dryness of the lips and protect the lips from foreign bodies, which makes lip balms different from lipsticks. There are many plant oils that can be used in making moisturizers, including lip balm, one of which is grapeseed oil. Although less popular with the public, Balinese grape has a higher flavonoid content than other grapes. The purpose of this study was to create a lip balm product derived from Balinese grape seed oil and find the best concentration of Balinese grape seed oil to create a lip balm product. The research method used in this research is experimental. Making lip balm preparations based on Balinese grape seed oil with various concentrations of 20%, 30%, 40%, 50%, 60%, and 70%. The ingredients used are Balinese grapeseed oil, lanolin, beeswax, propylene glycol and essential oils (perfume). Evaluation of lip balm preparations, namely homogeneity test, stability test carried out for three months at room temperature by observing changes in color, odor and dosage form, pH test, smear test, irritation test, and testing the ability of lip balm preparations to moisturize lips on the tested volunteers by using the preparation every day before going to bed and then measuring the moisture content of the lips every week until the fourth week using a skin analyzer. The result of this study is that grapeseed oil has the potential to be developed into cosmetic products, especially lip balm with the best concentration is 70%.

3. K.D. Rakhimov, 2020, Plant materials and preparations based on it continue to play an important role in the pharmacotherapy of many chronic and sluggish human diseases. Over the past two decades, there has been a very high consumer demand for medicines and preventive products obtained from natural plant sources. This is due to the complex effect of biologically active substances, vitamins, antioxidants of plant origin on the human body and the practical absence of side effects. An analysis of the development of phytopharmacology shows that the most promising direction in the field of the development of phytopreparations is the scientifically based use of the experience of traditional and modern medicine. One of the promising types of raw material - medicinal plant safflower (Carthamus tinctorius L). It contains vitamins A, E, unsaturated fatty acids and other biologically active substances in large quantities, that determine antimicrobial, antifungal, anti-inflammatory, antioxidant properties. Thanks to these pharmacological effects, the content of vitamins is promising for the development and introduction of a drug used in the field of ophthalmology. To this end we
have searched and analysed scientific publications about safflower – Carthamus tinctorius. All studies used in this review have been found using «Google Scholar» scientific search engine and were selected from publications indexed in Web of science, PubMed, Medline, E–library, and Cyberleninka databases. Key words: safflower, eye diseases, ophthalmopharmacology, phytopreparation.

4. Sura L. Alkhafaji, 2020, Carthamus tinctorius is an annual plant belonging to the Asteraceae family. It is known as safflower. It is cultivated in Southern Asia, North and South America. It contains many bioactive compounds for which it has the biological activities, involving antidiabetic, anticancer, antioxidant, anti-ageing, anticoagulant, hepatoprotective and anti-inflammatory, analgesic and antibacterial activities. The goal of this work is to identify the chemical constituents of safflower petals and to reveal their antimicrobial activities. The dried petals were extracted using three solvents, hexane, ethyl acetate and methanol. Safflower was studied by gas chromatography–mass spectrometry (GC–MS). A total of 78 compounds from the three extracts were defined, and it was indicated that the highest percentage in ethyl acetate extract go to 4’, 6- Dimethoxyisoflavone-7-O-βD-glucopyranoside (15.6%) and 7, 4’– dimethoxy-3-hydroxy flavone (8.17%). In methanol extract, the high percentage belongs to Ascorbic acid, per methyl- (25.16%), Papaverine (8.16%), Tetratricontane (5.99%). In contrast, Morin (14.06%) and Isolongifiol (22.67%) showed the highest concentration in hexane extract. The antibacterial activities of Carthamus tinctorius petals were evaluated against Staphylococcus aureus, Staphylococcus haemolyticus, Escherichia coli, and Pseudomonas aeruginosa by the disc diffusion method and the minimum inhibitory concentration (MIC). The results show that C. tinctorius has antimicrobial activity against all the tested bacteria with diverse degrees. The highest antibacterial activity was achieved by ethyl acetate extract against all gram-positive and gram-negative bacteria involved.

5. Dr Vinaykumar R Kadibagil, 2021, Beauty is of major concern in the present era and cosmetics plays a significant role in it. Natural and herbal cosmetics are mostly preferred nowadays due to its absence from numerous harmful chemicals. This study focuses on the varnya, vranahara and kandughna properties of drugs viz yastimadhu (Glycyrrhiza glabra), manjistha (Rubia cordifolia), and raktachandana (Pterocarpus santalinus). These drugs were used in the form of balm using ghritha and siktha (Bee wax) as a base. It is a form of sthanikchikitsa to relieve sthaniklakshana. Lip balms are formulations applied onto lips to prevent drying and protect against adverse environmental factor.

6. Beata W. Domagalska, 2010, Safflower (Carthamus tinctorius) is a plant known already in the ancient times, but nowadays rarely used in cosmetics. Safflower’s oil is still used in Asiatic countries but a natural dye, cartamin, has been replaced by cheaper synthetic dyes. In recent years studies have been conducted confirming safflower properties used in traditional Chinese and Indian medicine. Those studies confirmed anti-radical efficiency of alcohol extract of safflower flowers. Also pain relief properties of oil applied locally, used for years in pharma copuncature in Korea, were confirmed. Safflower extracts and oil are promising ingredients of skin whitening cosmetics due to the content of strong inhibitors of melanin synthesis.

7. Sheetal Verma, 2008, Nature always stands as a golden mark to exemplify the outstanding phenomena of symbiosis. In the western world, as the people are becoming aware of the potency and side effect of synthetic drugs, there is an increasing interest in the natural product remedies with a basic approach towards the nature. Throughout the history of mankind, many infectious diseases have been treated with herbas. A number of scientific investigations have highlighted the importance
and the contribution of many plant families i.e. Asteraceae, Liliaceae, Apocynaceae, Solanaceae, Caesalpinaceae, Rutaceae, Piperaceae, Sapotaceae used as medicinal plants. Medicinal plants play a vital role for the development of new drugs. The bioactive extract should be standardized on the basis of active compound. The bioactive extract should undergo safety studies. Almost, 70% modern medicines in India are derived from natural products. Medicinal plants play a demand of distant markets.

8. **Mr. Prathamesh S. Kore, 2022**, Herbal cosmetics are the beauty products, which possess desirable physiological properties like skin healing, smoothening, appearance, enhancing and conditioning properties due to the herbal ingredients. Cosmetics are safe, effective, elegant properties. Whatever may be the type of skin, these three steps acts as external care for skin to protect it from the constant effect of environment, stress and skins natural process of cell degradation decay. Natural Lip balm are used for heal cracked fingertips during winter; whenever you apply balm to your lips, cover the cracked area with a nice thick layer too, to seal in moisture and protect the area.

9. **Anuj N. Nahata, Nazma M, 2022**, Cosmeceuticals are the products of cosmetic that are biologically active ingredients that impersonates to medical or drug like benefits. The design, quality, formulation of lip balm made from natural ingredients was studied. In this study, lip balm has been made by using various ingredients like beetroot, almond oil, aloe vera, vitamin E and rose essence. Homogenous mixing method was used to produce the lip balm. The formulation of lip balm was tested by applying it on a glass slide. Various parameters such as chemical stability, pH melting point, and spreadability were carried out for the evaluation of lip balm. The pH was found to be 6.0 and the melting point was 63-65 °C. After performing stability studies at room temperature (25.0±3.0°C), refrigerated condition (4.0± 2.0°C) and oven temperature (40.0± 2.0°C), it proved that prepared lip balm was uniform in nature, was perfectly applied, without any deformation at room temperature and refrigeration. Lip balm prepared from above ingredients could be a better option for treatment of various lip issues.

10. **M.M. Karimkhani, 2016**, Antioxidant and antimicrobial activities were studied in safflower methanolic extracts of four different cultivars (IL111, Padide, Isfahan-28 and Mahali). The total phenolic and flavonoid content of the plant extracts ranged from 46.2 to 62.3 mg gallic acid equivalent/g dry extract and 7.5 to 9.6 mg catechin equivalent/g dry extract, respectively. The antioxidant capacity of methanolic extracts was assessed by reducing power assay, DPPH• (2,2-diphenyl-1- picrylhydrazyl) scavenging activity and β-carotene bleaching methods. Results showed that cultivar ‘IL111’ had the highest phenolic and flavonoid content, as well as an antioxidant activity comparable to synthetic antioxidants. In addition, the antioxidant activity of the safflower extracts was evaluated in crude soybean oil by monitoring peroxide and thiobarbituric acid values, which showed a stabilisation effect on the soybean oil in the accelerated condition at 60 °C (oven test). Medicinal plants play a vital role for the development of new drugs. The bioactive extract should be standardized on the basis of active compound. Cosmetics are safe, effective, elegant properties. Whatever may be the type of skin, these three steps acts as external care for skin to protect it from the constant effect of environment, stress and skins natural process of cell degradation decay.
MATERIAL AND METHODS:

Table 1: Ingredients used and Their suppliers:

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<th>Sr.no</th>
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<th>Suppliers</th>
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<tr>
<td>1.</td>
<td>Bees wax</td>
<td>THERMOSIL FINECHEM</td>
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<tr>
<td>2.</td>
<td>Paraffin wax</td>
<td>THERMOSIL FINECHEM</td>
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<tr>
<td>3.</td>
<td>Coconut oil</td>
<td>SHALIMAR</td>
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<td>4.</td>
<td>Tween 80</td>
<td>LOBACHEM</td>
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<tr>
<td>5.</td>
<td>Safflower extract</td>
<td>SAIPRO BIOTECH</td>
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<td>6.</td>
<td>Strawberry essence</td>
<td>KEVA</td>
</tr>
<tr>
<td>7.</td>
<td>Clove oil</td>
<td>LOBACHEM</td>
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<td>8.</td>
<td>Lemon juice</td>
<td>REAL LEMON</td>
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TABLE 2: Instrument used and their company

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DRUG AND EXCIPIENTS:

DRUG – SAFFLOWER:

Fig:1(SAFFLOWER)

Safflower is a highly branched, herbaceous, thistle-like annual plant in the family Asteraceae. It is commercially cultivated for vegetable oil extracted from the seeds and was used by the early Spanish colonies along the Rio Grande as a substitute for saffron.
TABLE 3 - TAXONOMICAL CLASSIFICATION

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<td>Kingdom of safflower</td>
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<td>2.</td>
<td>Family</td>
<td>Asteraceae</td>
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<tr>
<td>3.</td>
<td>Higher classification</td>
<td>Carthamus</td>
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<tr>
<td>4.</td>
<td>Scientific name</td>
<td>Carthamus tinctorius</td>
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<tr>
<td>5.</td>
<td>Order of neem</td>
<td>Sapindales</td>
</tr>
<tr>
<td>6.</td>
<td>Phylum of safflower</td>
<td>Asterales</td>
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TABLE 4 - BOTANICAL CLASSIFICATION

<table>
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<th>SYNONYM NAME</th>
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<tbody>
<tr>
<td>1.</td>
<td>Latin</td>
<td>Carthamus tinctorius</td>
</tr>
<tr>
<td>2.</td>
<td>Carthamus tinctorius</td>
<td>Kusumbha</td>
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<tr>
<td>3.</td>
<td>Hindi</td>
<td>kusum</td>
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<td>4.</td>
<td>Gujarati</td>
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<tr>
<td>5.</td>
<td>Tamil</td>
<td>Kusube</td>
</tr>
<tr>
<td>6.</td>
<td>French</td>
<td>carthame</td>
</tr>
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</table>

**Biological source**

Safflower (Carthamus tinctorius) is a highly branched, herbaceous, thistle-like annual plant in the family Asteraceae.

**Botanical and Morphological Characteristics:**

Safflower is a member of the Asteraceae family which constitutes approximately 22,750 genera and more than 1620 species in the order Asterales. Carthamus species may originate from Southern Asia, and are annual thistle-like plants with many spines on leaves and bracts, cultivated mainly in dry, hot climate conditions\(^{(24)}\). They can reach a height of 0.3 to 2.1 m and their axillary flowers grow in the leaf axils. Flowers are initially orange and later change into a red color. The total bloom stage may last for four weeks or more. The heads with upper leaves are up to 4 by 3 cm long. The bracts are light green and have thorny tips with a thorny appendage. The fruit is 6 to 8 cm long, obovate or pear-shaped, and bluntly wedge-shaped at the base with protruding long ribs. The species of Carthamus has a thin fusiform root and its stem is erect, simple, or branched at the top into stiffglabrous, whitish-yellow, and glossy branches. The leaves are long, rather soft, and glabrous with a thorny-serrate margin and tip. The size of the leaf varies widely from species to individual plant and usually ranges from 2.5 to 5 in width and 10 to 15 cm in length.\(^{(25)}\)

**Safflower Chemical Composition:**

Lipophilic Compounds
Fatty Acids:
Oilseeds are some of the major sources of vegetable oils used primarily for nutritional, industrial, or pharmaceutical applications, as determined by their fatty acid composition. The fatty acid composition is highly variable depending on the species of the plant and the environmental effects.\(^{26}\) Numerous studies were reported on the influence of environmental factors such as salinity reduction related to the fatty acid composition and/or the yield of essential oil.\(^{27}\) Safflower oil contains two main unsaturated fatty acids: Oleic (18:1) and linoleic acid (18:2), which compose 90% of the total fatty acids. The remaining 10% includes saturated fatty acids like palmitic (16:0) and stearic acid (18:0). Standard safflower oil contains about 6–8% palmitic acid, 2–3% stearic acid, 16–20% oleic acid, and 71–75% linoleic acid.\(^{28}\) However, in many other studies, the fatty acid composition of safflower seeds showed considerable variability.\(^{29}\)

Tocopherols:
The vitamin E (α-, β-, γ-, and δ-tocopherol) profile was identified in safflower germplasm \(^{35}\). Recently, Velasco and Fernández-Martínez reported that γ-tocopherol constitutes approximately 10% of the total tocopherols in C. tinctorius.\(^{30}\) whereas, the natural mutant of C. oxyacantha has >90% γ-tocopherol in seed, which is more than the standard high α-tocopherol content usually found in wild-type seeds. As the mutant showed introgression of C. tinctorius, simultaneous selection for high γ-tocopherol content and morphological traits produced a high γ-tocopherol safflower line, designated IASC-1.\(^{31}\)

Carotenoids:
In total, six carotenoid compounds (neoxanthin, violaxanthin, lutein, zeaxanthin, β-cryptoxanthin, and β-carotene) were identified in C. oxyacantha and C. tinctorius. β-carotene can be considered as a metabolite marker for distinguishing safflower species as the species found with a specific concentration. However, the most prevalent carotenoid compound found in safflower species is zeaxanthin, which constitutes around 37% and 58% of total carotenoids.\(^{32}\)

Phytosterols:
Ten and six sterols were identified in the seed oils of C. oxyacantha and C. tinctorius, respectively. Campestanol, 24-methylene cholesterol, gramisterol, 24-ethylcholesterol-7,24 dien-3beta-ol, cycloartenol, and 24-methylene cycloartenol are present in the C. oxyacantha species, whereas C. tinctorius contains avenasterol and 7-stigmasterol. In both species, β-sitosterol constituted the main source of phytosterols and accounted for 36.4% and 46.0% of the total amount of sterols

Flavonoids:
Flavonoids are secondary metabolites found in the several parts of plants and mainly consist of the glycosides derived from shannesol and quercetin, safflower yellow A, hydroxy safflor yellow A, red pigment, apigenin, rutin, myricetin, carthamidin, isocarthamidin, etc. Flavonoids include a number of antioxidative compounds that have significant pharmacological activity. Safflower extract including flavonoids provides a protective function in the cardiac system, improving the myocardial ischemia, reducing the region of myocardial infarction, and increasing the heart rate and oxygen supply to myocardium. The C. tinctorius extract induces adenosine diphosphate (ADP)-induced platelet aggregation and affects depolymerization of ADP in platelets. These effects can be improved by
increasing the dose of safflower flavonoids. The total flavones extracted from C. tinctorius had different hypotensive effects on the experimental animals.\(^{(33)}\)

Safflower Pharmacological Activity:

Anti-Inflammatory Effects: Several studies revealed that flower extract/compounds of hydroxysafflor yellows A and B (HSYA and HSYB) elicit various inflammatory responses, including proliferation and inflammatory responses of human fetal lung fibroblasts (MRC-5 cells), inhibition of platelet activating factor (PAF)-induced proliferation, and an asthma-related inflammatory response in human bronchial smooth muscle cells (HBSMCs). In vivo studies showed that direct administration of HSYA (50, 75, and 112.5 mg/kg) to guinea pigs enhanced the protective effect on ovalbumin (OVA)-induced asthma, playing a role in controlling the asthma. The flower extract, carthamin yellow (CY), reduced ischemia/reperfusion (I/R) injury in rats, aided by a reduced reactive oxygen species (ROS) release and inflammatory response. HSYA attenuated lipopolysaccharide (LPS)-induced neurotoxicity and neuro-inflammation in primary mesencephalic cultures. The results suggested that HSYA has protective effects in dopaminergic neurons induced by LPS, and the mechanisms may be associated with the inhibition of inflammatory responses.\(^{(34)}\)

Anti-Cancer Effects: The anti-cancer effects of HSYA were investigated in mice, where HSYA effectively blocked proliferation and migration and induced apoptosis, providing evidence as of its being an anti-cancer agent for human hepatocellular carcinoma (HCC). HSYA injected at 1.13 mg/kg in mice reduced the proportion of Tregs within the spleen and enhanced the immunity of mice, exerting an anti-cancer effect. The effect of HSYB on human breast cancer MCF-7 cells showed that HSYB arrested the MCF-7 cell cycle and induced cell apoptosis. Safflower seed extract treatments were orally administered 100 to 200 mg/kg weight in mice and the results showed that tumor growth decreased in cisplatin-treated mice.\(^{(35)}\)

Antioxidant Effects: The flower extract compound, Carthamus red, did not show any toxicity or mortality up to 2000 mg/kg doses in a rat model system; the results showed strong hepatoprotective effects and antioxidant activity in the rat model. The antioxidant and anti-adipogenic effects of seed extract (CSE) were examined and the results showed that the entire phenolic and flavonoid contents of CSE were 126.0 ± 2.4 mg gallic acid equivalent (GAE)/g and 62.2 ± 1.9 mg quercetin equivalent (QE)/g, respectively. These results indicated that CSE could be a valuable source of bioactive compounds with functional food and natural antioxidant properties. Safflower seed granular tea was orally administered to humans. The results showed strong antioxidant and potential bone protective effects in postmenopausal women without liver toxicity. In vitro and in vivo, safflower seed extract and synthetic serotonin derivative effects showed low density lipoprotein (LDL) resistance to in vitro-induced oxidation and aortic lesion development in apoE-deficient mice. Beneficial effects were observed for preventing human cardiovascular diseases.

Vascular Effects: Rats were treated with C. tinctorius (CT) extract (500 mg/kg/day) for four weeks, studying renovascular hypertension. The findings suggested that CT extract produces inhibitory effects of hemodynamic alteration and vascular remodeling in 2K-1C hypertensive rats and has potent antioxidant activity.
HSYA was injected at different doses (0, 10, 20, and 40 mg/kg) and the effects of HSYA on hypertensive ventricular remodeling was studied using the rat model of left ventricular hypertrophy, and findings included mechanism of inhibiting cell apoptosis and suppressing metalloproteinases expression.\(^{(36)}\)

**Osteoporosis Effects:** The injection of HSYA at different concentrations (0.1, 1.0, and 10.0 µM) prevented bone mineralization, osteoblasts viability, and inhibited bone resorption. In vivo, the effect of HSYA on bone formation and glucocorticoids-induced osteoporosis (GCIOP) was demonstrated using zebrafish. The effects of crude extract of safflower seed were examined on osteoblast differentiation and intracellular calcium ion concentration in MC3T3-E1 cells, showing the ability to prevent osteoporosis and protect against bone loss. The effect of safflower seed oil (SSO) on osteoporosis induced-ovariectomized rats was investigated, and the findings indicate that SSO has a potential function in improving osteoporosis. The effect of safflower seed extract (SSE) on periodontal tissue regeneration in a preclinical 1-wall model was evaluated in dogs and results showed improvement in bone\(^{(37)}\).

**Brain and Liver Disease Effects:**
The effects of safflower seed extract (100 mg kg/day) on scopolamine-induced memory impairment were tested using a mouse model. The findings suggested inhibition of cholinergic dysfunction and oxidative stress, indicating promise for memory improvement in Alzheimer’s disease (AD) patients. The mechanism of safflower yellow (SY) was evaluated in amyloid β-induced AD rats, and findings revealed that SY attenuates learning and memory deficits. In another study, SY improved cognitive function and astrocytes in an AD mouse model, the results showing that SY holds promise as a therapeutic approach for the treatment of AD. The injection of 30 µm HSYA in rat hepatic stellate cells (HSCs) showed inhibition of HSC activation and cell proliferation, indicating it is a potential candidate for the prevention and treatment of hepatic fibrogenesis. The effects of HSYA on lymphostatic encephalopathy (LE) induced brain changes in rats, supporting HSYA for the treatment of lymphostatic encephalopathy. The effects of a daily dose of HSYA (5 mg/kg) to rats subjected to biweekly carbon tetrachloride (CCl4) injections over 12 weeks significantly reduced liver fibrosis, indicating HSYA is a promising anti-fibrotic agent for chronic liver disease.\(^{(38)}\)

**USES:**
1. In Indian traditional medicine, safflower is typically used for scabies, arthritis, and mastalgia.
2. Also, this plant species finds a usual application for the treatment of amenorrhea, gastric tumors, as well as wounds, with internal or external origins among Chinese folklore.
3. This used as hair color promoters, skin patches, baldness, phlegm, and colic can be treated by using safflower based on Iranian traditional medicine for the treatment of diabetes, phlegmatic fever, melancholia, and dropsy.
4. The dried floret of *C. tinctorius* named Carthamiflos has found great popularity due to its wide use in treating coronary heart disease, angina pectoris, gynecologic disease, stroke, and hypertension.
EXCIPIENTS

Table 5 – excipients used and their physical properties

<table>
<thead>
<tr>
<th>Sr.no</th>
<th>Excipients</th>
<th>Boiling point</th>
<th>Melting point</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Bees wax</td>
<td>61-65 °C</td>
<td>62 to 64 °C</td>
<td>Thickeners</td>
</tr>
<tr>
<td>2.</td>
<td>Paraffin wax</td>
<td>37 °C</td>
<td>46 to 68 °C</td>
<td>Skin-softening</td>
</tr>
<tr>
<td>3.</td>
<td>Coconut oil</td>
<td>21-25 °C</td>
<td>24°C</td>
<td>Providing moisture</td>
</tr>
<tr>
<td>4.</td>
<td>Safflower extract</td>
<td>-</td>
<td>17°C</td>
<td>Moisturizer</td>
</tr>
<tr>
<td>5.</td>
<td>Tween 80</td>
<td>&gt;160 °C</td>
<td>-</td>
<td>Surfactant emulsifier</td>
</tr>
<tr>
<td>6.</td>
<td>Clove oil</td>
<td>251°C</td>
<td>251°C</td>
<td>Mild skin-irritating qualities</td>
</tr>
<tr>
<td>7.</td>
<td>Lemon juice</td>
<td>10 °C</td>
<td>-</td>
<td>Anti-oxidant property</td>
</tr>
</tbody>
</table>

EXPERIMENTAL WORK:

Collection of plant materials –
The plant material like leaves of species such as Carthamus tinctorius are collected from our locality. Leaves of safflower dried about a period of one week to remove moisture, dried in sun shade for one week. Then the dried leaves are crushed by using mortal pestal and it is finely grinded.

Extraction of plants –
The soxhlet extraction, as the reference method, was performed as follows: 15 g safflower powder was weighed and embedded in a thimble and put in the Soxhlet apparatus which was gradually filled with ether as the extraction solvent. The extraction experiment was carried out at 60°C within 8 hours. Upon completion of the extraction

Formulation of herbal lip balm: Table 6

<table>
<thead>
<tr>
<th>Sr.no</th>
<th>Ingredients</th>
<th>Quantity for Formulation 1 (F1)</th>
<th>Quantity for Formulation 2 (F2)</th>
<th>Quantity for Formulation 3 (F3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Bees wax</td>
<td>4g</td>
<td>3.5g</td>
<td>3g</td>
</tr>
<tr>
<td>2.</td>
<td>Paraffin wax</td>
<td>4g</td>
<td>3.5g</td>
<td>3g</td>
</tr>
<tr>
<td>3.</td>
<td>Coconut oil</td>
<td>7ml</td>
<td>7ml</td>
<td>7ml</td>
</tr>
<tr>
<td>4.</td>
<td>Lemon juice</td>
<td>1ml</td>
<td>1ml</td>
<td>1ml</td>
</tr>
<tr>
<td>5.</td>
<td>Tween 80</td>
<td>2ml</td>
<td>2ml</td>
<td>2ml</td>
</tr>
<tr>
<td>6.</td>
<td>Safflower extract</td>
<td>5.66 ml</td>
<td>5.66ml</td>
<td>5.66ml</td>
</tr>
<tr>
<td>7.</td>
<td>Strawberry essence</td>
<td>2 drops</td>
<td>2drops</td>
<td>2drops</td>
</tr>
<tr>
<td>8.</td>
<td>Clove oil</td>
<td>2 drops</td>
<td>2 drops</td>
<td>2 drops</td>
</tr>
</tbody>
</table>

Formulation batches for preparation of herbal lip balm

Herbal lip balm is prepared by using the following steps –
The herbal lip balm was formulated as per general method of formulation

Step 1
Bees wax and paraffin wax were melted in porcelain dish on water bath with the decreasing order of melting point
Step 2
Coconut oil with tween 80 were heated in porcelain dish then both the phases were mixed in the same temperature

Step 3
Fresh lemon juice and safflower extract were heated together in porcelain dish (just before mixing)
All the contents were mixed at 40°C with the essential oils and essence are added drop wise with continuous stirring. The mixture was transferred from water bath to ice – bath was allowed to solidify and then taken out of the ice -bath for further homogenization in mortar – pestle to get the desired texture. The homogenized herbal lip balm was kept in mold and kept under refrigeration condition.

Evaluation of herbal lip balm:
To achieve uniform standard of formulated herbal lip balm it is important to carry out its evaluations therefore, formulated herbal lip balm was evaluated through various parameter like melting point, spreadability test, perfume stability, etc.

1. Melting point:
Melting point determination of formulated herbal lip balm is important as it is an indication of the limit of safe storage and was determined by capillary tube method. In which the capillary was filled with formulated lip balm that was sealed at one end, then filled with lip balm and tied to a calibrated thermometer. The capillary along with thermometer was dipped in paraffin wax and was heated where temperature on the thermometer was noted when the lip balm in the capillary melted. Melting point of lip balm was found to be in the range of 66 - 68 °C, The procedure was repeated 3 times and the melting point was determined by taking the average of readings.

2. Spreadability Test:
The test of spreadability is carried out by applying the product at room temperature repeatedly on the glass slide to visually observe the uniformity in the formation of the protective layer and it is observed that whether the stick fragmented, broke or deformed during the application. For this test following criteria were established by analyst:
G - Good: uniform, perfect application, no fragmentation, without deformation of lip balm.
I – Intermediate: uniform, leaves few fragmentation, appropriate application, few deformation of lip balm.
B - Not uniform, leaves many fragments, inappropriate application, intense deformation of the lip balm

3. Surface Anomalies: This was studied for surface defects on formulated lip balm such as no formation of crystals no contamination by molds, fungi, etc.

4. Aging Stability: The stability of product was evaluated by storing at 40°C for 1 hr. Then various parameters such as bleeding, crystallization of on surface and ease of application were observed.

5. Solubility Test: The solubility of formulated herbal lip balm was estimated by dissolving in various organic solvent like ethanol, chloroform, etc.

6. pH parameter: The pH of the lip balm was determined to investigate the possibility of any side effects. As an acidic or alkaline pH may cause irritation to lips, it was determined to keep the pH of the formulation as close to neutral as possible. The pH measurement was studied by dissolving 1gm of sample into 100ml of water. The pH measurement was done by using pH meter.
7. **Skin Irritation Test**: It is carried out by applying small amount of formulated product on the dorsal surface of left-hand skin for 10.

**Result and discussion**:

<table>
<thead>
<tr>
<th>Sr .no</th>
<th>Evaluation parameter</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Colour</td>
<td>Pale Pink</td>
<td>Pale Pink</td>
<td>Pale pink</td>
</tr>
<tr>
<td>2</td>
<td>Melting point</td>
<td>66°C</td>
<td>66°C</td>
<td>67°C</td>
</tr>
<tr>
<td>3</td>
<td>Spreadability (qualitative)</td>
<td>G</td>
<td>G</td>
<td>G</td>
</tr>
<tr>
<td>4</td>
<td>Surface anomalies</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>Aging stability</td>
<td>Smooth &amp; Pale Pink</td>
<td>Smooth &amp; Pale Pink</td>
<td>Smooth &amp; Pale pink</td>
</tr>
<tr>
<td>6</td>
<td>Solubility</td>
<td>Chloroform</td>
<td>Chloroform</td>
<td>Chloroform</td>
</tr>
<tr>
<td>7</td>
<td>pH</td>
<td>7.1</td>
<td>7.1</td>
<td>7.0</td>
</tr>
<tr>
<td>8</td>
<td>Skin irritation test</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>Consistency</td>
<td>Smooth and Non - Granulated</td>
<td>Smooth and Non - Granulated</td>
<td>Smooth and Non - Granulated</td>
</tr>
</tbody>
</table>

**Discussion**:

Prepared lip balm formulations were evaluated for organoleptic characteristics, melting point, spreadability, pH, stability studies. It shows melting point in the range of 66°C, which matches the ideal melting point. The test of spreadability was found to be G- Good: uniform, does not leave fragments, perfect application, without any deformation of lip balm initially at room temperature. pH of lip balm was found near to neutral i.e 7.2 this would not cause irritation to lips. From the evaluation table it is confirm that the formulation 3 passes the all tests. Like colour, PH, consistancy, Solublity, skin irritation, spreadablity, and melting point show accurate results.

**CONCLUSION**:

The present work carried out the formulation and evaluation of herbal lipbalms was aimed to formulate a lip balm using herbal ingredients with an idea to minimize the side effects which occur by using available chemical based synthetic lip balms. The prepared formulation of lip balm was evaluated and it was found that the herbal lipbalm, based on the consistancy, Formulation-3 was best among the two formulations. Therefore, from present investigation it was concluded that this formulated herbal lip balm provides a better option for anyone applying lip balm with minimal side effects and also have antioxidant properties which help for better health benefits. The further studies can be carried out on the basis of present study of formulation and evaluation of herbal lipbalm using safflower extract are as follow:

- As melting point - 67°C
- Spreadability of lipbalm is G
- PH OF LIPBALM – 7.0
The formulated lip balm shows no redness, edema, irritation and inflammation during studies.

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