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Pharmaceutics

FORMULATION AND EVALUATION OF ORGANIC HERBAL LIPBALM

Ms. Mansi Sharma — Research Scholar, BPharm, Amity Institute of Pharmacy, Amity University, Noida, , India

Dr. Shikha Baghel Chauhan* — Assistant Professor, Department of Pharmaceutical Sciences, Amity University, Noida, India*Corresponding Author

ABSTRACT **Objective:** The current investigation involves preparing a lip balm with verified organic ingredients without exploiting the animal. Introduction: Natural cosmetics and organics self-care products have developed as a result of increased worldwide demand for environmental friendly products made from natural sources. The formulation of synthetic lip care items include heavy metals, chemicals and preservatives. Due to the harmful effects of the heavy metals on the lips, they can mistakenly enter the body via leaking through the pores of the lips. **Subject matter:** This project examines the natural components used in natural lip balm, as well as their benefits and drawbacks as the prepared organic lip balm is 100% vegan product. In order to prepare lip balms, the concentration of the primary ingredients, such as the base, oils, extracts, colours, and flavourings must be balanced and should be evaluated for their resistance to temperature changes, pleasant taste, smoothness during application, adherence, and ease of purposeful removal, among other qualities. Antioxidants found in beetroot & carrot extract are abundant, which improve skin suppleness and soften and hydrate lips. **Evaluation:** During the evaluation of prepared formulation that included stability tests, melting point estimation, evaluation of organoleptic properties and functionality assessment ,it was concluded that the product has the following qualities: resistance to temperature changes, palatable taste, smoothness during application, adherence, and simplicity of purposeful removal.

KEYWORDS : Lip balm, moisturize, odour, appearance, self-care, organoleptic properties.

INTRODUCTION:

Lip balm, also known as lip salve, is a wax-like substance that is applied directly to the lips to treat conditions such as angular cheilitis, stomatitis, and cold sores. Beeswax, camphor, cetyl alcohol, lanolin, paraffin, and petrolatum are among the substances that are frequently found in lip balm. Some variants include phenol, salicylic acid, sunscreen, flavouring, and colours.(Mayuri et al., 2015)

The utilisation of organic sources has drawn much public attention because cosmetics can contain dangerous synthetic excipients.(Christoplus et al.,2018) Due to the lack of oil glands on the lips, it is crucialto continuously apply for moisture and protection(B. H. Ali et al.,2005). Petrolatum, synthesised waxes, alumina, parabens, hydrogenated oils, and harmful chemical scents and colours are frequently included in conventional lip balm. Since lip balm is frequently used by the user, it poses a serious problem for health authorities.(M. S. Balsam et al.,2008)

Cosmetic compounds with medical advantages for topical action and protection against deteriorating skin conditions are known as cosmeceuticals(Dario MF et al.,2013). These substances with fewer adverse effects were used in the current study.Lip balms are well-known products that hydrate lips rather than adorn them. They produce an oily layer that adheres and is moisture resistant. typically devoid of colour.(Kadu M et al.,2015)

Almond oil's fatty acids aid to hydrate the lips as they deeply permeate the skin tissue. Almond oil's anti-inflammatory qualities help to lessen the pain and redness of chapped andsunburned lips.(P.L. Kole et al.,2005) To combat inflammation, aloe vera possesses anti-inflammatory effects. Antioxidants that combat wrinkles and other skin damage are infused into the lips.

ANATOMY OF LIPS:

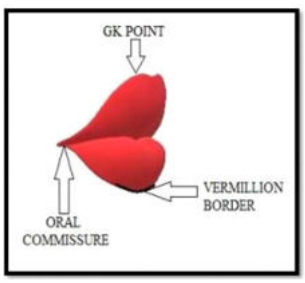

FIG.1: ANATOMY OF LIPS

Antioxidants found in abundance in beetroot help to increase skin elasticity and make lips soft and supple. Rose provides a natural hue and aids in curing dry lips. Rose can also beused to brighten lips by removing pigmentation and dead cells.(Kolkate et al.,2014)

The lips function as speech, suction, and prehension organs. It is made up of the muscles placed surrounding it, the superficial fascia, the skin, and the orbicularis muscle (areolar tissue & mucous membrane). Lip margins are covered in dry, red mucosal surfaces that are constantly with the skin and constant with the skin and are rich in touch corpuscles and vascular papillae. The superior and inferior folds of the mucous membrane are formed by the median line, which is internally reflected from the upper and lower lip onto the gums. The coronary arteries that completely surround the buccal orifice close to the free line of the lips are found in the areolar or sub-mucous layer. The superior and lower coronary arteries, which emerge from the face region, are the coronary vessels.(A.N. Nagappa et al.,2005)

A little artery called the septum arteria septinasi emerges from the superior coronary, which is bigger than the inferior and anastomoses with its partner on the other side. Nasal bleeding can sometimes be controlled by compressing this artery.The superior labial vein, also known as the coronary vein, starts like a plexus in the upper lip's orbicular muscle, travels alongside the coronary artery, and empties further into the facial vein just below the lower lip's veins that drain the alae of the nose. The major branch out from the lower lip typically descends to the submental vein, then to the facial or frequently to the anterior jugular. The inferiorcoronary dumps into the facial just below the superior labial. The mental, which protrudes from the bone thru the mental foramen & sends big twigs towards the mucus layer, the integument, as well as the fascia of said lip and chin, is where the nerves feeding the lower lip originate.(B.H. Ali et al.,2005)

Several of the lymphatic veins in the lips travel to a gland that is located right above the hyoid bone's body, while other lymphatic vessels go to the submaxillary glands. In the submucous layer of the lips, close to the mouth's entrance, are the labial glands. They expel a mucus substance. Cysts of mucous retention form whenever the ducts of such glands are blocked.(N.A.Wabel et al.,2005)

LIP-RELATED ILLNESSES AND DISORDERS:

1. Swelling: Lip swelling due to an allergic response is possible. Sensitivity to particular foods or drinks, medications, cosmetics, or airborne allergens may be to blame for the reaction

2. Sun damage: The lips, particularly the lower lip, may become dry and hard from sun exposure. Damage that raises the risk of later cancer is indicated by red flecks or a white filmy appearance.

3. Inflammation: The borders of the mouth could become uncomfortable, inflamed, red, cracked, & scalyas a result oflip inflammation (cheilitis).

4. Discoloration: Freckles & irregularly shaped brownish patches (called melanotic macules) are frequent and can stay for many years around the lips.

5. Sores: A lip sore or elevated region with sharp edges may be a sign of skin cancer. Various sores might appear as signs of other illnesses, like syphilis or an infection with the oral herpes simplex virus.(M.G. Denavarre et al.,2014)

ADVANTAGES AND DISADVANTAGES OF ORGANIC LIP BALMS:

Advantages:

1. Lip balms aid in preserving the lips'inherent health and beauty.
2. Sunblock lip balms have been shown to shield the lips from the damaging effects of UV light.
3. Both males and females could use them because they are not gender-specific products.
4. Lip balms work to protect lips fromchapping, dryness, and cold sores.

Disadvantages:

1. Lip balms prepared with inferior components might badly damage the lips. Such lip balms might not moisturise lips; they might even drythem out.
2. Lip balm habit is yet anotherdrawback associated with their use.
3. Homemade lip balms have a shorteraverage duration on the lips than lipbalms created in a factory. Consequently, you must frequentlyreapply.
4. Natural oils also suffer from other drawbacks such being stickier, comedogenic, and less spreadable.(R.G. Harry et al.,1973)

INGREDIENTS USED IN ORGANIC LIP BALM:

1. FLAVOURING AGENT:

It is frequently necessary to use flavours or flavouring chemicals to mask the four basic tastes. Taste, texture, smell, sight, and sound are all a part of the multisensory experience of flavours, which is influenced by a variety of physiological and physiochemical processes.

No irritating or dangerous substances should be present in lip balm tastes. These should taste good and just be able to mask the oily smell of the base. To mask the smells of such fatty or wax substrate and to add a palatable flavour, flavouring agents are required. They typically make up 2-4 % of the finished product when used. The lip balm's flavour needs to be consistent and complement the other elements. Another option is to use a food item.Common tastes include apricots, strawberries, cherries, nectar, and others.(P. P. Sharma et al.,2008)

2. COLORING AGENT:

Colorants or colouring agents are mostly employed to give cosmetic items a distinctive look. Since ancient times, colour has been a component of cosmetics. Basically, the three senses of sight, touch, and scent are used to regulate the impulse to purchase a cosmetic product. Shadeation is therefore a crucial component of beauty formulas.

Soluble dyes are used to satisfy the first condition, and insoluble colorants and pigments that increase or decrease the film's opaqueness satisfy the second. Both are included in contemporary lip balms to create a blended look. The licensed dyes list under the Medicine and Cosmetics Act must be used for the colors. The colors that are present in nature. The herbal colourant used must be safe and have no physiological activity. It must have a precise chemical composition since only then will its colouring electricity be trustworthy and its assay will be more doable and straightforward (B.M. Mittal et al.,2000).

3. OILS:

The physical forms of oils and fats vary; typically, they are solid at normal temperatures. Chemically, oils and fats—also known as triglycerides—are glycerol esters made of fatty acids and glycerol. Acids. The stability and characteristics of the oil are influenced by the fatty acids, which may be saturated or unsaturated. Coconut oil, cottonseed oil, and palm oil are among the oils with a high content of saturated acids (lauric, myristic, palmitic, and stearic acids). A formulation that makes it easy for the product to distribute and creates a thin coating with strong covering strength is excellent. Olive oil or sunflower oil will both give lips a beautiful shine. Because of its beneficial properties, castor oil is still included in many lip balms today, but certain other oils including solvents may also be present. Castor oil that has been refined has a pleasing colour and is flavourless and odourless. A very effective plasticizing agent is castor oil. Although castor oil is less susceptible to rancidification than other vegetable oils like olive oil or almond oil, it should nevertheless be given an antioxidant to prevent it. Because of its skin- softening qualities, jojoba oil can help keep lips from drying out. Although wolfberry seed oil is very well known for its ability to moisturise and condition theskin. Rosehip oil is quite effective at preserving the skin's normal moisture balance. A well-known antioxidant called vitamin E is crucial to the lip balm basis. The skin is energised and revived with peppermint essential oil. An excellent antioxidant is cinnamon essential oil. For skin, lavender essential oil is calming and nourishing. For dry lips, grapefruit essential oil is a light and revitalising option..(M.S. Balsam et al.,2015)

4. BASES:

Candelilla wax is employed as just an occlusive agent and hardening agent, it forms a barrier that holds water in place and prevents it from evaporating. The wax is made up of 12%-14% alcohol and sterol, 49%-50%hydrocarbon, 7%-9% free fatty acids, 2%-3% humidity, & 1% minerals. It also contains 20%-29% wax ester. Based on the age of the candelilla tree and the year that the wax was collected, the chemical and physical properties of the wax may change. While wax cannot be dissolved in water, it may be in organic solvents including acetone, chloroform, and benzene.

COMPOSITION OF LIP BALM:

Table No.1: Ingredients used in Organic lip balm

S.No.	INGREDIENTS	QUANTITY	USES
1.	Shea butter	6 ml	Base
2.	Essential oil	2-3 drops	Fragnance
3.	Water	¼ cup	Blending
4.	Vitamin E	1 capsule	Antioxidant
5.	Beetroot & carrot extract	3 ml	pigmentation

PREPARATION OF BEETROOT AND CARROT EXTRACT:

1. Under flowing water, scrub the carrot and beet and then pat them dry.
2. Carrot and beetroot are peeled and chopped into tiny pieces. There is no need to peel vegetables if they are organic.
3. Fill the container of a blender with 1/4 cup of water.
4. Add the carrot and the beetroot.
5. Till smooth, blend in the machine.
6. Pour prepared mixture into a big bowl, then place a fine mesh sieve over it. To strain the liquid, you can also use a cheesecloth or a nut-milk bag.
7. To extract the most liquid possible from the mixture, press it with a spatula. Throw away the remains.
8. The beetroot and carrot extract is ready.

METHOD OF LIP BALM PREPARATION:

1. On a weigh balance, the raw materials are precisely weighed.
2. The preparation method comprised utilizing a water bath to heat the solid raw ingredients while they were being observed until full melting and a homogeneousmixture was formed at the highest temperature.
3. Shea butter / coconut oil in the amount of 5 ml was added to a china dish, which was then put on a hot water bath.

ALTERNATIVE MTHOD: With a double boiler, it consists of a heat-safe bowl set atop a saucepan with boiling water, the item can also be put. Keep the bowl's bottom away from the boiling water. Then, gradually heat the oil / butter the oil/butter more gradually in a double boiler to prevent burning.

Since shea butter contains vitamin E, it is a better all-purpose moisturizer. Coconut oil is indeed hydrating, though.

4. The lowest setting was used to warm the shea butter because shea butter burns readily in such small amounts.

As the burner was turned to the lowest possible setting, the formation of a bubble was prevented.

After the shea butter/coconut oil melted, the temperature was sufficient.

5. Vitamin E extract was also added, along with beetroot or carrot juice extract.

6. There were 4-5 drops of essential oil added. The shea butter is removed from the heat and allowed to cool for a few minutes. The essential oils were then thoroughly mixed by being swirled.It includes rose and lavender oil.

7. The lip balm was next put into a jar to chill and kept at ambienttemperature for a while.(Mona Patel et al.,2021)

EVALUATION TESTS FOR LIP BALM:

1. Preliminary stability analysis:

The created formulation was tested for preliminary stability over not less than three days at ambient temperature (22.0 ± 3.0 °C) and oven temperature (40.0 ± 2.0 °C), as well as organoleptic properties (color, odor, and appearance). The oven condition was selected as the study's greatest temperature since this type ofaesthetic shape softens and deforms at temperatures higher than 50°C.This formulation was submitted for the Normal Stability Study since it showed no signs of organoleptic or spreadability alterations.

2. Normal stability analysis:

Lipstick's stability test typically starts 24 or 48 hrs after preparation since that amount of time has been shown in the literature to be sufficient for stabilizing the formulation.

3. The melting point:

The substance is made molten enough to fill capillaries in order to ascertain themelting point (duplicate). The capillaries were connected to a thermometer- equipped device and submerged in a vial of water that was kept at a set temperature. The melting point was defined as the temperature at which the lip balm sample started to melt.

4. Organoleptic characteristics:

The evaluator compared the odor while using a 10x loupe to visually describe color and appearance. Samples were tested in duplicate during the allotted period for each condition & compared against such a freshly made formulation at t0 in order to ascertain the organoleptic features according to the criteria laid out.

5. Spreadability test:

The spreadability test involved repeatedly applying the product to a glass slide at room temperature (22.0 ± 3.0) °C in order to visually assess the uniformity of the protective layer's creation and determine if the stick is fragmented, distorted, or split during application.(Golyea et al.,2007)

RESULTS:

1. STABILITY STUDIES:

The primary goal of a stability study is to provide proof of how the amount of a drug or drug product changes over time under the impact of various environmental factors, including temperature, light, and humidity. For not less than 3 days, stability tests were conducted at room temperature (22 ± 3)°C.

The prepared formulation was found to display at room temperature (22±3) 0C Shows G- Good: flawless application, uniformity, no fragmentation, and no lip balmdistortion.

2. NORMAL STABLITY ANALYSIS:

a. PH: Lip balm's pH, which is close to normal (7.2), ensures that lips won't become irritated.
b. COLOR: No change in color.
c. ODOUR: No change in odour.

3. MELTING POINT:

Melting point of lip balm was found to be in the range of 65°C.

ORGANOLEPTIC CHARACTERISTICS:

Prepared lip balm has shown dark pink tinted color.

Fig.2:Organoleptic characteristics analysis

All results are presented below:The parameters and observations were as follows-

- Color: Dark pink tinted color
- Odour: Pleasant
- Appearance: Excellent, smooth

5. SPREADABILITY TEST:

The spreadability of the prepared lip balm was tested, and the results originally indicated G - uniform, no splitting perfect application, without any distortion at ambient temperature as stated.

CONCLUSION:

During the stability experiments, the formulation kept in the refrigerator and at room temperature behaved similarly. Additionally steady were the organoleptic properties, and spreadability received a "Good" rating. Storage under these circumstances was taken into account, and since the product's functionality is kept, it is determined to be adequate. The prepared formulation of lip balm exhibits improved stability and a range in melting point (mean up to 680C). Spreadability test findings for the developed formulation indicated that storage in an oven (400C) was not advised due to product functionality loss seen during the standard stability test. It was determined that using a herbal lip balm could be a better choice for treating a variety of lip problems.

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