

An overview on: Cosmetic Science and Prepration and Evalution of Lip Balm

Nimbalkar Shivrudra Janardhan *,Proof Deokar Rani M, Dr.Megha Salve T.

*Department of Bachelor of Pharmacy
Shivajirao Pawar College of Pharmacy Pachegaon
Dist – Ahmednagar, Maharashtra 422602*

Submitted: 20-11-2023

Accepted: 30-11-2023

ABSTRACT:

Daily lip care products contain heavy metals and harmful preservatives. Not only are these heavy metals and other chemicals excreted through the pores of the lips, but they can also be accidentally absorbed. Lead damages the heart and brain, cadmium and chromium can cause cancer, preservatives can cause breast cancer. Lip balms are preparations applied to the lips that prevent dehydration and protect against the harmful effects of environmental factors.

Organic lip balm nourishes the lips and helps moisturize them and protect the affected lips from cracking and dryness.They help protect the natural health and beauty of your lips. Lip balms are not gender-specific products and can be used by both men and women. In this study, many organic products such as ghee and honey can help keep lips moisturized and healthy. The lip balm produced was evaluated for its organoleptic properties, lubricity, pH measurement and stability. After carrying out the stability tests at room temperature (22.0°C) in the refrigerator (4°C) and at oven temperature (40.0°C) for 2 days.

Key words : Organic, lip Balm, lips, stability, Spreadability, Deformation.

I. INTRODUCTION :

cosmetics are constituted from a mixture of chemical compounds derived from either natural sources or synthetically created ones.

Products intended for personal hygiene and skin care can be used to cleanse or protect the body or skin. Cosmetic products to enhance appearance (makeup) can be used to conceal imperfections, enhance natural features (e.g. eyebrows and eyelashes), They add color to a person's face and can be used to completely change the appearance of a face so that it resembles another person, creature, or object. cosmetics can also be designed to perfume your body. Cosmetics are very trendy and are

considered essential products. The role of cosmetics in everyday life was increasingly recognized after the Second World War. Social and medical scientists have recognized that cosmetics are not only popular, but also have a psychological effect on those who use them, and especially on the skin.They maintain the elasticity of the skin and delay the formation of wrinkles.

They also work against skin infections and prevent sunburn. Cosmetics have been used for thousands of years, the ancient Egyptians and Sumerians used them. In Europe, the use of cosmetics continued into the Middle Ages, when the face was whitened and the cheeks painted, although attitudes towards cosmetics have changed over the centuries and the use of cosmetics was openly frowned upon in many periods of Western history. Despite changes in society's approach to cosmetics, many people have achieved their aesthetic ideals through the use of cosmetic products.According to a source, the first major developments in the cosmetics sector include:

Khol was used by the ancient Egyptians Castor oil was also used as a protective balm in ancient Egypt Skin creams based on beeswax and rose water described by the Romans Vaseline and lanolin in the 19th century.

The word "cosmetics" comes from the Greek word "kosmetikos," which means "to decorate." Since then, any material that is used to beautify or improve appearance is called cosmetic. The desire to decorate one's body and be beautiful has accompanied humanity since tribal times. Men and women used to be equal competitors in improving their appearance.Men decorated themselves with animal parts, plant leaves, etc., while women also wore colored stones or flowers around their necks and wrists. Colored earths were then used on the face and body and then colored ointments. Making bracelets and necklaces. At the dawn of civilization, scorched

earth and various types of shells obtained from nature were also widespread. There is a lot of light during excavations of ancient Egyptian tombs stumbled upon ancient beauty practices.

In general, cosmetics are external preparations that are intended for use on external parts of the body. That means they can be used on skin, hair and nails to cover, color, soften, cleanse, nourish, curl, fix, soften, preserve, remove and protect. Cosmetics can be divided into 41 main groups, namely

- (1) skin cosmetics
- (2) hair cosmetics
- (3) nail cosmetics.
- (4) Cosmetic hygiene products (dental, bath, etc.)

Cosmetic products for the skin:

The skin restores a huge body surface area and cosmetic products are applied to designated areas, the face being the most important. Skin care cosmetics come in solid, semi-solid and liquid forms. Solid substances consist of powders with different degrees of flow and different angles of repose or compaction. Semisolids can be emulsions or simple mixtures, while liquids are either single-phase or two-phase.

Drugs And Cosmetics Act, 1940:

The Drugs and Cosmetics Act, 1940 is an Act of the Indian Parliament that regulates the import, manufacture and distribution of medicines in India. The main objective of this Act is to ensure that drugs and cosmetics sold in India are safe and effective and conform to the quality standards of the State.] The Drugs and Cosmetics Rules, 1945 contain provisions for classification of drugs according to prescribed schemes and they are not guidelines. for storage, sales, dispensing and

recipes of each program. This law was originally called the Narcotics Act and was passed in 1940. The original Law was drafted in accordance with the recommendations of the Chopra Committee, established in 1930. The drug laws were passed in 1945. Since 1940, the Act has undergone several amendments and is now known as the Drugs and Cosmetics Act, of 1940.

The term “drug” within the meaning of the law covers a wide range of substances, diagnostic devices and medical devices. The law defines a “cosmetic” as any product intended to be applied to the human body for beautifying or cleansing purposes. However, the definition does not include soaps. In 1964, the law was amended to include Ayurvedic and Unani medicines. Article 16 of the law defines quality standards for medicines.

Article 17 defines the term “false branding”. A drug is considered “misbranded” if it claims to have greater therapeutic value than it actually has. The manufacturer of such a medicinal product may be required to stop producing the medicinal product in accordance with Article 18. Article 27 deals with counterfeit and adulterated medicines. The law requires that the label must contain additional information about the composition of the drug. Section 22 defines the powers of drug inspectors and Section 23 sets out a strict procedure that inspectors must follow in every search.

Study of Schedules :

Appendix G: Most of these medications are hormonal medications. The drug label must contain text. “Warning: Taking this preparation is dangerous unless under medical supervision.” Examples: testolactone etc.

Appendix H: The wording “Rx” must appear on the drug label; in the upper left corner of the label and “Schedule H Drug.” Note: Retail sales only upon prescription from a licensed physician. clearly. It can only be delivered to approved companies. It is not available without a prescription and may only be sold in the quantity specified on the prescription. Please note the time and date of your prescription. Examples: androgenic, anabolic, estrogenic etc.

Appendix M: It is defined as “that part of quality assurance aimed at ensuring that the product is manufactured consistently while maintaining quality consistent with the intended use.

Appendix N: Describes the facilities and equipment that enable the efficient operation of a pharmacy.

Appendix P: Describes the shelf life of a drug in months (unless otherwise stated) from the date of manufacture to the expiry date, not exceeding the duration of action stated on the drug label under certain storage conditions.

Appendix T: Contains various regulations and requirements for the manufacture of Ayurveda, Siddha and Unani products.

Appendix U: describes the details that must be presented in the manufacturing documentation, raw material and analytical drug registers.

Appendix V: describes standards for patented or proprietary medicines. Patented or special medicines containing vitamins with a preventive effect, For therapeutic or pediatric purposes, they may contain vitamins in quantities neither less nor greater than those expected in one or two divided daily doses.

Appendix Y: Describes the requirements and guidelines for clinical trials for the importation and manufacture of new drugs.

\

Manufacturing of cosmetics science :

To start producing cosmetics, a license is currently required, which can be obtained from the licensing authority. Licenses are granted upon payment of required fees and compliance with other specified conditions. In principle, the rules that apply to licenses for the production of allopathic medicines also apply to these licenses. It is prohibited to produce cosmetics containing hexachlorophene or mercury compounds, mislabeled or counterfeit cosmetics, or cosmetics that do not meet quality standards.

A person authorized to manufacture cosmetics must comply with the following conditions:

(i) The factory premises must be maintained, clean, located in a hygienic environment and separated and separated from the premises used for residential purposes.

(ii) Adequate space and staff must be provided and production must be carried out under the personal direction and supervision of competent technical staff, at least one of whom must be a full-time employee and hold a recognized pharmacy qualification from the pharmacy. You have passed or passed an intermediate examination in one of the subjects of chemistry. However, they no longer hire employees from small producers. If there are more than 5 people, a person with general education and at least 4 years of experience in cosmetics production can be recognized by the licensing authority as a qualified specialist.

(iii) Adequate facilities for testing raw materials and manufactured products must be provided on site or appropriate arrangements must be made with approved institutes for the purpose. Records of these tests must be retained for at least 3 years from the date of manufacture.

Store and sale of cosmetic science :

Wholesale, retail and restricted sales licenses

1. Wholesale: From seller to store owner.
2. Retail: from the seller (pharmacy, parapharmacy, drugstore or parapharmacy) to the patient. The Drug Control Organization issues two types of licenses, one of which is the Retail Drug License (RDL) to operate a pharmacy and is only given to those who have a Pharmacy Diploma from a recognized university to pay fees and the other is the Wholesale Drug License (WDL), which is issued to a person who carries on a business

related to the wholesale sale of medicines. License conditions for total sale:

1. Area: Not less than 10 m².
2. Storage: It is necessary to have a refrigerator and air conditioning in the premises as some medicines such as vaccines, insulin injections, etc. must be stored in the refrigerator.
3. Competent Personnel: The sale can be made either by a registered pharmacist or by any other competent person who must be qualified and have one year of experience in the field of medicines, or in the presence of a person who is the S.S.L. has passed. C with four years of experience in the drug field, specially approved by the Drug Control Department.
4. The permit must be posted in a clearly visible place.
5. Medicines are purchased from a licensed seller or manufacturer.
6. Medicines are delivered by bill of exchange. Carbon copies are retained for a period of 3 years from the date of the last recording.
7. Maintains purchasing records and displays all logs and records during inspections. Records must be retained for a period of 2 years from the last registration.
8. The control booklet is kept on form 35.
9. Medicines past their expiry date, health samples and medicines intended for state supply are not stored or sold.
10. Plan deliveries

Documentation :

Documents required to obtain a drug approval:

1. Application form.
2. Cover letter stating the name and designation of the applicant.
3. A copy of the application you receive by submitting the drug registration fee.
4. Declaration in accordance with the prescribed methods.
5. Kite plan and floor plan of the rooms.
6. Ownership of the premises.
7. For rental properties: proof of ownership.
8. A document relating to the formation of a company, such as a B. Memorandum of Association/MOA (Memorandum of Company)/AOA (Memorandum of Association)/Memorandum of Association.
9. Declaration regarding the failure to condemn the managing director/partner/owner.

10. Certificate from a member of the Register of Pharmacists or a qualified person and letter of appointment if an employee.

Types of Drug Licenses:

Considering the definition of “drugs”, the pharmaceutical industry in India requires the following types of licenses:

Manufacturing License – A license issued to a company that manufactures drugs, including allopathic medicines/homeopathic medicines.

Sales License – License for the sale of medicines. It contains the following subdivisions: - Drug wholesale license - Drug retail license

Wholesale license - A drug wholesaler must obtain a wholesale license. Wholesaling is the sale of a medicine to a person/seller for resale. **Retail License**

– A retail license is required for the retail sale of drugs. Retail refers to the sale of pharmaceuticals or cosmetic products intended for consumption by the end consumer. Retailers can sell it to a clinic, hospital, educational, medical or research institution. Retailers of medicines, cosmetics, independent pharmacists, Ayurveda shops etc. need this license. **Loan License** – License issued to a company that does not own the production facility but uses the production facilities of another licensee.

Import License – License for the import of medicinal products.

Multidrug License – A license issued to companies with pharmacies in multiple states under the same name.

CGMP as per regulatory authorities :

The FDA ensures the quality of pharmaceutical products by closely monitoring drug manufacturers. Compliance with current Good Manufacturing Practices (CGMP) regulations. The CGMP drug regulations contain minimum requirements for methods, facilities and controls used in the manufacture, processing and packaging of a drug product. Regulations ensure that the product is safe to use and contains the ingredients and strengths it claims to contain.

The approval process for new and generic drug applications includes a review of the manufacturer's compliance with the CGMP. FDA assessors and investigators determine whether a company has the facilities, equipment, and capacity to produce the drug it wants to market.

Cosmetic Good Manufacturing Practices (GMP) refers to a set of comprehensive guidelines that help cosmetic companies consistently produce safe, high-quality products. The word “cosmetics” here refers to products or materials that are intended to change, refine, cleanse or care for the face or body. This can include makeup and perfume, as well as products such as soaps, lip balms, shower gels, creams, lotions, body powders and hair products. In addition to cosmetics, good manufacturing practices also apply to other consumer products, including food, medicines and dietary supplements.

GMP is sometimes called “CGMP”. These are current good manufacturing practices that highlight the need for companies to use tools and technologies that meet current standards. As the name suggests, GMP deals with manufacturing or manufacturing processes that affect the safety, consistency and quality of the final product. Every cosmetic company has a responsibility to ensure that the products they manufacture and sell are safe, effective and of consistent quality. This need arises from various regulations that regulate the sale of cosmetic products. For example, in the United States, the Federal Food, Drug, and Cosmetic Act (Section 301), enforced by the FDA, prohibits the sale of “adulterated” cosmetic products. or “mislabelled.” In Canada, the Food and Drugs Act (Sections 16 and 18) states that cosmetics sold must be manufactured and stored in a clean and hygienic environment.

ICH guidelines for stability study :

When designing a cosmetic stability study, the stability study should consider the following questions (discussed in more detail later):

- Identify tests that “accelerate and predict” the effects of normal storage and use conditions. Where appropriate, limitations, particularly temperature, must be taken into account to enable assessment of product integrity under expected product exposure conditions.
- Consider evaluating important aesthetic properties such as color, odor, texture, and fluidity, particularly after exposure to conditions designed to enhance each property.
- Consider different process conditions.
- Consider the impact of the packaging on the product it contains, as well as the potential impact of the product on the packaging.

General considerations:

1) Global stability of the cosmetic product

Whether conducted in real time or under accelerated conditions, tests must be carried out to ensure:

- The stability and physical integrity of cosmetic products under appropriate storage, transport and use conditions,
- Chemical stability ,
- Microbiological stability,
- Compatibility of contents with container.

2) Accelerated stability tests

Accelerated tests, developed due to the relatively short development cycle of cosmetic products, enable their stability to be predicted. It is common practice to support predictions from accelerated stability

testing by periodically monitoring preserved samples stored at room temperature after launch. The information obtained could also be useful to further improve the product and refine the methodology for accelerated stability testing.

Introduction of Lip Balm :

Lip balm or lip ointment is a waxy substance applied topically to the lips to moisturize and soothe chapped or dry lips, angular cheilitis, stomatitis, or cold sores. Lip balms often contain beeswax or carnauba wax, camphor, cetyl alcohol, lanolin, paraffin and petroleum jelly, among other things. Some varieties contain dyes, flavors, fragrances, phenol, salicylic acid and sunscreens.



Overview

Lip balm was introduced to the market in 1880 by Charles Browne Fleet, although its origins can be traced to earwax. More than 40 years before the commercial introduction of Fleet lip balm, Lydia Maria Child recommended earwax as a solution to chapped lips in her wildly popular book, *The American Frugal Housewife*. The child noted, "For people who suffer from chapped lips, this earwax remedy has proven effective where others have failed." It's one of those types of drugs that people often make fun of. However, I know there have been very positive results.

In 2019, the global lip balm market was valued at \$660 million. This market is expected to grow by 7.3% over the next five years and reach \$1,010 million by 2024. Due to growing public concern about the presence of dangerous synthetic excipients in cosmetics, new techniques are being developed to develop products produced from biological sources.

Chapped, dry or cracked lips are a very common cosmetic problem, especially in adverse weather conditions. Lips do not have sebaceous glands and therefore require additional moisture

and protection during the day [1]. Many people suffer from dry mouth in winter, but the problem can persist even in sunny seasons. Conventional lip balms often contain petroleum jelly, synthetic waxes, aluminum oxide, parabens, hydrogenated oils, and toxic artificial fragrances and colors. Since users frequently consume lip balm, it is imperative that health authorities closely examine the ingredients of lip balm. The dyes that give color to lip balm are dangerous to humans if swallowed. Lips contain a small amount of melanin, which provides some protection from the sun. Although many organic products such as ghee, honey and vitamin E can help nourish lips hydrated and healthy when used as part of a broader diet.

The word "organic" is a symbol of safety, as opposed to a synthetic word that has harmful effects on human health. Cosmeceuticals are cosmetic products that contain biologically active ingredients with medicinal or healing effects. These ingredients have medicinal properties that provide local beneficial effects and protect against degenerative skin diseases. We did this work to develop organic lipsticks with fewer side effects.

Products that protect the lips rather than decorate them are called lip balms.



Formulation Of Lip Balm:

Weigh all excipients. Add ghee, beeswax and castor oil to the jar and melt in a water bath at a temperature of 55-600°C. Add the honey and vitamin E to the jar and stir vigorously to prevent the

honey from forming lumps. Add the vanilla flavoring. Pour the contents into the lipstick molds. Before pouring the mixture in lipstick moulds; on the mould applying glycerine with the help of cotton. Put the filled moulds into ice bath for 30 min.

Composition Of Lipbalm:

INGREDIENT	QUANTITY	USES	MFG.BY
Bees Wax	5 gm	Moisturizer and Glossiness	R.C.L.F.I,Mumbai
Ghee	2 gm	Moisturizer	DC Group and Company
Castor Oil	15 ml	Emulsifier	R.C.L.F.I,Mumbai
Honey	5 ml	Lighten up the darker lips	Merck Consumer Health Ltd.
Vanillin	1 ml	Flavouring Agent	R.C.L.F.I,Mumbai
Vitamin E	5 ml	Antioxident	Eagle Glass Deco Pvt.Ltd.

Machine information to preparation :

A griddle is a small, portable, standalone cooktop equipped with one or more electric heating elements or gas burners. The hob can be used as a standalone appliance, but is often used as a replacement for one of the Anovenrange range of

burners or a stove. Griddles are often used to prepare food, usually in places where a full stove would not be convenient or practical. The heating plate can have a flat or round surface. Heating pads can be used when traveling or in areas without electricity.



**Evaluation Of Lip Balm :
Organoleptic properties:**

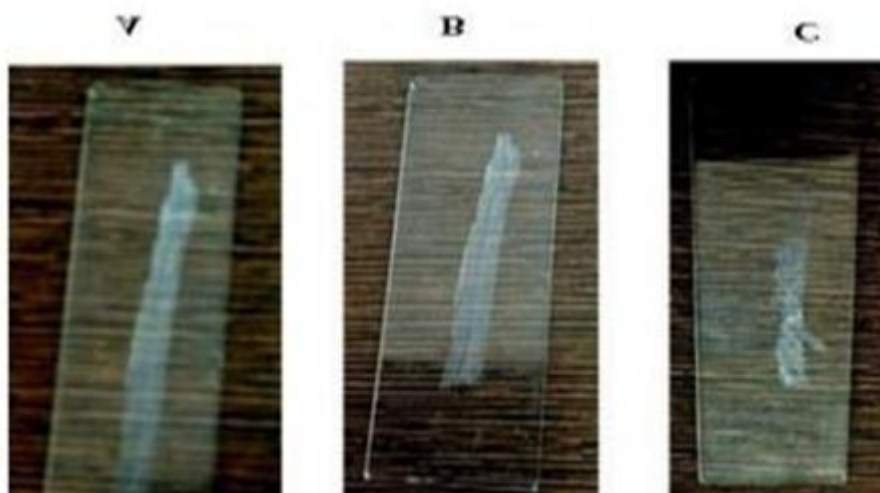
The lip balm was tested for its organoleptic properties such as color, smell, taste and appearance. Diffusion Test In the diffusion test, the product was applied to a glass slide several times (at room temperature) to visually observe the uniformity of formation of the protective layer and to determine whether the stick was fragmented, deformed or

cracked during application. For this test, the analyst noted the following criteria:

G – Good: uniform, without fragmentation; perfect application, no deformation of the lip balm.

I – intermediate level: uniform; leaves some fragments; fair use; slight deformation of the lip balm.

B – Bad: irregular; leaves many fragments behind; difficult or incorrect application, severe deformation of the lip balm.



Measurement Of PH:

The lip balm had an almost neutral pH value, i.e. H. 6.5, which didn't irritate the lips. Lip

balm is insoluble in water and therefore dissolves in organic solvents such as alcohol and benzene.



II. RESULT AND CONCLUSION:

The preparation stored at room temperature and in the refrigerator showed similar behavior in the stability test. The organoleptic properties proved to be stable and the spreadability was rated as “good”. Storage under these conditions was considered appropriate primarily to

preserve the functionality of the product. The prepared lip balm has good diffusion properties at normal temperatures. According to the lubrication test results, storage is at normal room temperature (22°C). It has been found that organic lip balm can be a better option for treating various lip problems.

Parameters	Observations
Colour	Cream
Appearance	Excellent, Smooth
Odour	Pleasant
pH	6.5
Spreadability	Good

REFERENCE:

- [1]. Christopulos A, Mouth anatomy <https://emedicine.medscape.com/article/1899122-overview> Sep 11, 2018.
- [2]. Fernandes, A.R., Dario, M.F., Pinto, C.A.S.D.O., Kaneko, T.M., Baby, A.R. and Velasco, M.V.R., 2013. Stability evaluation of organic Lip Balm. Brazilian Journal of Pharmaceutical Sciences, 49, pp.293-299.
- [3]. Kadu, M., Vishwasrao, S. and Singh, S., 2015. Review on natural lip balm. International Journal of Research in Cosmetic Science, 5(1), pp.1-7.
- [4]. American academy of dermatology. “Protection against photo aging” <http://www.skincarephysicians.com/agingskinnet/photoaging.html>
- [5]. Pugliese PP "Vitamin e: a skin care ally." skin, inc. Magazine.
- [6]. <http://www.skininc.com/skinscience/ingredients/55400207.html>. Des 23 2017.
- [7]. Barel, AO Handbook of cosmetic science and technology. New York: Marcel Dekker, 2001, 904.
- [8]. Sharma PP, cosmetics- Formulation, manufacturing and quality control, Edn 5. Vandana publications, Delhi, 2008
- [9]. A Handbook of Cosmetics Science By R.M.Mithal & R.N
- [10]. A Textbook of Phrmaceutical Jurispudence By Dr.R.Narayana



- Charyulu, Sandeep D.S. & Shabana S.
Published By Nirali Prakashan.
- [11]. https://en.m.wikipedia.org/wiki/Drugs_and_Cosmetics_Act,_1940<https://cleartax.in/s/drug-license>
- [12]. <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics>
- [13]. <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulation>.
- [14]. Brazilian Journal of Pharmaceutical Sciences 49, 293-299, 2013
- [15]. Journal of Public Health and Pharmacy 1 (2), 39-42, 2021