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REVIEW ON COSMETIC SCIENCE PREPARATION AND EVALUATION OF LIPBALM

Mr.Chavhan Shankar Parmeshwar

Mr.Awargand Karan Pandurang

Mr.Dhole Nilesh Vijaykumar

Mr.Kokane Amol Kashinath

Department : Pharmaceutics

Shivajirao Pawar College Of Pharmacy Pachegaon Tal.Newasa Dist.A.Nagar,Maharashtra

ABSTRACT

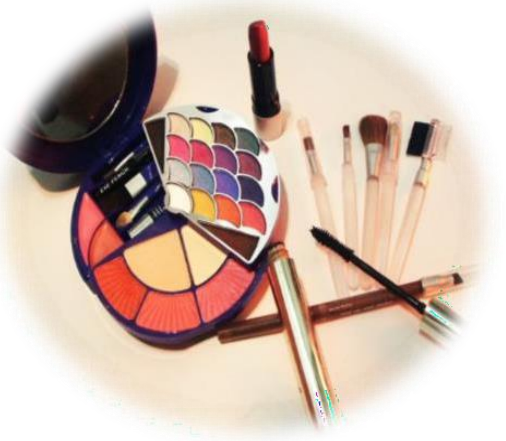
The lip care products for everyday basis contain harmful heavy metals and preservatives.Other than leaching through the pores on your lips, these heavy metals and other chemicals can also be accidently ingested. Lead affects heart and brain, Cadmium and Chromium can cause cancer, Preservative could cause breast cancer. Lip balms are formulations applied onto the lips to prevent drying and protect against adverse environmental factors. Organic lip balms nourishes the lips and help to get hydrated and protect lips affected by chapping and dryness. They help to protect the natural health and beauty of the lips. Lip balms are not gender specific products and both men and women can use them. In the present study many organic products like Ghee and Honey, can help to keep lips hydrated and healthy. Prepared lip balm was evaluated for organoleptic characteristics, spreadability, pH
measurement and stability studies. After performing stability studies at room temperature (22.0 ºC) ,refrigeration (4ºC) and oven temperature (40.0ºC) for 2 days.

It was concluded that prepared lip balm shows uniform nature, perfect application, without any deformation at room temperature (22.0ºC) and at refrigeration (4ºC) Mean pH was 6.5, which is near to the neutral pH. Storage in the oven (40.0°C) is not recommended because of loss of product functionality observed during the normal Stability. Organic lip balm can be a better option for treatment of various lip issues.

KEY WORDS : Organic, lip Balm, lips,stability, Spreadability, deformation

INTRODUCTION :

Cosmetics are constituted mixtures of chemical compounds derived from either natural sources, or synthetically created ones.
Cosmetics have various purposes.
Those designed for personal care and skin care can be used to cleanse or protect the body or skin.
Cosmetics designed to enhance one's appearance (makeup) can be used to conceal blemishes, enhance one's natural features (such as the eyebrows and eyelashes), add color to a person's face and can be used to change the appearance of the face entirely to resemble a different person, creature or object.



Cosmetics can also be designed to add fragrance to the body.

In modern days cosmetics are the rage and are considered to be essential commodities of life. The role of cosmetics in everyday life met greater acceptability after World War II. It was realized by social and medical scientists cosmetics not only adore but they exercise psy chological effect on users and specially on the skin. They keep the skin supple delaying the onset of wrinkling. They are also helpful in skin infections and prevention of sunburns.

Cosmetics have been in use for thousands of years, with ancient Egyptians and Sumerians using them. In Europe, use of cosmetics continued into the Middle Ages—where the face was whitened and the cheeks rouged though attitudes towards cosmetics varied throughout time, with the use of cosmetics being openly frowned upon at many points in Western history. Regardless of the changes in social attitudes towards cosmetics, ideals of appearance were occasionally achieved through the use of cosmetics by many.

According to one source, early major developments in cosmetics include:

- Kohl used by ancient Egyptians
- Castor oil also used in ancient Egypt as a protective balm
- Skin creams made of beeswax, olive oil, and rose water, described by the Romans
- Vaseline and lanolin in the nineteenth century.

The word 'cosmetics' arises from a Greek word 'kosmeticos' which means to adorn. Since that time any material used for beautification or improvement of appearance is known as cosmetic. The urge to adorn one's own body and look beautiful has been an urge in the human race since the tribal days. Earlier both males and females were equal competitors for improvement of appearance. Males decorated them selves with animal parts and vegetable leaves etc. while women did so by wearing any coloured stones or flowers round their neck and the wrists. At a later stage they employed coloured earth for faces and bodies and still later coloured ointments. Bangles and necklaces made. of baked earth also became common in the early civilization as well as shells of various kinds obtained from nature. In digging up ancient Egyptian tombs much light has fallen on the ancient practices of beauti fication.

Pharaohian tombs have revealed that coloured earths were like malachite green. The copper ore was used as eye shadows. Lamp black was common too for eyes. For dyeing of hairs red was also practised. The dancing ladies applied ointments perfumed with materials like myrrh to head so that when they danced the perfumed ointment would flow down their bodies emitting pleasant smell all over. The history also records that when Jehu went to the town of Jezebel she painted her face and looked out from window. The use of cosmetics in ancient Egypt reached heights with the famous queen Cleopatra who tried to beguile Caesar and Antony the Romans when they visited Egypt.

Shakespeare has summarized it by this line, "Had Cleopatra's nose been longer, the shape of the world would have been different." The women of the world feel inspired when they have a mental feeling that they are looking good.

Hence, the practice of adornment or improvement of appearance contin ued unabated across the centuries. Various kinds of natural materials were used for the purpose. The practice of use of cosmetics must have grown to an appreciable extent because the British Parliament enacted a Law in 1770, which still stands unrepealed and is as follows:

"That all women of whatever age, rank, profession or degree whether virgins, maids or widows that shall from and after such Act impose upon, seduce and betray into matrimony any of His Majesty's sub jects by the scents, paints, cosmetics, washes, artificial teeth, false hair, Spanish wool, iron stays, hoops, high heeled shoes, bolstered hips, shall incur the penalty of law in force against witchcraft and like misdemeanours and that such marriage upon conviction shall stand null and void."

The cosmetics in general are external preparations and are meant to be applied to external parts of the body. In other words they may be applied to skin, hair and nails for the purposes of covering, colouring, softening, cleansing, nourishing, waving, setting, mollification, preserva tion, removal and protection.
The cosmetics may be classified into 41 main groups namely

(1) Cosmetics for Skin
(2) Cosmetics for Hair
(3) Cosmetics for Nails.
(4) Cosmetics for Hygiene (Dental, Bathing, etc.)

Cosmetics for the Skin :

The skin covers vast area of body and cosmetics are applied to many parts, the most important part being the face. The skin cosmetics are formulated in the form of solids, semi-solids and liquids. The solids consist of powders with different degrees of flow and angle of repose or of compacts. The semi-solids may be emulsions or simple admixtures and liquids are both monophasic and biphasic.

DRUGS AND COSMETICS ACT, 1940

The **Drugs and Cosmetics Act, 1940** is an act of the Parliament of India which regulates the import, manufacture and distribution of drugs in India. The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards.[1] The related Drugs and Cosmetics Rules, 1945 contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule. This act was originally known as the Drug Act and was passed in 1940. The original act was prepared in accordance to the recommendations of the Chopra Committee formed in 1930. The related Drugs Rules was passed in 1945. Since 1940, the act has undergone several amendments and is now known as the Drugs and Cosmetics Act, 1940.

The term "drug" as defined in the act includes a wide variety of substance, diagnostic and medical devices. The act defines "cosmetic" as any product that is meant to be applied to the human body for the purpose of beautifying or cleansing. The definition however excludes soaps. In 1964, the act was amended to include Ayurveda and Unani drugs.

The Section 16 of the act defines the standards of quality for drugs. The Section 17 defines "misbranding". A drug is considered misbranded if it claims to be of more therapeutic value than it actually is. The manufacturer of such a drug may be asked to suspend manufacture of the drug under Section 18. Section 27 deals with fake and adulterated drugs. The act requires more of that ingredients of the drugs should be printed on the label.

The Section 22 defines the powers of the drug inspectors and Section 23 defines the strict procedure which should be followed by the inspectors during any raids.

STUDY OF SCHEDULES :

Schedule G: Most of these drugs are hormonal preparations. The drug label must display the text. "Caution: It is dangerous to take this preparation except under medical supervision"prominently. Examples: Testolactone, Hydroxyurea, Carbutamide, Primidone, Mercaptopurine, Methsuximide, Thiotepa etc.

- Schedule H: The drug label must display the texts "Rx" on the left top corner of the label and "Schedule H drug. Warning : To be sold by retail on the prescription of a Registered Medical practitioner only" prominently. It can only be supplied to licensed parties. It cannot be sold without a prescription and only the amount specified in the prescription should be sold. The time and date of prescription must be noted. Examples: Androgenic, anabolic, oestrogenic and progestational substances; Alprazolam, Hepatitis B vaccine, Adrenocorticotrophic hormone, Ibuprofen, Vasopressin etc
- Schedule M (GMP-GOOD MANUFACTURING PRACTICES): It is defined as “the part of quality assurance which is aimed to ensure that the product are consistently manufactured to the quality appropriate to their intended use”. It prescribes the requirements of premises, plant and equipment needed for setting up manufacturing unit. Also documents every stage of manufacture, packing, storage, transportation checking and testing of medicinal product, maintenance or keeping records.
- Schedule N: Describes the facilities and equipments for efficient running of a Pharmacy.

- Schedule P describes the life period of drugs in months (unless otherwise specified) between date of manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specific
- Schedule T: Contains various regulations and requirements for manufacture of Ayurvedic, Siddha and Unani products.
- Schedule U describes the particulars to be shown in manufacturing record, records of raw materials and analytical drugs.
- Schedule V describes the standards for patent or proprietary medicines. Patent or Proprietary medicines containing vitamins for prophylactic, therapeutic or paediatric use shall contain the vitamins in quantities not less than and not more than those specified in single or in two divided daily doses.
- Schedule X: Drugs which are habit forming, psychotropic and other drugs likely to be misused for addictive purposes. Hence import, manufacture, sale and distribution of these are regulated under special provisions.
- Schedule Y:Describes requirements and guidelines on Clinical trials for import and manufacture of new drugs.

LICENSING AUTHORITIES

1. These are appointed by the Central and State governments for the grant and the

renewal of a licence for the import, manufacture, sale, distribution etc. of any drug or cosmetic.

2. The licenses once issued, shall remain valid forever, unless suspended or cancelled by

the licensing authority.

3. The licensing authorities are mostly designated as Drug Controller.

4. The Drug Controller, India has recently been notified as the Central License

Approving Authority.

Qualification of a Licensing Authority:

1. He must be a graduate in Pharmacy or Pharmaceutical chemistry or medicine with

specialization in Clinical Pharmacology or Microbiology, from a recognized university.

2. He must be experienced in manufactuacture or testing of drugs for a minimum period of 5 years.

LIST OF INGREDIENT WHICH PROHIBITED FROM DRUG AND COSMETICS ACT :

Although it's against the law to use any ingredient that makes a cosmetic harmful when used as intended, FDA has regulations that specifically prohibit or restrict the use of the following ingredients in cosmetics:

Bithionol : The use of bithionol is prohibited because it may cause photocontact sensitization (21 CFR 700.11).

Chlorofluorocarbon propellants : The use of chlorofluorocarbon propellants in cosmetic aerosol products intended for domestic consumption is prohibited (21 CFR 700.23).

Chloroform : The use of chloroform in cosmetic products is prohibited because it causes cancer in animals and is likely to be harmful to human health, too. The regulation makes an exception for residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient (21 CFR 700.18).

Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide): These are prohibited in cosmetic products because they may cause serious skin disorders (21 CFR 700.15).

Hexachlorophene : Because of its toxic effect and ability to penetrate human skin, hexachlorophene (HCP) may be used only when no other preservative has been shown to be as effective. The HCP concentration in a cosmetic may not exceed 0.1 percent, and it may not be used in cosmetics that are applied to mucous membranes, such as the lips (21 CFR 250.250).

Mercury compounds : Mercury compounds are readily absorbed through the skin on topical application and tend to accumulate in the body. They may cause allergic reactions, skin irritation, or neurotoxic problems. The use of mercury compounds in cosmetics is limited to eye area products at no more than 65 parts per million (0.0065 percent) of mercury calculated as the metal and is permitted only if no other effective and safe preservative is available. All other cosmetics containing mercury are adulterated and subject to regulatory action unless it occurs in a trace amount of less than 1 part per million (0.0001 percent) calculated as the metal and its presence is unavoidable under conditions of good manufacturing practice (21 CFR 700.13).

Methylene chloride. It causes cancer in animals and is likely to be harmful to human health, too (21 CFR 700.19).

Prohibited cattle materials. To protect against bovine spongiform encephalopathy (BSE), also known as "mad cow disease," cosmetics may not be manufactured from, processed with, or otherwise contain, prohibited cattle materials. These materials include specified risk materials*, material from nonambulatory cattle, material from cattle not inspected and passed, or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, and hides and hide-derived products, and milk and milk products** (21 CFR 700.27).

Sunscreens in cosmetics. Use of the term "sunscreen" or similar sun protection wording in a product's labeling generally causes the product to be subject to regulation as a drug or a drug/cosmetic, depending on the claims. However, sunscreen ingredients may also be used in some cosmetic products to protect the products' color. The labelling must also state why the sunscreen ingredient is used, for example, "Contains a sunscreen to protect product color." If this explanation isn't present, the product may be subject to regulation as a drug (21 CF700.35).

MANUFACTURING OF COSMETICS SCIENCE :

A license obtainable from the Licensing Authority is now essential for undertaking manufacture of cosmetics. The licenses are granted on payment of requisite fees and fulfilment of other prescribed conditions and, in general, rules applicable to the licenses granted for the manufac ture of allopathic drugs are applicable to these licenses as well. Manufacture of cosmetics containing hexachlorophene or mercury com pounds or misbranded or spurious cosmetics or cosmetics which are not of standard quality is prohibited. A person licensed to manufacture cosmetics should fulfil following conditions:

(i) The factory premises should be maintained in clean condition, should be situated in hygienic surroundings, and should be distinct and separate from premises used for residential purposes.

(ii) Adequate space and staff should be provided and manufacture should be conducted under the direction and personal supervi sion of competent technical staff at least one of whom should be a whole time employee and should either hold diploma in phar macy approved by the Pharmacy Act or should have passed intermediate examination with chemistry as one of the subject. However, for small scale manufacturers, employing not more. than 5 persons, a person with general training and experience, extending over not less than 4 years in the manufacture of cosmetics, may be deemed to be competent technical staff by Licensing Authority.

(iii) Either adequate facilities should be provided on the premises for the testing of raw materials and manufactured products or suit able arrangements should be made with approved institutions for the purpose. Records relating to such tests should be maintained for at least 3 years from the date of manufacture.

(iv) Cosmetics containing colors other than those specified by Bu reau of Standards or colors which contain more than 2 p.p.m. of arsenic or more than 20 p.p.m. of lead or more than 100 p.p.m. of heavy metals other than lead and eyebrows or eye-lashes etc. containing any coal tar color should not be manufactured. The use of arsenic or lead compounds for coloring cosmetics is also prohibited. (v) The Inspectors should be allowed to inspect premises, records etc., and to take samples of manufactured products. An inspec tion book should also be maintained wherein the inspectors can enter their remarks.

(vi) Records of manufacture should be kept as per Schedule U(1) for at least 3 years.

As in the case of drugs, licenses for the manufacture of cosmetics remain valid up to 31st December in the year following the year of issue and may be suspended or cancelled if the licensee fails to observe any of the conditions, discussed above. A licensee, aggrieved by this decision can appeal to the State Government within 3 months of suspension or cancellation. Cosmetics can also be manufactured under loan licenses as is the case with drugs.
Anyone manufacturing any spurious cosmetic shall be punishable with imprisonment up to 3years and fine. Persons convicted of manufacture of cosmetics in contravention of any other provision are liable to imprisonment for a term up to 1 year and or fine up to Rs. 1000.

STORE AND SALE OF COSMETIC SCIENCE :

Wholesale, Retail and Restricted Sale Licenses

1. Wholesale: From stockists to shopkeepers.
2. Retail sale: From shopkeepers (drug store, chemists and druggists, pharmacy or dispensing chemist) to patients.

Drug control organization issues two type of license, out of which one is Retail Drug License (RDL) to run a chemist shop, and it is issued to only those persons who possess degree or diploma in pharmacy from a recognized university on the payment of the requisite fees and other is Wholesale Drug License (WDL) which is issued to a person who is engaged in the business of wholesale of drugs and medicines.

Conditions of Whole Sale License:

1. Area: Shall not be less than 10 sq. m.
2. Storage: It is necessary to have a refrigerator and air conditioner on the premises because certain drugs such as vaccines, insulin injections etc. are needed to be stored in the fridge.
3. Competent Staff: The sale can be made either by a registered pharmacist or another competent person who must be a graduate with one year experience in drugs or in the presence of any one who has passed S.S.L.C having experience of four years in drugs, specially approved by drug control department.
4. License shall be displayed in a prominent place.
5. The drugs shall be purchased from a duly licensed dealer or a manufacturer.
6. Supply of drugs shall be made against a cash memo. Carbon copies of the same shall be preserved for 3 years from the date of last entry.
7. Shall maintain the records of purchase, and produce all the registers and records during inspection. Records must be preserved for 2 years from the last entry.
8. An Inspection book shall be maintained in Form 35.
9. The drugs after expiry, Physician's sample and the drugs meant for Government supply, shall not be stocked or sold.
10. A separate record shall be maintained for the supply of Schedule X drugs, the copies of invoices of sale of such drugs to the retailer, shall be forwarded to the Licensing authority.
11. No sale of any drug should be made for the purpose of resale to a person not holding the license to sell or distribute the drugs.

DOCUMENTATION :

Required Documents for Obtaining Drug License:

1. Application Form.
2. Cover letter with the name and designation of the applicant.
3. Copy of challan achieved by depositing fees for obtaining drug license.
4. Declaration in a prescribed manner.
5. Kite plan and site plan for the premises.
6. The basis of possession of premises.

7. In the case of rented property, ownership proof.
8. Document related to the constitution of business such as Incorporation certificate/ MOA (Memorandum of association)/AOA (Articles of association)/Partnership Deed.
9. Affidavit related to non-conviction of director/partner/proprietor.
10. Testimony of registered pharmacist or competent person and their appointment letter in case of an employed person.

Types of Drug License :

Looking at the definition of "drug", the pharmaceutical business in India requires the following types of licenses:

Manufacturing License– License issued to a business that manufactures drugs inclusive of allopathic/homoeopathy medicines.
Sale License – License issued for the sale of drugs. It has the following bifurcations: – Wholesale Drug License – Retail Drug License
Wholesale License – A drug wholesaler must obtain a wholesale licence. Wholesale means the sale of the drug to a person/retailer to further sell it.
Retail License – A retail license is required for the retail sale of drugs. A retail sale means the sale of drugs or cosmetics for the consumption of the end consumer. Retailers can sell it to a dispensary, hospital, educational, medical, or research institute. Retailers engaged in pharmaceuticals, cosmetics, stand-alone pharmacists, ayurvedic shops, etc need this license.
Loan License – License issued to a business that does not own the manufacturing unit but uses the manufacturing facilities of another licensee.
Import License – License issued for the import of drugs.
Multi-Drug License – License issued to businesses that own pharmacies in multiple states with the same name.

CGMP AS PER REGULATORY AUTHORITIES :

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMPs. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

Cosmetic Good Manufacturing Practices (GMP) relate to a set of comprehensive guidelines that help cosmetic businesses consistently manufacture products that are safe and of high quality. The word 'cosmetic' here refers to goods or materials intended to alter, enhance, cleanse, or groom one's face or body. They can range from makeup and fragrances to produ cts such as soap, lip balms, shower gels, creams, lotions, body powders, and hair products. Apart from cosmetics, Good Manufacturing Practices also exist for other consumer products including food, drugs, and supplements.

GMP is sometimes also called 'cGMP'. This refers to current Good Manufacturing Practices, which emphasizes the need for companies to adopt tools and technologies that are

consistent with today's standards. As its name implies, GMPs are concerned with the manufacturing or production processes that impact the **safety**, **consistency**, and **quality** of the end product. Every cosmetic business has a responsibility to ensure that products created and ultimately sold are safe, effective, and of consistently high quality. This need is linked to various regulations that govern the sale of cosmetic products. For instance, in the US, the Federal Food, Drug and Cosmetic Act (Section 301) enforced by the FDA forbids the sale of cosmetic products that are "adulterated" or "misbranded". In Canada, the Food and Drugs Act (Sections 16 and 18) states that cosmetics sold must be produced and stored in clean, hygienic environments.

Safety refers to the prevention of unintentional contamination, spoilage, or misuse of final products that may cause undesirable reactions and other health effects. It can involve practices such as sourcing raw materials from a reputable supplier, ensuring facilities are cleaned appropriately, educating staff about regular hand washing, and proofreading labels before printing.

Consistency relates to the ability to control manufacturing variables and processes so that a consistent outcome is achieved each time. For example, the formulation used, the types of raw materials selected, the sanitation protocols followed, and the technical ability of the cosmetic chemist are just some of the variables that can influence product quality. Each, if not controlled, can lead to quality variations from batch to batch. Creating accurate and thorough documentation, and then following them through, is vital in reproducing product quality and achieving consistency.

ICH GUIDELINES FOR STABILITY STUDY :

❖ Designing a cosmetic stability study

A stability study should include the following considerations (each of which will be Discussed in more detail later):

• Identify tests that will “accelerate and predict” the effects of normal conditions of Storage and use. Where relevant, consider stresses, including temperature, that will enable assessment Of product integrity under anticipated product exposure conditions.

• Consider evaluation of critical aesthetic properties such as color, fragrance, texture, And flow, particularly after exposure to conditions designed to stress each specific Property.

• Consider variation in process conditions.

• Consider the impact of packaging on the contained product, as well as any effects Which the product might have on the packaging.

❖ General considerations:

1)General Stability of a Cosmetic Product

Whether conducted in real time or under accelerated conditions, tests should be done In order to assure:

• Stability and physical integrity of cosmetic products under appropriate conditions of Storage, transport and use,

• Chemical stability,

Microbiological stability,

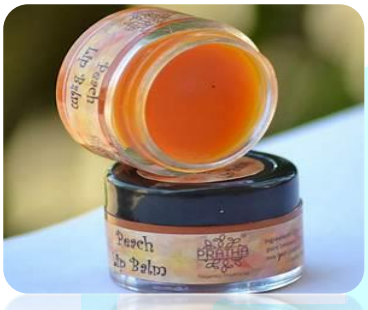
• The compatibility between the contents and the container.

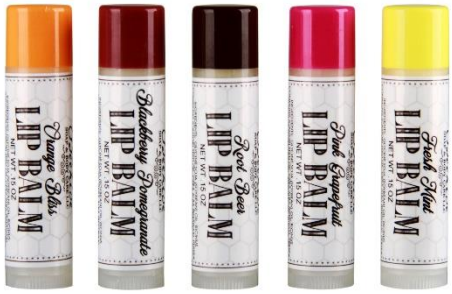
2)Accelerated Stability Tests

Accelerated tests, developed because of the relatively short development cycle for Cosmetic products, enable the prediction of stability. A commonly accepted practice is To support the forecasts obtained from accelerated stability testing by carrying out Periodic post-launch monitoring of retained samples stored at ambient temperatures. The resultant information can also be useful in further improving the product and in Refining the methodology used for accelerated stability testing.

INTRODUCTION OF LIP BALM :

Lip balm or lip salve is a wax-like substance applied topically to the lips to moisturize and relieve chapped or dry lips, angular cheilitis, stomatitis, or cold sores. Lip balm often contains beeswax or carnauba wax, camphor, cetyl alcohol, lanolin, paraffin, and petrolatum, among other ingredients. Some varieties contain dyes, flavor, fragrance, phenol, salicylic acid, and sunscreen.





Overview

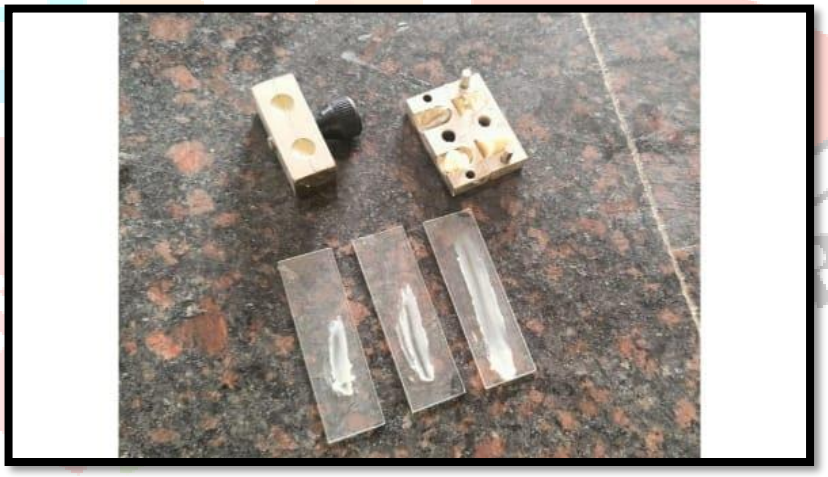
Lip balm was first marketed in the 1880s by Charles Browne Fleet,though its origins may be traced to earwax. More than 40 years prior to the commercial introduction of lip balm by Fleet, Lydia Maria Child recommended earwax as a treatment for cracked lips in her highly-popular book, The American Frugal Housewife. Child observed that, "Those who are troubled with cracked lips have found this earwax remedy successful when others have failed. It is one of those sorts of cures, which are very likely to be laughed at; but I know of its having produced very beneficial results."

In 2019, the global lip balm market was valued at US$660 mln. The market is predicted to grow at a rate of 7.3% within the next five years and is likely to reach US$1010 mln by 2024. Due to increasing public concern, on the presence of hazardous synthetic excipients in cosmetics, new techniques are gained to produce products using organic sources. Chapped, dry or cracked lips are very common beauty dilemma, particularly in harsh weather. Lips have no oil glands, so they really need that extra moisture and protection throughout the day [1]. Many people deal with dried-out lips during the winter, but the problem can continue in sunny seasons, too. Conventional lip balms often contain petrolatum, synthetic waxes, alumina, parabens, hydrogenated oils and artificial fragrances and colours which are toxic. 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. The dyes that contribute to the color of the lip balm are dangerous to humans on consumption. Lips contain little melanin, which provides some protection from the sun. Although many organic products like Ghee, Honey, vitamin E can help keep lips hydrated and healthy when used as part of a larger regimen

Organic word is the symbol of safety in contrast to synthetic one which has adverse effects on human health.Cosmeceuticals are cosmetic products with biologically active ingredients purporting to medical or drug like benefits. These ingredients have medicinal properties that

manifests beneficial topical actions and provides protection against degenerative skin condition. The present work was carried out by us to formulate organic lipstick having less side effects. Products that are used to protect lips rather than decorate them are known as lip balms. They form an adherent, flexible, moisture resistant film of oily substances. Usually they do not contain dye.

Honey helps to lighten up the dark lips. Honey is rich with bleaching action that generally removes the darkness of the lip skin. It is also high in antioxidants that help repair daily UV damage. Ghee contains essential fatty acids that help condition and nourish dry and chapped lips. The application of pure ghee on chapped lips will help to cure the problem of cracked lips as well as discoloured lips with quick effects. Beeswax is a natural compound secreted by female bees that is often used in cosmetics, particularly lip balm. This substance is very moisturizing, can help protect the lips from the harmful rays of the sun, and has a pleasant smell. Beeswax act as a natural emulsifiers. Castor oil penetrates deep into the skin tissue and its fatty acids help to moisturize the lips. The anti-inflammatory properties of castor oil reduce redness and pain associated with chapped and sunburnt lips. Vitamin E is an antioxidant and a natural conditioner. Vitamin E helps to maintain the soft, youthful texture of your lips by reducing the signs of aging Stability studies are useful as a screening tool for all potential manifestations of instability of a formulation, even if they never occur under conditions of product use. Furthermore, possible changes in the product can be identified before it is released for use by consumers.



FORMULATION OF LIP BALM

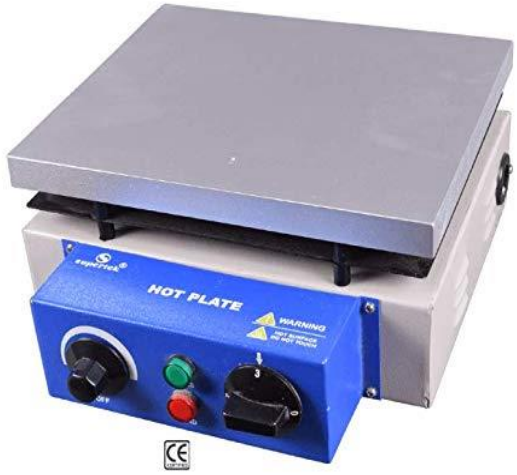
Weigh all the excipients. Add ghee, beeswax, castor oil in beaker and melt it in water bath at 55-60^{0}C. Add honey and vitamin E into beaker and mix vigorously so that honey will not clump. Add vanillin flavour. Pour the content into the lipstick moulds. Before pouring the mixture in lipstick moulds; 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 **hot plate** is a portable self-contained tabletop small appliance cooktop that features one or more electric heating elements or gas burners. A hot plate can be used as a stand-alone appliance, but is often used as a substitute for one of the burners from an oven range or a kitchen stove. Hot plates are often used for food preparation, generally in locations where a full kitchen stove would not be convenient or practical. A hot plate can have a flat surface or round surface. Hot plates can be used for traveling or in areas without electricity.



EVALUATION OF LIP BALM :

Organoleptic properties

The lip balm was studied for organoleptic characters such as colour, odour, taste and appearance.

Test of spreadability

The test of spreadability consisted of applying the product (at room temperature) repeatedly onto a glass slide to visually observe the uniformity in the formation of the protective layer and whether the stick fragmented, deformed or broke during application. For this test, the following criteria were established by the analyst:

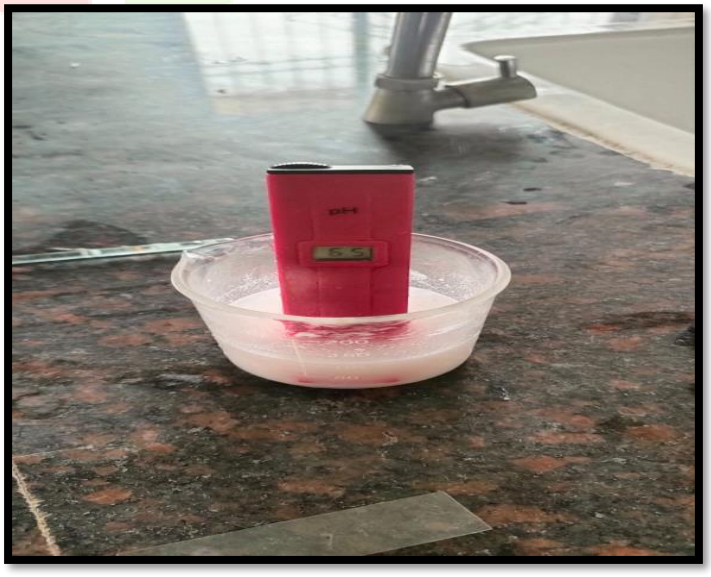
G - Good: uniform, no fragmentation; perfect application, without deformation of the lip balm.

I - Intermediate: uniform; leaves few fragments; appropriate application; little deformation of the lip balm.

B - Bad: not uniform; leaves many fragments; difficult or inappropriate application, intense deformation of the lip balm.

Measurement of pH

pH of lip balm was near to neutral pH i.e. 6.5 this would not cause any irritation to lips.
Lipbalm is insoluble in water so Lipbalm is soluable in Organic Solvent like as Alcohol and Benzene.



Result And Conclusion

The formulation stored at room temperature and refrigerator showed similar behavior during the stability test. The organoleptic characteristics were stable and spreadability was evaluated as "Good." Storage under these conditions was considered adequate, particularly because the functionality of the product was maintained. Prepared lip balm shows good spreadability at normal temperature. According to results of the spreadability tests, storage in the normal room temperature is (22°C). It was concluded that Organic lip balm can be a better option for treatment of various lip issues.

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

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