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AN OVERVIEW ON COSMETIC AND SCIENCE

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ABSTRACT

Everyday lip care products can sometimes contain heavy metals and harmful preservatives that can be accidentally ingested. Lead, cadmium and chromium in these products can have harmful effects, particularly on the heart and brain, and can cause cancer. Additionally, some preservatives have been linked to problems such as breast cancer. Lip balms are formulated to moisturize the lips and protect them from environmental influences. Organic lip balms are a healthier alternative as they moisturize and protect chapped and dry lips while preserving their natural beauty and well-being .Remember that lip balms are not gender specific and can be used by both men and women. In a recent study, various organic ingredients such as ghee and honey were found to be effective in keeping lips healthy and moisturized. The tested lip balm was evaluated for its sensory properties, its spreadability, its pH measurements and its stability. The results of stability tests conducted at various temperatures (room temperature, refrigeration and oven conditions) over a period of 2 days showed that the prepared lip balm had a consistent consistency at room temperature (22.0 °C) and in the environment even application in the refrigerator (4°C). The pH of lip balm has been found to be close to neutral, at 6.5. However, storage at elevated temperatures (40.0°C) is not recommended as this will result in loss of product functionality during stability assessment.

KEYWORDS: Lip Balm, D & C Act, Hot Plate, pH Meter**,** lips.

INTRODUCTION

Cosmetics cover a broad category of health and beauty products that perform many functions besides improving appearance. These products not only serve to transform your appearance

but also play an important role in general skin and body care. In addition, they often contribute to making a person's personality smell pleasant.[5]

Cosmetics are made up of various chemical compounds from both natural sources and artificially synthesized materials. They serve various purposes including body and skin care, including cleansing and protecting the body and skin. Nowadays, cosmetics have become an important and necessary part of daily life. Their importance was widely recognized after World War II, when social and medical experts realized that cosmetics not only improved appearance but also had a psychological effect on users, particularly on skin health. They help maintain skin elasticity and can delay the formation of wrinkles. Additionally, cosmetics can be helpful in preventing skin infections and protecting against sunburn. Cosmetics have been used for thousands of years and were used by ancient civilizations such as the Egyptians and Sumerians. In Europe, the use of cosmetics continued throughout the Middle Ages, including practices such as facial whitening and cheek blushing. However, public attitudes toward cosmetics have changed over the years, and there have been periods in Western history when their use was openly discouraged.

The cosmetics industry includes the manufacture and distribution of a wide range of cosmetic products. This category includes products such as makeup products such as foundation and mascara, skin care products such as moisturizers and cleansers, hair care products such as shampoos, conditioners and hair dyes, and cosmetics such as shower gel and soaps.[6]

Major players in the cosmetics industry include Johnson & Johnson, L'Oreal, Gillette, Nivea and Chanel.

India is making significant strides in terms of technological advancement in various sectors including medical sciences. During the Covid-19 pandemic, India has demonstrated impressive innovation and active commitment to protecting public health and improving safety measures. However, to support these efforts, it is important to continually adapt the regulatory framework to the evolving health sciences landscape.[7]

The Drugs and Cosmetics Act, 1940 (DCA) is the principal law regulating the manufacture, import and distribution of medicines in India. This was followed by the Medicines and Cosmetics Regulations of 1945, which classified medicines according to schemes and contained rules for their sale, storage and prescription. The purpose of this article is to review

the provisions of the DCA 1940, highlight legislative changes made over the past two decades, and discuss new legal principles and provisions introduced by the Act.[8]

Overview of drug and cosmetic act 1940 & 1945

Revision of Drugs and Cosmetics Act, 1940 & 1945

The Drugs and Cosmetics Act, 1940 is an Indian legislative act falling under the jurisdiction of Parliament. Its main objective is to regulate the import, production and distribution of medicines in the country. The main aim of this law is to ensure that all medicines and cosmetics available in the Indian market meet strict standards of safety, effectiveness and quality.

This Act is supplemented by the Medicines and Cosmetics Regulations 1945, which provide a framework for the classification of medicines into various schedules. These guidelines also provide guidance on appropriate practices for storing, selling, dispensing and prescribing medicines as detailed in each guideline.

This legislation was originally known as the Narcotics Act and was first enacted in 1940. The wording of the original law was based on the recommendations of the Chopra Committee, established in 1930. Subsequent anti-drug laws were introduced in 1945. Over the years, the Drugs and Cosmetics Act of 1940 has been amended several times and is now recognized under its current title.[9]

According to this law, a “cosmetic” is any product intended for use on the human body to enhance beauty or to provide a cleansing effect. It should be noted that this definition specifically excludes soaps. In a major change in 1964, Ayurvedic and Unani medicines were also included in the regulatory framework.

According to the law, a “cosmetic” is any product intended to be applied to the human body or any part thereof by methods such as rubbing, pouring, sprinkling or spraying. These products are intended to cleanse, enhance beauty, increase attractiveness, or alter appearance. The definition also includes products intended to be used as cosmetic ingredients.

Chapter III Medicines and cosmetics The Cosmetics Act applies to the import of medicines and cosmetics. The Act together with provisions 134A, 135 and 135A of the Medicines Act and the Medicines Act. The Cosmetics Ordinance of 1945 imposes restrictions on the import of certain cosmetic products.

These are

1. Any cosmetic products that do not meet standard quality.
2. Any cosmetic product for which an import license is issued, except on the basis of and in accordance with such license.
3. Any cosmetic that contains an ingredient that could be dangerous or harmful if used according to stated or recommended instructions.
4. All cosmetics whose import is prohibited by the regulation
5. All cosmetics containing hexachlorophene
6. All cosmetics in which lead or arsenic compounds have been used for coloring;
7. All cosmetics containing mercury compounds
8. All mislabeled or counterfeit cosmetics.

Objectives of the Drugs and Cosmetics Act

The main objective of the Drugs and Cosmetics Act is to establish the liability of medical technology companies and pharmaceutical companies in case of negligence or provision of substandard services. One of the main objectives of introducing this law is to protect against counterfeit medicines. In addition, other goals are described below:8. Any misbranded or spurious cosmetic.

- Regulating the sale, import and distribution of medicines and cosmetics through licensing.
- Ensure that only qualified persons are involved in the importation, distribution and sale of medicines and cosmetics.
- Prevent poor quality medications, possibly to maintain high standards of care. Regulating the production and sale of Ayurvedic, Siddha and Unani medicines.[10]
- Establishment of Drug Technical Advisory Board (DTAB) and Drug Advisory Committee (DCC) for allopathic and allied drugs and cosmetics.

Relevant definitions in the Drugs and Cosmetics Act

- To fully understand the provisions of this Act, you should familiarize yourself with the specific terms that are clearly defined in the legislation. In this document we provide definitions of various terms used in the Act. • • Cosmetics:
- Article 3 of the Law contains a definition of this term, which includes any product intended to be “sprayed, poured, rubbed or sprayed, introduced or applied”; on the human

body or its parts to purify it, enhance beauty, increase attractiveness, or alter appearance. In addition, this definition includes items intended to be used as cosmetic components.[11]

(i) Manufacture in relation to drugs or cosmetics

Although the law does not specifically define the term "manufacture", it includes all processes, in whole or in part, that are used for "manufacture, modification, decoration, finishing, packaging, labeling", dismantling ". or otherwise handle or adapt pharmaceutical or cosmetic products for distribution or sale. However, this excludes the manufacture or distribution of pharmaceuticals or cosmetics in a normal retail context.[12] or • if the label or container of a cosmetic

(ii) Misbranded cosmetic

According to Article 17D, a cosmetic is classified as a counterfeit cosmetic if:

- It was imported under the name of another cosmetic, or
- If the cosmetic is a Is an imitation or a substitute for another cosmetic or "deceptively resembles" another cosmetic or the name of a cosmetic appears on the label or packaging of another cosmetic, or
- If the label or packaging of another cosmetic is the cosmetic contains the first and last name of a fictitious person or company, you indicate that you are the manufacturer of the cosmetic, or
- If the cosmetic states that you are the product of a manufacturer who did not actually produce it.

Salient features of the Drugs and Cosmetics Act

The Act has made significant strides in regulating the pharmaceutical sector in India, thereby ensuring protection of public health and safety. The salient features of the Act can be summarized as follows:

- The maximum penalty is life imprisonment and a fine of Rs. 10 lakh or three times the value of the property seized, whichever is higher.
- In addition to the agents of the Office of the Drug Controller, other newspaper officials are also authorized under the law to initiate criminal proceedings; Some offenses are cognizable and cannot be granted bail.
- Special courts for the trial of statutory crimes; Aggravating provisions for minor crimes.[13] 1. Drugs and Cosmetics Regulations: supplementing the Drugs and Cosmetics

Act In 1940, further regulations were introduced to take into account developments in the pharmaceutical industry influenced by technological advances and other changes in the industry.

2. DRUGS AND COSMETICS Regulations, 1945

1. **The New Drugs and Clinical Trial Rules, 2019**

The Government of India introduced the New Drugs and Clinical Trials Rules 2019 (New Rules) through publication in the Gazette of India on March 19, 2019. These regulations are formulated to bolster clinical research within the country and bring about changes in the regulatory framework for authorizing new drugs and overseeing clinical trials. The New Rules encompass provisions that promote clinical research and address complex subjects.

Cosmetics can be produced through loan licenses, similar to the practice in the pharmaceutical industry. Manufacturing counterfeit cosmetics can result in a prison sentence of up to 3 years and a fine. Individuals found guilty of producing cosmetics in violation of any other regulations could face imprisonment for up to 1 year and/or a fine of up to Rs. 1000.

Store and sale of cosmetic science

Wholesale, Retail and Restricted Sale Licenses

1. Wholesale

From wholesalers to retailers.

2. Retail sale

The flow of pharmaceutical products extends from shopkeepers (such as drug stores, chemists, and druggists, as well as pharmacies or dispensing chemists) to patients. The Drug Control Organization issues two types of licenses. The first is the Retail Drug License (RDL), granted to individuals who hold a degree or diploma in pharmacy from a recognized university. They obtain this license by paying the necessary fees. The second is the Wholesale Drug License (WDL), issued to those involved in the wholesale distribution of drugs and medicines.

Conditions of Whole Sale License

(i) Area

Shall not be less than 10 sq. m.

(ii) 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.[16]

(iii)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 anyone who has passed S.S.L.C having experience of four years in drugs, specially approved by drug control department.

(iv)License

License shall be displayed in a prominent place.

(v) The drugs shall be purchased from a duly licensed dealer or a manufacturer.

(vi) 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.

(vii) 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. **(viii)** An Inspection book shall be maintained in Form 35.

(ix) The drugs after expiry, Physician's sample and the drugs meant for Government supply, shall not be stocked or sold.

(x) 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.

(xi) 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.[17]

Offences and penalties under Drug and Cosmetic

In India, import, manufacturing, sale, and distribution of drug is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945.

A license is required under the Drugs & Cosmetics Rules for manufacture of cosmetics for sale/distribution.

This license is issued by the state regulatory authorities (State Drug Control Department or State Food and Drug Administration).

Sr. No.	Offence	Penalties	
		First conviction	Subsequent conviction
1.	Import of adulterated or spurious drugs or cosmetics or any cosmetic containing any ingredient which may render it unsafe or harmful for the use under directions recommended.	Imprisonment upto 3 years and fine upto ₹ 5000.	Imprisonment upto 5 years or fine upto ₹ 10,000 or both.
2.	Import of drugs or cosmetics other than referred above the import of which is prohibited.	Imprisonment upto 06 months or fine upto ₹ 500 or both.	Imprisonment upto 1 year or fine upto ₹ 1000 or both.
3.	Import of drugs or cosmetics in contravention of any notification issued under section 10-A.	Imprisonment upto 3 years or fine upto ₹ 5000 or both.	

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.[18]
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.

CGMP AS PER REGULATORY AUTHORITIES

The FDA guarantees the quality of drug products by vigilant oversight of drug manufacturers' adherence to Current Good Manufacturing Practice (CGMP) regulations. These regulations set forth essential standards for the procedures, facilities, and controls involved in the production, processing, and packaging of drug products. They serve to ensure the safety and authenticity of a product, verifying that it contains the stated ingredients and potency as claimed.

The approval process for both new and generic drug marketing applications involves a comprehensive assessment of the manufacturer's compliance with CGMPs. FDA evaluators and inspectors determine whether the company possesses the necessary facilities, equipment, and capabilities for producing the intended drug. GMP, also known as 'cGMP,' stands for current Good Manufacturing Practices, which emphasize the importance of adopting contemporary tools and technologies that meet current industry standards. GMPs primarily focus on the manufacturing and production processes that impact the safety, consistency, and quality of the final product.

Safety in this context involves measures to prevent inadvertent contamination, spoilage, or misuse of end products, which could lead to adverse reactions and other healthrelated issues. These practices encompass sourcing raw materials from reputable suppliers, maintaining proper facility cleanliness, educating staff on regular handwashing, and thorough label checks before printing.

Consistency pertains to the capacity to manage manufacturing variables and procedures to ensure a uniform outcome on every occasion. Various factors, including the formulation, raw material choices, sanitation procedures, and the technical expertise of the cosmetic chemist, can influence product quality. Without proper control of these elements, product quality may fluctuate from one batch to another. Accurate and comprehensive documentation, along with strict adherence to these protocols, is crucial for maintaining product quality and ensuring consistency.

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, which were introduced due to the relatively brief development timeline for cosmetic products, allow for the prediction of product stability. It's a widely adopted approach to reinforce the predictions derived from accelerated stability tests through periodic post-launch monitoring of samples stored at room temperature. This data can also be valuable for product enhancement and refining the methods used for accelerated stability testing.

Understanding basic concepts

1. Instrumentation of Hot Plate

Principle

The major component of the heating plate is electric alloy wire, and the electric effect is the only real functioning principle. Electric work involves a current flowing through an electric alloy wire that heats up and conducts heat through the outer shell.

Construction

Hot plate apparatus has been constructed using a metal- surfaced laminated design, in which an electrical heater on a central electrically insulating plate is sandwiched between two thin electrically insulating plates.

Fig. Laboratory Hot Plate.

- **Working**

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 standalone 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.[21]

Advantages

- Hot plates are used in a laboratory as a heat source that can uniformly heat solutions and materials.
- They are considered much safer than traditional Bunsen burners because there is no open flame involved, just a heated plate.
- Hot plates are frequently used in the laboratory to perform chemical reactions, to heat samples, and for numerous other activities.

Disadvantages

- Hot plates used in labs present many potential dangers, such as burns, fires, and electrical shock, which can cause injuries, significant disruption of lab operations, and loss of scientific data.
- The hot plate is a source of heat when on, and for some time after it has been turned off.[22]

Preparation of SOP for Operation and Calibration of Hot Plate

1. Objective

To lay down the procedure for Operation and Calibration of hot plate.

2. Scope

This procedure is applicable for procedure for Operation and Calibration of hot plate.

3. Responsibility

QC Officer / QC Executive

4. Accountability

QC Manager.

5. Procedure

- **Operation Procedure**

✦ Ensure that the instrument is clean and suitable for use if not, then clean the all parts of the instrument with clean and dry cloth or by tissue paper.

✦ Switch 'ON' the main power supply of the instrument.

✦ Set the require temp. Speed low, medium and high with the help of knob.

✦ Put the sample container on hot surface.

✦ After completion of the work switch 'OFF' the main power supply. [23]

- **Calibration**

✦ Operate the instrument according to the operating instructions.

✦ Take the 100 ml of purified water in 500 ml of glass beaker; set the temperature at 50, 60, 70, 80, 90, 100° C and record the results in Calibration Record.

✦ Limit of temperature variation is ±2°C from the desired temperature. ▪ Frequency of oven Calibration is once in three months.

7. Precautions

- Instrument should be handled properly.
- If the instrument does not produce satisfactory results it should be labelled ' ▪ Under maintenance' or 'Out of Order'.[24]

8. Frequency

Calibration Frequency: Every month.

Instrumentation of pH Meter

- **Principle**

The working principle behind pH meters is potentiometry. This is the measurement of a solution's electric potential (voltage).

- **Construction**

It consists of thin glass with a glass bulb. It consists of a narrow tube or glass with a glass bulb filled with a potassium chloride chemical with a pH of 7.0. It also consists of a silver block of silver chloride attached to a silver element and generates the voltage.[25]

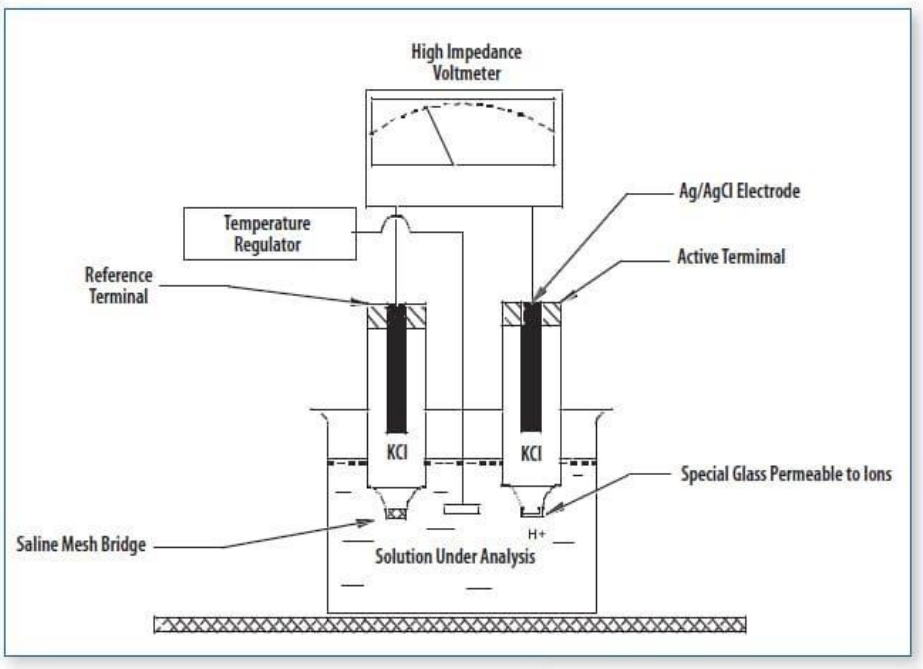


Fig. Parts Of pH meter

- **Working:** Potentiometric pH meters measure the voltage between two electrodes and display the result converted into the corresponding pH value. They comprise a simple electronic amplifier and a pair of electrodes, or alternatively a combination electrode, and some form of display calibrated in pH units.

- **Advantages**

✦ This is a quick and easy process for measuring pH.
✦ This gives precise results and provides an accurate pH value.
✦ It is used for various types of applications.
✦ Covers the acid and alkaline pH range (pH 01 to 14).
✦ The user can calibrate it with the standard buffer solution (pH 07, pH 04 and pH 09).
✦ An added advantage of the pH meter is that it is portable.
✦ Compared to reading a color strip or a pH indicator, a pH meter provides very accurate results.
✦ A small, battery-powered meter is a great option when using it at a specific site. [27]

Disadvantages

✦ Deposits on the electrode membrane can disrupt processes.
✦ The pH meter is often necessary to calibrate it.
✦ A special buffer solution is needed to calibrate it.

- PH calibration can be influenced by temperature and carbon dioxide uptake.
- There is a risk of breakage due to brittle glass electrodes.

Preparation of SOP for Operation and Calibration of pH Meter

1. Objective

To outline the procedure for operation of typical pH meter in the TRACES Centre and the undergraduate laboratories. [28] This procedure describes how to accurately measure the pH of a solution.

2. Scope

Applicable to digital pH meters located in TRACES Centre and UG Laboratory.
These include (but not limited to) Sartorius, Oakton and Mettler-Toledo brand devices.

3. Responsibility

User

4. Accountability

TRACES Manager/Course Instructor.[29]

5. Procedure / Calibration

Let all the samples get to the same temperature since pH readings rely on temperature. It is advised to compensate for temperature if the samples are not at 25 °C. Determine the temperatures of the samples using a thermometer and manually enter them into the meter, or use an ATC probe to communicate the temperatures automatically.

- Uncover the sample beakers and prepare the samples.
- Rinse the pH electrode in the sample beaker after rinsing it with deionize water beforehand. To prevent sample contamination, rinse the electrode with deionized water over a waste beaker. The identical beaker used for sample measurement should never be used to rinse the electrode. [30]
- The electrode should be inserted into the first sample measurement beaker with the electrode tip and junction completely submerged in the sample. The sample should then be stirred moderately and uniformly.
- Set the meter to begin taking a reading.
- Record the pH and temperature of the sample after waiting at least 1 to 2 minutes for a stable reading in the sample.

- If more samples are needed, repeat steps 3 through 6 again. For the most accurate sample measurements, submerge the electrode in each sample to the same depth [31]. After measuring the samples, clean the electrode with deionized water and put it in a pH electrode storage solution.

6. Precaution

- ✦ Handle buffer solutions with care.
- ✦ Always wear gloves, goggles, and lab coats while handling solutions.
- ✦ Buffers should always be read at accurate pH.
- ✦ Do not immerse electrodes in the buffer solutions before rinsing the electrodes thoroughly with deionized water.

7. Frequency: The frequency of calibrating a pH meter depends on usage and possible contamination.[32]

Introduction of lip balm

Dry lips are a common issue not only in winter but also in sunny seasons. Traditional lip balms frequently include harmful ingredients such as petrolatum, synthetic waxes, alumina, parabens, hydrogenated oils, and synthetic fragrances and dyes.

Lips have minimal melanin, which offers limited sun protection. Incorporating organic items like ghee, honey, and vitamin E into a broader skincare routine can effectively maintain lip hydration and health.

- **Honey** can assist in lightening dark lips by virtue of its natural bleaching properties, which effectively reduce lip skin darkness. Additionally, honey's high antioxidant content aids in the repair of daily UV damage.[33]
- **Ghee** contains vital fatty acids that effectively condition and nourish dry, chapped lips. Applying pure ghee to chapped lips can swiftly resolve issues of cracked and discolored lips.[34]
- **Beeswax** a naturally occurring substance secreted by female bees, is a common ingredient in cosmetics, especially lip balms. It offers excellent moisturizing properties, aids in shielding the lips from sun damage, has a pleasing aroma, and serves as a natural emulsifier.
- **Castor** oil deeply penetrates the skin tissue and its fatty acids effectively provide moisture to the lips

- **Vitamin E** assists in preserving the youthful, soft texture of your lips by minimizing signs of aging.

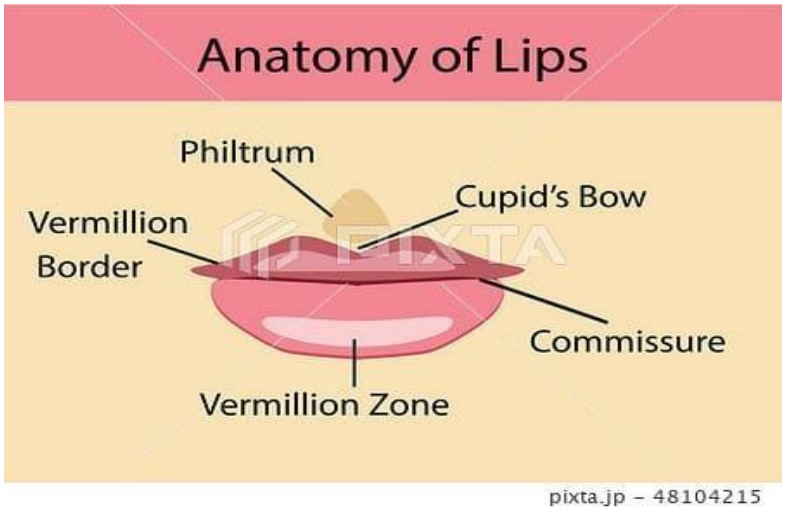
Anatomy of Lips

The lips perform many functions such as grasping, sucking and speaking. They consist of layers such as skin, superficial fascia, dark circle and surrounding muscles as well as areola tissue and mucous membrane. The edges of the lips are covered with a dry, red mucous membrane that blends seamlessly into the skin and contains numerous vascular papillae and tactile bodies.[35] Inside, the mucous membrane extends from the upper lip to the lower lip, forming two folds called the upper lip and upper lip. weaker inside. The areolar or submucosa tissue supports the coronary arteries surrounding the foramen orally near the free edge of the lip.

The coronary arteries include the upper and lower coronary arteries, which originate from the facial artery. The superior coronary artery is larger and communicates with its counterpart on the opposite side while giving off a small artery to the septic nasal arterial septum. Sometimes compression of this artery can help control nosebleeds. The labial or superior coronary vein begins as a network within the orbicularis oculi muscle of the upper lip. It runs along the coronary artery and finally flows into the facial vein just below the wings of the nose.

However, the veins that drain the lower lip, primarily the inferior coronary arteries, also connect to the facial vein, but are usually located slightly inferior to the superior labial vein. The primary branch from the lower lip generally passes to the submental vein and may then continue to the facial vein or sometimes to the anterior jugular vein.[36]

The nerves that provide sensory and motor functions to the lower lip come from the mental nerve, which exits the bone through the mental foramen. This nerve sends large branches to the mucous membrane, skin and fascia of the lip and chin.



Some lymphatic vessels from the lips lead to the gland just above the hyoid bone, while others direct their flow to the submandibular glands. The labial glands are located in the submucosa of the lips around the mouth. These glands produce mucus. If the ducts of these glands become blocked, cysts containing mucus can form.

Lip Disorders

Oral diseases and disorders can manifest themselves in different ways. Allergic reactions, often triggered by certain foods, drinks, medications, lipstick or environmental influences, can lead to swollen lips. Identifying and eliminating the cause usually solves the problem, but sometimes the cause of the swelling remains unknown. Conditions such as hereditary angioedema can lead to recurrent lip swelling.[37] Non-hereditary factors such as erythema multiforme, sunburn, cold, dryness or trauma can also cause lip swelling. Prolonged exposure to the sun can cause the lips, especially the lower lip, to dry out and harden, increasing the risk of future cancer. To avoid this, it is recommended to use a lip balm with sunscreen or wear a wide-brimmed hat to protect yourself from the sun.

Inflammation of the lips, called cheilitis, can affect the corners of the mouth and cause discomfort, irritation, redness, cracking, and anxiety. A lack of vitamin B2 in the diet can be a cause of cheilitis. Freckles and irregular brownish areas (melanotic patches) are common around the mouth and are generally harmless and long-lasting. However, many small, isolated brownish-black spots may indicate a hereditary disease called Puisz.

Jeghers syndrome, which leads to the formation of polyps in the stomach and intestines. Kawasaki disease, an unexplained illness that primarily affects infants and children up to 8 years of age, can cause dry, cracked lips and redness of the oral mucosa.[38,39]

Remember that lip balm is different from lip gloss and can be used by both men and women. The presence of melanin in the lips provides natural protection from the sun's harmful rays. Ingredients such as ghee, honey and vitamin E contribute to long-lasting hydration of the lips. The basis of the preparation is beeswax from natural sources, which acts as a natural emulsifier. Sesame oil is used in the preparation for its soothing properties, nourishes tissues, promotes healing, protects against UV rays and is even used to treat burns. Sesame oil has various effects on wound healing and is said to reduce blood cholesterol and glucose levels while having antioxidant properties.

Combining honey with olive oil and sesame oil may enhance their healing effects and possibly reduce bacterial colonization, although there is a lack of formal research to support this hypothesis. Castor oil penetrates deep into the skin, moisturizes it and is used to treat dry, chapped lips. Honey is known to lighten dark lips and protect them from UV rays. Recent research has examined the use of honey to prevent infections and treat burns, including its ability to promote tissue healing, granulation, epithelialization, and scar reduction. The antibacterial properties of honey make it ideal for preventing the growth of bacteria on the surface of the skin. This is attributed to its acidic nature, high osmotic properties, and ability to prevent granulation tissue from attaching to and detaching dressings.

1. Swelling

Allergic reactions can cause lip swelling, which may be due to hypersensitivity to certain foods, drinks, medications, lipstick, or environmental irritants. Identifying and addressing the underlying cause usually resolves the problem, but sometimes the cause of the swelling remains unknown. Hereditary angioedema is a condition that can cause recurring swelling of the lips. In addition, non-hereditary factors such as erythema multiforme, sunburn, cold, dry climate or trauma can also contribute to lip swelling.

2. Sun Damage

Sun damage, especially to the lower lip, can cause lips to become dry and hard. The presence of red spots or a clear white appearance indicates damage that increases the risk of possible

cancer.[42] To reduce this damage, it is recommended to use a lip balm with sunscreen or protect your face from the sun's harmful rays by wearing a widebrimmed hat.

3. Inflammation

Cheilitis, characterized by sore, irritated, red, cracked, and scaly corners of the mouth, may be associated with inflammation of the lips. This condition may be related to a lack of vitamin B2 in the diet.

4. Discoloration

Freckles and irregular brownish spots (melanotic spots) often appear around the mouth and can persist for a long time. These symptoms are usually mild and do not cause concern. On the other hand, if there are numerous small, isolated brown-black spots, this may indicate a hereditary disease called Puisz-Jeghers syndrome, which is characterized by the formation of polyps in the stomach and intestines. Kawasaki disease, a disease of unknown cause that primarily affects infants and children up to 8 years of age, can cause dry, cracked, and red oral mucosa.

5. Sores

A raised area or sore on the lip with clear edges could potentially be a sign of skin cancer. Some sores can develop as symptoms of various diseases, such as oral herpes simplex virus infection or syphilis. In addition, there are cases such as keratoacanthoma where the cause remains unknown.

Application of Lip Balm

Lip balms are products designed to be applied on the lips to prevent dryness and shield against adverse environmental factors. Various chemically formulated lip balms are currently available in the market, produced by companies like The Body Shop, Nivea, Himalaya, and Blister, among others.[43,44] Although cosmetic literature provides limited data on this type of formulation, references related to lipstick are often applicable because lip balm and lipstick share cosmetic similarities. This resemblance encompasses organoleptic and stability requirements, including resistance to temperature changes, pleasant taste, safety, ease of application, adherence, and simple removal. It's important to note that lip balm is distinct from lip gloss and is suitable for both men and women.

Creating lip balms involves a delicate balance of key ingredients, including butters, oils, waxes, and various additives. While many individuals diligently focus on maintaining healthy and radiant skin through weekly facials, daily exfoliation, anti-aging products, and more, lip care is often overlooked.[45] Natural lip balms provide a wholesome approach to preserve and enhance lip health. It's important to recognize that lip balms are often ingested by users, highlighting the need for regulatory scrutiny of their ingredients.

Dyes responsible for the color of lip balms can pose health risks when consumed.[46]

CONCLUSION

The Drugs and Cosmetics Act of 1940 is a comprehensive piece of legislation aimed at effectively regulating the pharmaceutical industry in India.

The formulation stored at both room temperature and in the refrigerator exhibited similar behaviour during stability tests. The organoleptic characteristics remained stable, and spread ability was assessed as "Good." It was concluded that storage under these conditions is sufficient, and the product's functionality is maintained. The melting point displayed a range, with the lip balm formulation showing improved stability. However, storage in an oven at 40 degrees was not recommended due to observed loss of product functionality during normal stability testing.

In summary, the lip balm prepared with natural ingredients is deemed safe for use, offering a better option for lip balm formulation. Adjusting the excipients or exploring different combinations may lead to new formulations with enhanced qualities. Based on the current studies, it is anticipated that the formulation will remain stable.

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