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An overview on Cosmetic and Science

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ABSTRACT:
Lip care products used daily may sometimes contain harmful heavy metals and preservatives that can inadvertently be ingested. Lead, cadmium, and chromium in these products can have adverse effects, including impacts on the heart, brain, and the potential to cause cancer. Additionally, certain preservatives have been linked to concerns such as breast cancer. Lip balms are formulated to keep the lips moisturized and shielded from environmental factors [1]. Organic lip balms are a healthier alternative, offering hydration and protection for chapped and dry lips while preserving their natural beauty and well-being [2]. It's important to note that lip balms are not gender-specific and can be used by both men and women. In a recent study, various organic ingredients like ghee and honey were found to be effective in maintaining lip health and hydration [3]. The lip balm in question was subject to evaluation based on sensory characteristics, spread ability, pH measurements, and stability. The results of stability tests conducted at different temperatures (room temperature, refrigeration, and oven conditions) for a period of 2 days revealed that the prepared lip balm exhibited a consistent texture and smooth application at room temperature (22.0°C) and under refrigeration (4°C). The pH of the lip balm was found to be close to neutral at 6.5. However, storage at elevated temperatures (40.0°C) is not advisable, as it led to a loss of product functionality during the stability assessment [4].

Keywords: Lip Balm, Lips, D & C Act, Hot Plate, pH Meter

I. INTRODUCTION:

Cosmetics encompass a broad category of products related to health and beauty, serving multiple functions that extend beyond enhancing one's appearance. These products are not only used for altering one's look but also play a significant role in skincare and overall body care. Additionally, they often contribute to adding a pleasant fragrance to an individual's persona [5].

Cosmetics consist of diverse chemical compounds, derived from both natural sources and artificially synthesized materials. They serve a range of purposes, such as personal hygiene and skincare, including cleaning and safeguarding the body and skin. In the modern era, cosmetics have become a prominent and essential part of daily life. Their significance gained considerable recognition post-World War II when it was acknowledged by social and medical experts that cosmetics not only enhance one's appearance but also have psychological effects on users, particularly on skin health. They contribute to maintaining the skin's suppleness and can delay the onset of wrinkles. Moreover, cosmetics can be valuable in preventing skin infections and protecting against sunburn. Cosmetics have been in use for millennia, with ancient civilizations like the Egyptians and Sumerians employing them. In Europe, the use of cosmetics persisted through the Middle Ages, involving practices like whitening the face and adding rouge to the cheeks. However, societal attitudes toward cosmetics have varied over time, with periods when their use was openly discouraged in Western history.

The cosmetic industry encompasses the production and distribution of a wide range of cosmetic products. This category includes items like makeup products such as foundation and mascara, skincare essentials like moisturizers and cleansers, hair care products such as shampoos, conditioners, and hair colours, as well as toiletries like bubble bath and soap [6].

The leading players in the cosmetic industry include Johnson & Johnson, L'Oréal, Gillette, Nivea, and Chanel.

India is making significant strides in technological advancements across various sectors, including medical science. During the COVID-19 pandemic, India demonstrated impressive innovation and active involvement in safeguarding public health and advancing safety measures. However, to support these efforts, it's crucial that the legal framework continually adapts to accommodate the evolving landscape in the field of medical science [7].

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The Drugs and Cosmetics Act of 1940 (DCA) is a key law governing the manufacture, import, and distribution of medicines in India. It was followed by the Drug and Cosmetics Rules of 1945, which categorized drugs into schedules and provided regulations for their sale, storage, and prescription. This article aims to explore the provisions of the DCA from 1940, highlight the legislative enhancements made over the past two decades, and discuss the new rules and legal provisions introduced within the Act [8].

Overview of drug and cosmetic act 1940 & 1945:

The Drugs and Cosmetics Act, 1940 is a legislative act in India that falls under the jurisdiction of the Parliament. Its primary purpose is to regulate the import, manufacturing, and distribution of drugs within the country. The primary objective of this act is to ensure that all drugs and cosmetics available in the Indian market meet strict safety, effectiveness, and quality standards.

Complementing this act, the Drugs and Cosmetics Rules, 1945, provide a framework for categorizing drugs into different schedules. These rules also offer guidance on the proper storage, sale, display, and prescription practices for drugs falling within each schedule.

Originally, this legislation was known as the Drug Act and was initially enacted in 1940. The formulation of the original act was based on the recommendations of the Chopra Committee, which was established in 1930. Subsequently, the related Drugs Rules were introduced in 1945. Over the years, the Drugs and Cosmetics Act, 1940, has undergone several amendments and is now recognized under its current title [9].

Under this act, a "cosmetic" is defined as any product designed for the application on the human body to enhance beauty or provide cleansing benefits. It's worth noting that this definition explicitly excludes soaps. In a notable amendment made in 1964, Ayurveda and Unani drugs were also incorporated into the regulatory framework.

According to the Act, a "Cosmetic" is defined as any product designed to be applied to the human body or any of its parts, through methods like rubbing, pouring, sprinkling, or spraying. These products are intended for purposes such as cleansing, enhancing beauty, improving attractiveness, or changing appearance. The definition also encompasses products meant to be used as ingredients in cosmetics.

Chapter III of the Drugs & Cosmetics Act pertains to the import of drugs and cosmetics. The Act, along with rules 134A, 135, and 135A of the Drugs & Cosmetics Rules, 1945, imposes restrictions on the import of specific cosmetics.

These are:
1.Any cosmetic which is not of standard quality.
2.Any cosmetic for the import of which a license is prescribed, otherwise than under, and in accordance with, such license.
3.Any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended.
4.Any cosmetic the import of which is prohibited by rule
5.Any cosmetic containing hexachlorophene
6.Any cosmetic in which lead or arsenic compound has been used for coloring purpose;
7.Any cosmetic which contains mercury compounds
8.Any misbranded or spurious cosmetic.

Objectives of the Drugs and Cosmetics Act:

The primary goal of the Drugs and Cosmetics Act is to establish accountability for medical technology and pharmaceutical companies in cases of negligence or the delivery of substandard services. One of the central purposes behind the enactment of this law is to safeguard against the adulteration of medicines. Additionally, there are further objectives outlined below:

- Regulation of the sale, import, and distribution of drugs and cosmetics by means of licensing.
- Ensuring that only qualified individuals are involved in the import, distribution, and sale of drugs and cosmetics.
- Preventing substandard drug quality, presumably in order to maintain high medical treatment standards. Regulation of the production and sale of Ayurvedic, Siddha, and Unani drugs. [10]
- To form a Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committees (DCC) for allopathic and allied drugs, as well as cosmetics.

- **Relevant definitions in the Drugs and Cosmetics Act**:

To gain a comprehensive grasp of the Act's provisions, it is essential to acquaint ourselves with specific terms explicitly defined within the legislation. Herein, we present definitions of several terms used throughout the Act.

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- **Cosmetic:**

Section 3 of the Act provides a definition for this term, which encompasses any product meant to be "sprayed, poured, rubbed, or sprinkled on, introduced into, or applied" to the human body or any of its parts with the purpose of cleansing, enhancing beauty, promoting attractiveness, or changing appearance. Additionally, this definition encompasses items designed for use as components within cosmetics [11].

(i) **Manufacture in relation to drugs or cosmetics:**

Even though the Act doesn't expressly define the term 'manufacture,' it encompasses any process, whether complete or partial, employed in the "creation, modification, adornment, finalization, packaging, labelling, disassembling, or other handling or adjustment of any drug or cosmetic for the purpose of its distribution or sale." However, it excludes the compounding or dispensing of drugs or cosmetics as part of regular retail business [12].

(ii) **Misbranded cosmetic**:

Under Section 17C, a cosmetic is considered misbranded if it falls into one of the following categories:

- When it contains an unprescribed colour, or
- When the cosmetic is not labelled as it was prescribed to be, or
- When the label or container of the cosmetic or anything that accompanies the cosmetic happens to bear any statement that is false or misleading in nature.

(iii) **Spurious cosmetic:**

As per Section 17D, a cosmetic is classified as a spurious cosmetic when:

- If it has been imported under a name belonging to some other cosmetic, or
- If the cosmetic is an imitation of or a substitute for another cosmetic, or happens to resemble another cosmetic in a "manner likely to deceive", or bears on it or on its label or container the name of some other cosmetic, or
- If the label or container of the cosmetic bears the name of any fictitious person or company claiming to be the manufacturer of the cosmetic, or
- If the cosmetic claims to be the product of a manufacturer who hasn't really produced the cosmetic.

❖ **Salient features of the Drugs and Cosmetics Act:**

The Act has made substantial strides in regulating the pharmaceutical sector in India, thus ensuring the safeguarding of public health and safety. Key highlights of the Act can be summarized as follows:

- The maximum penalty is life imprisonment and a fine of Rs. 10 lakhs or three times the confiscated goods' value, whichever is greater.
- Other gazette officers, in addition to officers from the Drug Controller's Office, are authorized to initiate prosecution under the Act; some of the offences are cognizable and non-bailable.
- Specialised courts for the trial of offences covered by the Act; Provision for the aggregation of minor offences. [13]

1. **Drugs and Cosmetics Rules:**

To complement the Drugs and Cosmetics Act of 1940, additional sets of rules have been introduced to adapt to the evolving pharmaceutical industry, influenced by technological advancements and other industry changes.

2. **Drugs and Cosmetics Rules, 1945:**

The Drugs and Cosmetics Rules of 1945 serve as supplementary Indian government regulations to support the Drugs and Cosmetics Act of 1940. These rules classify medicines into schedules and provide directives for their storage, sale, display, and prescription based on the respective schedule. Within these rules, there are provisions for categorizing drugs into schedules, stipulations for the handling of drugs, and requirements for labelling as outlined in Rule 67G and Rule 97. Moreover, these rules establish the Drugs Technical Advisory Board as the ultimate authority for decisions concerning drug technical specifications.

3. **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

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encompass provisions that promote clinical research and address complex subjects,

4. **Manufacturing of cosmetics science:**

Manufacturing cosmetics now requires obtaining a license from the Licensing Authority. These licenses are granted upon payment of the necessary fees and meeting specified conditions. In most cases, the regulations that apply to licenses for manufacturing allopathic drugs also apply to cosmetic licenses. The production of cosmetics containing hexachlorophene or mercury compounds, as well as misbranded, spurious, or substandard cosmetics, is strictly prohibited. [14] Manufacturers of cosmetics must adhere to the following conditions:

(i) The manufacturing facility must be kept clean, located in a sanitary environment, and must be separate from any areas used for residential purposes.

(ii) Sufficient space and personnel should be available for the manufacturing process, and it should be carried out under the guidance and personal supervision of qualified technical staff. At least one of these staff members should be a full-time employee and possess a pharmacy diploma approved by the Pharmacy Act or have passed the intermediate examination with chemistry as one of the subjects. However, for small-scale manufacturers employing no more than 5 individuals, the Licensing Authority may consider someone with at least 4 years of general training and experience in cosmetic manufacturing as competent technical staff.

(iii) The manufacturing facility must have suitable facilities for testing both raw materials and finished products, or arrangements should be in place with approved institutions for this purpose. Records of these tests must be kept for a minimum of 3 years from the manufacturing date.

(iv) It is prohibited to manufacture cosmetics that contain colours not specified by the Bureau of Standards, colours with arsenic levels exceeding 2 parts per million (P.P.M), lead levels exceeding 20 P.P.M, or heavy metals (other than lead) exceeding 100 P.P.M. in their composition. Additionally, the use of arsenic or lead compounds for cosmetic colouring is not allowed.

(v) Inspectors must have the authority to examine premises, records, and obtain samples of manufactured products. An inspection logbook should be kept to record the remarks made by the inspectors.

(vi) Manufacturers must maintain production records in accordance with Schedule U (1) for a minimum of 3 years. Similar to pharmaceuticals, cosmetic manufacturing licenses are valid until December 31 of the year following their issuance. These licenses may be revoked or suspended if the licensee does not adhere to the aforementioned conditions. In case of a dispute, a licensee can appeal to the State Government within three months of suspension or cancellation.

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

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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.	

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. [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.

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❖ **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 license. 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 [19]

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 health-related 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.

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

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flow, particularly after exposure to conditions designed to stress each specific Property.
- Consider variation in process conditions. [20]
- 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, 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**

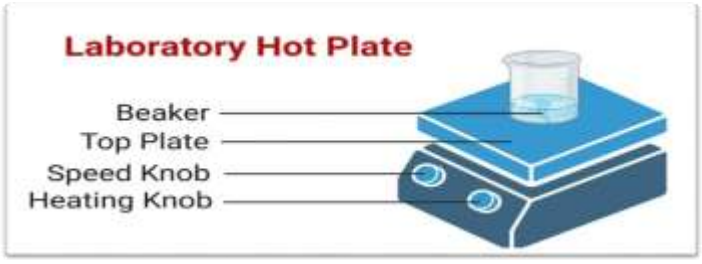
1. Instrumentation of Hot Plate:

- **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.



- **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 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. [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:**

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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

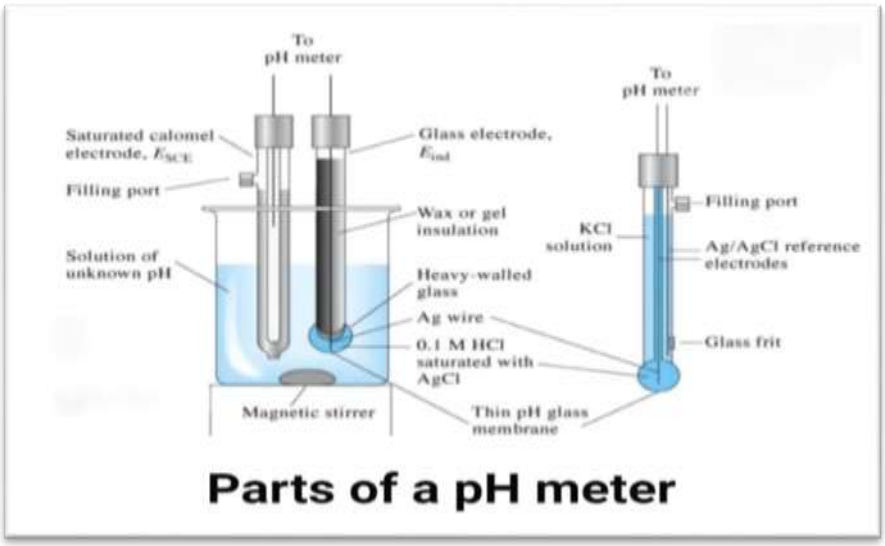
❖ **Instrumentation of pH Meter:**

● **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 filledwith 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]



● **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 alternativelya combination electrode, and some form of display calibrated in pH units.

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- **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 01to14).
- The user can calibrate it with the standard buffer solution (pH07, pH04 and pH09).
- 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 specificsite. [27]

- **Disadvantages:**
- Deposits on the electrode membrane can disrupt processes.
- The pHmeter is o ten necessary to calibrate it.
- A special buffer solution is needed to calibrate it.
- PH calibration canbe influenced by temperature and carbon dioxide up take.
- 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 asolution.

2. Scope:

Applicable to digital pH meters located in TRACES Centre and UG Laboratory. These include (butnot limitedto)Sartorius, OaktonandMettler-Toledo brand devices.

3. Responsibility:

User

4. Accountability:

TRACESManager/CourseInstructor [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 tipand 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 stablereadingin 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 labcoats 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

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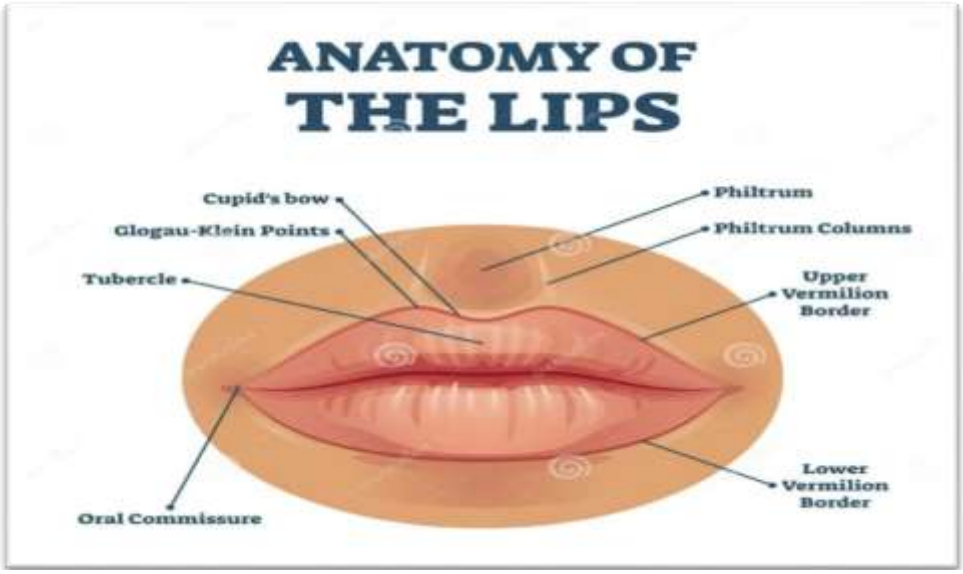
limited sun protection. Incorporating organic items like ghee, honey, and vitamin E into a broader skincare routine can effectively maintain lip hydration and health.

- **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 serve multiple functions such as grasping, suction, and speech. They are composed of layers including the skin, superficial fascia, the orbicularis muscle, and surrounding muscles, along with areolar tissue and the mucous membrane. The lip margins are covered with dry, red mucous membrane, which seamlessly connects with the skin and contains numerous vascular papillae and touch corpuscles [35] Internally, the mucous membrane extends from the upper to the lower lip, forming two folds known as superioris and inferiors in the middle. The areolar tissue or sub-mucous layer holds the coronary vessels, which encircle the buccal orifice near the lip's free edge. The coronary vessels include the superior and inferior coronary arteries, originating from the facial artery. The superior coronary artery is larger and connects with its counterpart on the opposite side while also giving off a small artery to the septum arterial septicnasi Occasionally, compressing this artery can help control nasal bleeding.

The superior labial or coronary vein begins as a network within the orbicularis muscle of the upper lip. It follows the path of the coronary artery and eventually joins the facial vein just below the nose's wings. In contrast, the veins that drain the lower lip, mainly the inferior coronary, also connect to the facial vein, but it typically occurs slightly below the superior labial vein. The primary branch from the lower lip commonly descends towards the submental vein and then may 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 originate from the mental nerve, which emerges from the bone through the mental foramen. This nerve sends substantial branches to the mucous membrane, skin, and fascia of the lip and chin.



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A portion of the lymphatic vessels from the lips leads to a gland located just above the hyoid bone, while others direct their flow toward the submaxillary glands. The labial glands are positioned within the submucous layer of the lips around the mouth's opening. These glands produce a mucous fluid. In cases where the ducts of these glands become blocked, it can result in the development of mucous retention cysts.

❖ **Lip Disorders:**

Diseases and disorders related to the lips can manifest in various ways. Allergic reactions, often triggered by specific foods, beverages, drugs, lipstick, or environmental irritants, may lead to lip swelling. Identifying and eliminating the underlying cause usually resolves the issue, but sometimes the source of the swelling remains unknown. Conditions like hereditary angioedema can cause recurrent episodes of lip swelling [37]Non-hereditary factors, such as erythema multiforme, sunburn, cold weather, dry conditions, or injuries, can also result in swollen lips. Prolonged sun exposure may cause the lips, especially the lower lip, to become dry and hardened, increasing the risk of subsequent cancer. To prevent this, using lip balm with sunscreen or wearing a wide-brimmed hat for sun protection is recommended.

Inflammation of the lips, known as cheilitis, may affect the corners of the mouth, leading to discomfort, irritation, redness, cracking, and scariness. A deficiency of vitamin B2 in the diet can be a contributing factor to cheilitis. Freckles and irregular brownish areas (melanotic macules) are common around the lips, typically harmless and long-lasting. However, multiple small, scattered brownish-black spots may indicate a hereditary condition called Peutz-Jeghers syndrome, which results in polyp formation in the stomach and intestines. Kawasaki disease, an unexplained condition primarily affecting infants and children up to 8 years old, can lead to dry, cracked lips and reddening of the mouth lining [38] [39]

Lip balms are designed to be applied to the lips to prevent dryness and shield them from environmental factors. Various chemically formulated lip balms are available in the market, produced by companies such as The Body Shop, Nivea, Himalaya, Blister, and others. However, there's limited data in cosmetic literature specifically addressing lip balm formulations, although references to lipstick are often relevant because of the similarities in their cosmetic nature. These commonalities include organoleptic and stability requirements, such as resistance to temperature changes, a pleasant taste, safety for use, smooth application, adhesion, and easy removal.

It's important to note that lip balm differs from lip gloss and is suitable for use by both men and women. The presence of melanin in the lips offers some natural protection against harmful sunrays. Ingredients like ghee, honey, and vitamin E contribute to long-lasting lip hydration. Beeswax forms the base of the formulation, obtained from natural sources and functioning as a natural emulsifier. Sesame oil is included in the formulation for its soothing properties, tissue nourishment, assistance in healing, protection against UV radiation, and even its use in treating burns. Sesame oil has shown various effects on wound healing and has been reported to reduce cholesterol and blood glucose levels while exhibiting antioxidant properties.

Olive oil has been studied for its antioxidant properties and has demonstrated positive effects in cardiovascular diseases and certain types of cancer. In traditional medicine, olive oil has been considered effective for skin healing, although this aspect hasn't been extensively studied in modern medicine. There have been limited investigations into the healing properties of sesame oil and olive oil, despite some studies showing their potential benefits. Conversely, honey has been thoroughly studied in both animal and human subjects for its healing properties.

Combining honey with olive oil and sesame oil may enhance their wound-healing effects and potentially reduce bacterial colonization, although this hypothesis lacks formal research. Castor oil deeply penetrates the skin, providing moisture and is used for treating dry and chapped lips. Honey is known for lightening dark lips and protecting them from UV radiation. Recent studies have explored honey's application in preventing infections and treating burns, including its ability to facilitate tissue healing, granulation, epithelialization, and scar reduction. Honey's antimicrobial properties make it suitable for preventing bacterial growth on the skin surface. This is attributed to its acidic nature, high osmotic properties, and its capacity to prevent wound dressings from sticking and dislodging granulation tissue.

Vitamin E, sourced as tocopherol acetate,

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has long been recognized as an antioxidant. Although it is generally safe for skin care products, it can, in rare cases, cause allergic contact dermatitis (ACD). While tocopherol acetate is included in various lip care and cosmetic products, it is important to note the increasing incidence of sensitization to vitamin E. Vitamin E is also used to maintain lip softness and as an anti-aging agent [41] Additionally, rose oil is incorporated for fragrance in the formulation.

1. Swelling:

Allergic reactions can lead to lip swelling, which can result from sensitivities to certain foods, beverages, medications, lipstick, or environmental irritants. Identifying and removing the underlying cause typically resolves the issue, but sometimes the cause of the swelling remains unknown. Hereditary angioedema is a condition that can cause recurrent episodes of lip swelling. In addition, non-hereditary factors such as erythema multiforme, sunburn, cold and dry weather, or injuries can also contribute to lip swelling.

2. Sun Damage:

Sun damage, particularly to the lower lip, can cause the lips to become dry and hardened. The presence of red speckles or a white filmy appearance indicates damage that elevates the risk of potential cancer [42]. To mitigate this damage, it's advisable to use a lip balm containing sunscreen or to protect the face from the sun's harmful rays by wearing a wide-brimmed hat.

3. Inflammation:

Cheilitis, characterized by painful, irritated, red, cracked, and scaly corners of the mouth, can be associated with inflammation of the lips. This condition may be linked to a dietary deficiency of vitamin B2.

4. Discoloration:

Freckles and irregular brownish areas (melanotic macules) are frequently found around the lips and can persist for an extended period. These marks are typically benign and not a cause for concern. On the other hand, if multiple small, scattered brownish-black spots are present, this could indicate a hereditary condition known as Peutz-Jeghers syndrome, characterized by the formation of polyps in the stomach and intestines. Kawasaki disease, a condition of unknown origin that primarily affects infants and children up to 8 years old, can result in lip dryness, cracking, and redness in the mouth lining.

5. Sores:

A raised area or a sore on the lip with well-defined edges could potentially be a manifestation of skin cancer. Some sores might arise as symptoms of different medical conditions, like oral herpes simplex virus infection or syphilis. Additionally, 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].

II. 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

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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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