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Design, Development, and Evaluation of Lozenges: A Comprehensive Study

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Abstract: Lozenges are solid, flavored medicated dosage forms designed for slow dissolution in the oral cavity, offering both localized and systemic drug delivery. They provide a convenient alternative to conventional tablets and syrups, enhancing patient compliance, especially in pediatric and geriatric populations. This study focuses on the formulation and evaluation of medicated lozenges using different pharmaceutical excipients to optimize drug release, stability, and organoleptic properties. Lozenges were formulated using various base materials such as sucrose, sorbitol, and hydrocolloids, along with active pharmaceutical ingredients (APIs) targeting conditions like sore throat, cough, or fungal infections. The formulations were developed using the molding, compression, and heating methods to achieve desired characteristics. Excipients such as sweeteners, flavors, and binders were incorporated to enhance palatability and stability. The prepared lozenges were subjected to extensive evaluation, including hardness, friability, weight variation, drug content uniformity, dissolution profile, and stability studies. Results indicated that the optimized formulation exhibited adequate mechanical strength, uniform drug distribution, and a controlled release profile, making it suitable for therapeutic applications. The study concludes that lozenges provide an effective and patient-friendly drug delivery system, particularly beneficial for treating localized oral and throat infections. Further research can explore advanced formulation techniques and novel excipients to enhance the efficacy and patient acceptability of medicated lozenges.

Keywords: Lozenges, Excipients, Sweeteners, Chewable tablet, OTC, API, PEG, WHO, USP.

I. INTRODUCTION

The word "lozenge" is derived from the Old French word "losenge", which originally meant a rhombus or diamond-shaped object. This, in turn, came from the Latin "lausia", meaning a stone or slab ⁽¹⁾. Lozenges are solid oral dosage forms designed to dissolve slowly in the mouth. They are not meant to be swallowed whole or chewed. Lozenges are solid dosage forms that come in various shapes, such as disc, round, oblong, or triangular, and are designed to be dissolved slowly in the mouth. The viscous liquid produced during dissolution stays in contact with the affected area for an extended period. They are used to treat local infections in the mouth and throat. Common active ingredients include anesthetics, antitussives, and antiseptics ⁽²⁾. Lozenges are a solid dosage form that contains flavoring and sweetening agents, designed to dissolve or slowly disintegrate in the mouth or oral cavity. They are primarily used for localized effects in the oral cavity but can also produce systemic effects if effectively absorbed through the buccal lining and pharynx ⁽³⁾⁽⁵⁾. A lozenge is a solid formulation made of sugar and gum, with the gum providing strength and cohesion while also enabling the gradual release of the medication. Lozenges are used to deliver medication to the mouth and throat, allowing for slow absorption in digestion or cough treatments. They may contain an anesthetic, a demulcent, or an antiseptic ⁽⁴⁾. Lozenges, a unique mouth freshener with distinct flavors, are part of the Rs 100-crore Parle brand portfolio, which ranks among Parle's top ten best-selling products. The product line is now expanding to include new variants. Popular flavors such as orange, pineapple, mango, mint, pan, strawberry, and grapes are already well-received, especially among children ⁽⁶⁾.

A. Advantages:- ⁽⁷⁾⁽⁸⁾

- 1) It can be administered to patients who have difficulty swallowing.
- 2) Easy to use for both elderly and pediatric patients.
- 3) Prolongs the presence of the medication in the oral cavity for enhanced effectiveness.
- 4) Enables drug absorption through the buccal cavity.
- 5) The taste of the medication can be masked using sugars and flavoring agents.
- 6) It Can improve bioavailability.
- 7) Reduces the frequency of dosing.
- 8) Does not require disintegration.
- 9) It Can be taken without water.
- 10) It requires less time for production.
- 11) More cost-effective to manufacture.
- 12) Can be discontinued if the dose is no longer needed.

B. Disadvantages:- ⁽⁷⁾⁽⁸⁾

- 1) Some drugs may not be compatible with lozenge formulations, such as those containing aldehyde-based candies (e.g., Benzocaine).
- 2) Uneven drug distribution in saliva may limit effectiveness for localized therapy.
- 3) There is a possibility of the drug being swallowed along with saliva, reducing its intended effect.
- 4) Lozenges may be mistaken for candy by children, leading to accidental consumption.
- 5) Risk of accidental swallowing of the entire dose.
- 6) May be mistaken for candy by children, leading to accidental ingestion.
- 7) Hard candy lozenges require high temperatures for production.
- 8) Hard lozenges may develop a grainy texture over time.

II. HISTORICAL NAMES OF LOZENGES ⁽⁹⁾

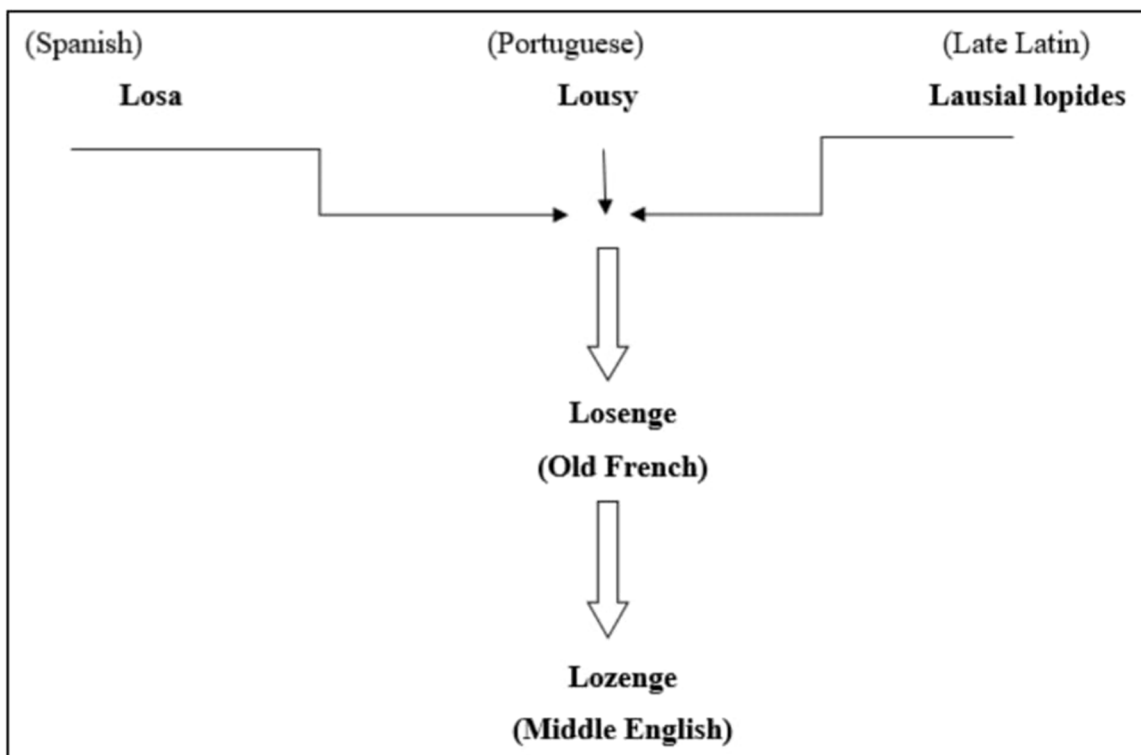


Fig 1

III. TYPES OF LOZENGES ⁽³⁾⁽⁸⁾⁽¹⁰⁾

Lozenges can be classified based on different criteria:

1) Based on Site of Action

- Local effects: Used for antiseptics, decongestants, etc.
- Systemic effects: Used for vitamins, nicotine, and other systemic medications.

2) Based on Texture and Composition

- Chewy or caramel-based medicated lozenges:- eg- Vitamins
- Compressed tablet lozenges:- eg- Troches
- Soft lozenges:- eg- Bentsil
- Hard candy lozenges:- eg- Lollipops

A. *Chewy or caramel-based medicated lozenges* ⁽¹¹⁾⁽¹²⁾⁽¹⁴⁾⁽¹⁵⁾⁽¹⁶⁾⁽¹⁷⁾

Chewable tablets are a type of oral dosage form that must be chewed before being swallowed, rather than taken whole. They should be designed with a pleasant taste and texture to ensure ease of use. These tablets are especially useful for various patient groups, including children, adults, and the elderly, who may struggle with swallowing whole tablets due to their size or personal difficulty. The availability of safe and convenient dosage forms plays a vital role in clinical practice, helping to improve medication adherence. Chewable tablets are widely available in both prescription and over-the-counter (OTC) medications.



Fig 2 ⁽¹³⁾

1) *Benefits of Chewable Tablets*

Chewable tablets are designed to be chewed before swallowing, eliminating the need to swallow them whole. Their primary purpose is to provide a convenient and accurate dosage form, especially for children or elderly individuals who have difficulty swallowing tablets. The advantages of chewable tablets include:

- Enhanced bioavailability by bypassing the disintegration step, leading to faster dissolution.
- Better patient compliance, particularly in children, due to their pleasant taste.
- Greater convenience as they do not require water for consumption.
- Alternative to liquid dosage forms, especially in situations where a rapid onset of action is needed.
- Faster drug absorption, leading to quicker therapeutic effects.
- Unique product identity, offering a competitive edge in the market.
- Easier consumption for larger doses, as they eliminate the need to swallow large tablets.
- Improved drug effectiveness, as chewing breaks the tablet into smaller particles before ingestion, aiding absorption.

2) Drawbacks of Chewable Tablets

Despite their benefits, chewable tablets have certain limitations, particularly with unpleasant-tasting medications or those requiring high doses.

Some common disadvantages include:

- Contains sorbitol, which may cause diarrhea and bloating in some individuals.
- Flavored agents in chewable tablets might lead to oral ulcers.
- Prolonged chewing may cause discomfort or strain in facial muscles.
- Hygroscopic nature, meaning they absorb moisture and must be stored in a dry environment.
- Fragile structure, often displaying effervescent or brittle properties.
- Lower mechanical strength, making them prone to breaking, requiring careful handling.
- Special packaging needs, ensuring the stability and safety of the medication.

3) Ingredients

- **Candy Base:** The base consists of a mixture of sugar and corn syrup in a ratio ranging from 50:50 to 75:25 (sugar to corn syrup).
- **Humectants:** These ingredients enhance the chewiness and texture of the candy. Examples include glycerine, propylene glycol, and sorbitol.
- **Whipping Agents:** Used to incorporate air into toffee-based confections, these agents help achieve the desired soft chew texture. Common examples include milk protein, egg albumin, gelatin, xanthan gum, starch, pectin, algin, and carrageenan.
- **Lubricant:** Vegetable oils and fats act as lubricants to prevent the candy from sticking to the teeth while chewing.
- **Medicament:** Lozenges contain 35-40% of the active medicinal ingredient.
- **Seeding Crystals:** Fine powdered sugar (3-10%) is added to warm candy mass to accelerate crystallization, helping the base solidify into tablets more quickly.

4) Manufacturing Process

The candy mixture is cooked at a temperature range of 95–125°C and then transferred to a planetary or sigma blade mixer.

↓

The mixture is allowed to cool to 120°C, after which a whipping agent is added when the temperature drops below 105°C.

↓

Next, medicaments are incorporated when the temperature is between 95–105°C.

↓

Color is dispersed in humectants and added when the temperature falls below 85°C, followed by the addition of a lubricant when the temperature is above 80°C.

B. Compressed Tablet Lozenges ⁽¹⁹⁾⁽²⁰⁾⁽²¹⁾⁽²²⁾⁽²³⁾

If the active ingredient is sensitive to heat, it can be formulated into a lozenge through compression. The granulation process follows a method similar to that used for conventional compressed tablets. However, lozenge tablets differ from regular tablets in terms of taste, non-disintegrating properties, and slower dissolution rates. Lozenges are produced using high-pressure compression equipment to create a harder tablet, ensuring it dissolves gradually in the mouth. The ingredients for compressed lozenges include sugar-based or sugar-free vehicles. Sugar-based vehicles commonly used are dextrose and sucrose, while sugar-free alternatives include mannitol, sorbitol, and polyethylene glycol (PEG) 6000 or 8000. Some commercially available sugar-based vehicles are Emdex, Nu-tab, Sweetrex, Mola-tab, Hony-tab, and Sugartab. Additional fillers include dicalcium phosphate, calcium sulfate, calcium carbonate, lactose, and microcrystalline cellulose. To bind the granules together, ingredients such as acacia, corn syrup, sugar syrup, gelatin, polyvinyl-pyrrolidone, tragacanth, and methylcellulose are used. Lubricants, which enhance the flow of the final lozenge mixture, include magnesium stearate, calcium stearate, stearic acid, and PEG. For coloring, water-soluble and lakolene dyes are used.



Fig 3⁽¹⁸⁾

1) *Ingredients*

Tablet Base:

- Sugars: Dextrose, sucrose.
- Sugar-Free Vehicles: Sorbitol, mannitol, polyethylene glycol 6000 and 8000.
- Additional Fillers: Calcium carbonate, dicalcium phosphate, calcium sulfate, and microcrystalline cellulose.
- Binders: Binders help maintain the integrity of the tablet by holding particles together as granules. Common binders used in the production of compressed tablet lozenges include acacia, corn syrup, sugar syrup, gelatin, polyvinylpyrrolidone, tragacanth, and methylcellulose.
- Lubricants: Lubricants enhance the flow of the final troche mixture and may include magnesium stearate, calcium stearate, stearic acid, and polyethylene glycol (PEG).
- Colors: Water-soluble and lakolene dyes.
- Flavors: Ginger, clove, etc.

2) *Manufacturing Processes*

In this method, all ingredients are thoroughly mixed and directly compressed into lozenge tablets.

3) *Wet Granulation*

The wet granulation process involves grinding sugar using mechanical agitation and passing it through a sieve with a mesh size of 40–80. The medicament is then added to the sugar mass and mixed uniformly. To facilitate granulation, an adequate amount of sugar syrup or corn syrup is incorporated into the mixture. The homogenized mass is then screened through a sieve with a mesh size of 2–8 to form wet granules. These granules are dried and further milled, passing through a sieve with a mesh size of 10–30. Finally, suitable flavors and lubricants are added before compressing the granules into the desired tablet lozenge size.

4) *Process Flow*

Sugar is finely ground using a mechanical agitator and passed through a sieve with a 40–80 mesh size.



The medicament is added, and the mixture is blended.



The blend undergoes granulation with sugar or corn syrup and is screened using a 2–8 mesh sieve.



The wet granules are dried, milled, and passed through a 10–30 mesh sieve. Flavors and lubricants are added before final compression into lozenges.

C. Soft Lozenges⁽²⁵⁾⁽²⁶⁾⁽²⁷⁾⁽²⁸⁾

Soft lozenges are a type of medicated confection designed to dissolve gradually in the mouth, offering both therapeutic effects and a pleasant flavor. They are made with a soft, chewable base, making them easy to consume without the need for chewing or swallowing, unlike traditional tablets or capsules. Unlike hard lozenges, soft lozenges have a flexible texture due to the presence of humectants such as glycerin, sorbitol, or propylene glycol. These components help maintain moisture, improve texture, and enhance stability. Soft lozenges are commonly used to deliver active ingredients like cough suppressants, throat soothers, vitamins, and herbal extracts.



Fig 4⁽²⁴⁾

1) Ingredients

- Base: Polyethylene glycol 1000, Polyethylene glycol 1450, chocolate, sugar acacia base.
- Suspending agent: Silica gel, etc.

2) Manufacturing Process

Soft lozenges are produced either by hand-rolling and cutting into pieces of the desired size and thickness or by heating all ingredients with the medication to approximately 50°C and pouring the mixture into a plastic mold. When using polyethylene glycol, the mold cavity should be slightly overfilled to account for contraction as it cools. However, this is unnecessary for chocolate, as it does not shrink.

For soft lozenges containing Clotrimazole, the molding method is used with increased amounts of polyethylene glycol, xanthan gum, or xylitol. These agents enhance the hardness of the lozenges, affecting their disintegration time, so careful control of their quantity is necessary.

D. Hard Candy Lozenges⁽³⁰⁾⁽³¹⁾⁽³²⁾

Hard candy lozenges are made from sugar and other carbohydrates, forming an amorphous (noncrystalline) or glassy texture. They can also be described as solid sugar syrups. The moisture content of hard candy lozenges should be between 0.5% and 1.5%, with a weight range of 1.5 to 4.5 grams. These lozenges should dissolve slowly and evenly over 5 to 10 minutes without disintegrating. Since their preparation requires high temperatures, heat-sensitive ingredients cannot be included. The main ingredient is corn syrup, typically measured on the Baume scale, with 43° Baume corn syrup being preferred. Sweeteners such as sucrose, dextrose, maltose, and lactose are added to enhance taste. Acidulants, including citric, tartaric, fumaric, and malic acid, are used to improve flavor. Colors such as FD&C dyes, orange color paste, and red color cubes may be added. Flavoring agents commonly used include menthol, eucalyptus oil, spearmint, and cherry flavoring. Medicinal ingredients can also be incorporated into hard candy lozenges at concentrations of 2% to 4%, in either liquid or solid form. Additionally, salvage solutions can be used in the formulation.



Fig 5 ⁽²⁹⁾

1) *Ingredients*

- **Base:** The formulation includes corn syrup, which is available on a Baume scale. A 43° Baume corn syrup is preferred for hard candy lozenges. Other options include sugar bases and candy bases.
- **Sweeteners:** This category comprises sucrose, dextrose, maltose, and lactose.
- **Acidulants:** Citric acid, tartaric acid, fumaric acid, and malic acid are utilized as acidulants. These components are added to the candy base to enhance the flavor profile of the final product.
- **Colorants:** Approved FD&C colors such as orange, red, green, and yellow are used.
- **Flavors:** Menthol, eucalyptus oil, spearmint, and cherry flavoring are commonly incorporated.
- **Active Ingredients:** Medicinal compounds can be integrated into hard candy lozenges at a concentration of 2–4%.

2) *Manufacturing process*

A hard-candy lozenge containing an antacid, produced through a process that involves:

- ↓
- Mixing liquid sucrose, corn syrup, and a carbonate antacid.
- ↓
- Heating the mixture to a first temperature using a cooking method.
- ↓
- Transferring the mixture to a second cooking chamber and heating it to a second temperature.
- ↓
- Exposing the mixture to a vacuum.
- ↓
- Transferring the mixture to an in-line mixer.
- ↓
- Mixing it while adding a cold-flow enhancer, flavoring, and optional coloring.
- ↓
- Forming the mixture into lozenges.
- ↓
- The lozenge produced as described in claim 1, where the sucrose-to-corn syrup ratio ranges from 1.22:1 to 1:1.
- ↓
- The lozenge produced as described in claim 1, where the sucrose solids-to-corn syrup solids ratio is 11:9.
- ↓
- The lozenge produced as described in claim 1, where the first heating temperature ranges from 105°C to 115°C.
- ↓
- The lozenge produced as described in claim 1, where the first heating temperature ranges from 108°C to 112°C.

↓
The lozenge produced as described in claim 1, where the first heating temperature is approximately 110°C.

↓
The lozenge produced as described in claim 1, where the second heating temperature ranges from 140°C to 155°C.

↓
The lozenge produced using the method described in claim 1, where the second temperature falls within the range of 143°C to 147°C.

↓
The lozenge manufactured according to claim 1, where the second temperature is approximately 145°C.

↓
The lozenge created following the procedure in claim 1, where the carbonate-based antacid used is magnesium carbonate.

↓
The lozenge developed using the process outlined in claim 1, where the carbonate antacid present is calcium carbonate.

↓
The lozenge formulated via the process in claim 1, where the carbonate antacid constitutes 15-30% of the lozenge's weight.

↓
The lozenge produced under the method of claim 1, where glycerine is used as the cold-flow enhancer.

↓
The lozenge made according to claim 1, where the cold-flow enhancer utilized is propylene glycol.

↓
The lozenge formed using the process of claim 1, where the cold-flow enhancer is incorporated in an amount ranging from 0.5% to 2.0% of the total weight.

↓
The lozenge prepared under the method in claim 1, where corn syrup is continuously added while heating the mixture to the initial temperature.

↓
A hard-candy lozenge containing an antacid is produced through a process that involves mixing 67% concentrated aqueous liquid sucrose, 80% concentrated aqueous corn syrup, and calcium carbonate. The mixture is then heated to approximately 110°C using a cooking method. Next, it is transferred to a vacuum-cooking chamber, where it is further heated to around 145°C under a negative pressure vacuum of 0.8 to 1.2 bar. The heated mixture is then moved to an in-line mixer, where it is blended while incorporating approximately 1.5% propylene glycol or glycerin, 0.14% flavoring, and 0.14% coloring. Finally, the mixture is shaped into lozenges.

IV. INGREDIENTS USED IN LOZENGES ⁽⁵⁴⁾⁽⁵⁵⁾⁽⁵⁶⁾

Medicated lozenges are made using a variety of ingredients, including sugar, corn syrup, acidulants, lubricants, binders, colorants, flavoring agents, and the active medicinal component.

A. Candy Base

- 1) **Sucrose:** Sucrose, a disaccharide composed of glucose and fructose, is derived from sugarcane or beet. The choice between beet or cane sugar depends on availability and geographical factors. Medicated lozenges commonly use sucrose and its derivatives due to their role as neutral sweeteners.
- 2) **Invert Sugar:** Invert sugar, derived from sucrose, has the beneficial property of controlling crystallization in concentrated sugar solutions. It also helps maintain the freshness of the final product due to its humectant properties.
- 3) **Corn Syrup:** Corn syrup is widely used in confectionery to prevent sucrose and dextrose from crystallizing, which can cause candies to become crumbly. When combined in the right proportion with sucrose and dextrose, corn syrup helps create an amorphous texture, giving candies a desirable appearance. It plays a crucial role in medicated candy production, contributing to properties such as density, dextrose equivalent (DE), hygroscopicity, sugar crystallization control, viscosity, freezing point depression, and osmotic pressure.

- 4) Isomalt: Isomalt acts as a binding agent, helping to hold individual particles together in lozenges, especially during the kneading process. Beyond its binding properties, isomalt also serves as a softener. Lozenges that contain isomalt are generally softer compared to those without it.
- 5) Colorants: Colorants are added to medicated lozenges for visual appeal, product identification, and to mask physical degradation.
- 6) Acidulants: These substances are commonly added to medicated lozenges to enhance and strengthen their flavor profile. The most frequently used organic acids include citric, malic, fumaric, and tartaric acids, with citric acid—either alone or in combination with tartaric acid—being the most prevalent. Another key function of acids in medicated lozenges is to modify the pH to help maintain the drug's stability. Regular corn syrup typically has a pH between 5.0 and 6.0. To enhance flavor, a weak organic acid may be added, lowering the pH to 2.5–3.0, a range where certain medications achieve maximum stability. If needed, some drugs can be stabilized by adjusting the pH to a range of 7.0–8.0 using an appropriate agent.
- 7) Flavours: Flavours used in medicated lozenges must be compatible with both the drug and excipients while also withstanding the demands of the manufacturing process. These flavours consist of various chemicals that may interact with excipients or active ingredients and can degrade when exposed to heat or light. Aldehydes, ketones, and esters are among the compounds that can react with drugs. A well-known example of a flavour–drug interaction involves primary amine drugs, such as benzocaine and phenylpropanolamine, reacting with aldehyde-containing flavour components like cherry and banana. This reaction can lead to the formation of a Schiff base, causing drug decomposition and reduced effectiveness. Additionally, adjusting the lozenge base pH to enhance certain flavours (e.g., citrus) may result in incompatibility with specific drugs, such as benzocaine.
- 8) Salvage: A key ingredient in lozenge production is salvage, which consists of lozenges rejected due to imperfections in shape, size, air bubble formation, or inconsistent drug concentration. When properly heated, salvage can be reused in finished products without affecting colour, texture, lozenge base composition, or drug concentration. Before incorporating salvage into a medicated lozenge base, its pH should be adjusted to a range of 4.5–7.5. This adjustment helps prevent excessive and uncontrolled formation of reducing sugars. Additionally, it is essential to assess the stability of the drug throughout cooking cycles to ensure product consistency and effectiveness.

V. FORMULATION OF LOZENGES ⁽³³⁾⁽³⁴⁾⁽³⁵⁾⁽³⁶⁾

Lozenges are designed to be a stable dosage form, providing an effective method for administering various drugs.

A. General Procedure for Preparing Medicated Lozenges

- 1) Heat sugar, corn syrup, and water together until well combined.
↓
- 2) Incorporate the drug into the candy mixture.
↓
- 3) Add polymers, colorants, and flavoring agents as needed.
↓
- 4) Pour the mixture into molds of the desired shape and size to form the lozenges.
↓
- 5) Seal and package the lozenges in polyethylene wrapping.

VI. EVALUATION OF LOZENGES ⁽³⁷⁾⁽³⁸⁾⁽³⁹⁾⁽⁴⁰⁾⁽⁴¹⁾⁽²⁶⁾⁽⁴²⁾⁽⁴³⁾⁽⁴⁴⁾⁽⁴⁵⁾⁽⁴⁶⁾⁽⁴⁷⁾⁽⁴⁸⁾⁽⁴⁹⁾

A. Organoleptic Evaluation

The formulated lozenges were assessed in the laboratory for their acceptability based on visual inspection of various organoleptic properties.

B. Diameter and Thickness

A vernier caliper is an instrument used to measure the diameter and thickness of lozenges.

C. Average Weight and Weight Variation Test

A total of 20 lozenges were selected and weighed both collectively and individually using an electronic balance. The average weight was determined by dividing the total weight of the 20 lozenges by 20.

Each lozenge's weight was then compared to the average weight to check if it was within the acceptable limits. No more than two individual lozenges should deviate from the average weight by more than 7.5% for 300 mg tablets, and none should exceed twice that deviation.

Formulas:

Average weight = weight of 20 lozenges/20 weight variation = average weight-weight of each tablet/average weight x 100

D. Hardness

Lozenges require adequate hardness to withstand mechanical handling during manufacturing, packaging, and transportation. This test measures the crushing strength of the lozenges to ensure they are not too fragile or too hard.

E. Friability Test

The friability of 20 tablets from each batch was assessed using a friabilator, operated at a speed of 25 rpm for 4 minutes. After testing, the lozenges were dedusted, reweighed, and the percentage of weight loss was calculated using the following equation:

% Friability = (initial wt.-wt.after friability) x 100 / initial wt.

F. Disintegration Test

The disintegration test for lozenges is a quality control procedure used to assess how quickly a lozenge breaks down when it is exposed to the conditions that mimic the oral cavity. This test is important to ensure that the lozenge dissolves or disintegrates appropriately during use, releasing its active ingredients at the proper rate. The USP Disintegration Apparatus is used to measure the disintegration time of lozenges. The disintegration time is recorded in a pH 6.8 phosphate buffer or artificial saliva at 37°C.

G. Dissolution Test

A dissolution test for lozenges is typically conducted to evaluate the release of active pharmaceutical ingredients (APIs) under controlled conditions, ensuring that the lozenges dissolve appropriately in the oral cavity. The test often follows guidelines such as those outlined in the USP (United States Pharmacopeia) or EP (European Pharmacopoeia), using specific apparatus (e.g., USP Apparatus 2 or basket method) with media mimicking saliva or buffer solutions.

H. Moisture Content

The moisture content in lozenges is crucial for their stability, shelf life, and effectiveness. Typically, lozenges have a moisture content of around 1-5%. This is low to prevent microbial growth, preserve the product, and ensure it maintains its shape and consistency.

I. Mouth Dissolving Time Test

The mouth dissolving time test for lozenges is typically carried out to assess how quickly the lozenge breaks down or dissolves in the mouth, ensuring its effectiveness and ease of use. The test is commonly conducted according to pharmacopeial standards such as those outlined by the Indian Pharmacopoeia (IP) or similar guidelines from WHO and USP.

General Test Procedure:

- 1) Lozenge Placement: A lozenge is placed in the mouth, and the time taken for it to dissolve or break down completely is measured.
- 2) Conditions: The test may be done under controlled conditions, including temperature and moisture level, similar to the conditions in the human mouth.
- 3) Outcome: The lozenge should dissolve within a set time frame (usually 10-15 minutes), and the dissolution should be uniform.

J. Stability Study

A stability study for lozenges involves testing their quality, safety, and efficacy over time under different environmental conditions. The study typically focuses on factors like appearance, hardness, dissolution, microbial limits, and active ingredient stability.

K. Storage

Lozenges should be stored in a cool, dry place, away from direct sunlight and moisture similar to how spices are preserved in airtight containers in Indian kitchens to maintain their potency and freshness.

L. Packaging

lozenges are typically packaged in blister packs, sachets, or small tins, designed for convenience and hygiene. Blister packs, often made from aluminum and PVC, offer protection from moisture and contamination, ensuring the lozenges remain fresh. These packs usually contain a few pieces, making them easy to carry and consume on the go. For bulk packaging, lozenges are also available in bottles or jars, particularly for medicinal or herbal varieties. The packaging often features bright, colorful designs with clear labeling in multiple languages, including English, Hindi, and regional languages, to appeal to a wide demographic. Popular Indian brands, like Strepsils and Dabur Honey, use this type of packaging to maintain product quality while also emphasizing trust and affordability.

VII. HERBAL MARKETED LOZENGES ON TREATMENT OF MOUTH ULCER – (50)(51)

SR.NO	TRADE NAME	INGREDIENTS	DEVELOPER
1.	Sambucus immune lozenges	Elder berry extract, vit c, zinc gluconate.	Nature’s way
2.	Horehand lozenges-hound	Marrubium vulgare	Sydler remedies
3.	Halls lozenges	Menthol, eucalyptus oil, hexylresorcino.	Mondelez international Cadbury-USA
4.	Golden throat lozenges	Honey suckle flower (jin yin hua), peppermint oil, Eucalyptus oil, luo-han-guo fruit, Tangerine , peel, star anise oil, sucrose.	Solstice medicine company
5.	Koflet	Ginger, pepper, clove, licorice.	Himalaya drug company-India
6.	Phyto-Reliefcc	Turmeric, pomegranate, ginger.	Alchemlife
7.	Vira bloc	Elderberry extract	GNC
8.	Lozenges in ginger and garlic	Cofsils ginger lemon lozenges	Cipla health Lth.

VIII. EXAMPLES OF FORMULATIONS (52)

A. Soft lozenges

Formula for 10 lozenges

Drug	1 gm
Polyethylene glycol	10 gm
Aspartame	20 gm
Mint extract	1 ml
Color	q.s

B. Hard lozenges

Formula for 30 lozenges

Drug	1 gm
Powdered sugar	42 gm
Corn syrup	16 gm
Water	24 ml
Mint extract	1.2 ml
color	q.s

C. Chewable lozenges

Formula for 40 lozenges

Drug	0.5 gm
Glycerin	70 ml
Gelatin	18 gm
Water	12 ml
Methylparaben	0.4 gm
Flavoring oil	3 to 4 drops
Color	q.s

IX. MEDICATIONS ADMINISTERED THROUGH LOZENGES (53)

Various drug candidates can be formulated into lozenges, falling into the following categories:

- 1) Antiseptics
- 2) Local anesthetics
- 3) Antibiotics
- 4) Antihistamines
- 5) Antitussives (cough suppressants)
- 6) Analgesics (pain relievers)
- 7) Decongestants
- 8) Antifungals

X. CONCLUSION

the formulation and evaluation of lozenges involve a careful balance of selecting appropriate active ingredients and excipients, optimizing manufacturing processes, and assessing critical factors like dissolution rate, taste, stability, and patient acceptability. Effective lozenge formulation ensures consistent drug delivery, enhanced therapeutic outcomes, and improved patient compliance. Rigorous evaluation ensures that lozenges maintain their intended quality, safety, and efficacy throughout their shelf life.

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