



Review Article

Review on lozenges in pharmaceutical field globally

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Abstract

Lozenges are a common form of dosage widely used in the pharmaceutical industry to treat local problems of throat and oral cavity. This review aims to provide a comprehensive overview of lozenges in the global pharmaceutical market, to study their formulations, therapeutic applications and advances. The capsules are designed to dissolve slowly in the mouth and release active ingredients gradually, providing both local and systemic effects. The review explores the different types of lozenges, including those that contain active ingredients such as analgesics, antimicrobials and vitamins, while also highlighting the role of the chemicals in the formulation process. In addition, it addresses global trends in the development of lozenges, such as innovations in taste masking, controlled release and the incorporation of natural ingredients. In addition, it discussed regulatory considerations, manufacturing challenges and consumer preference for lozenges over traditional oral medications. Finally, the review emphasizes the expanding role of lozenges in the treatment of oral and throat diseases and their continuing relevance in the evolving pharmaceutical landscape.

Keywords: Lozenges, controlled release, Trend, Consumer, Emphasizes

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1. Introduction

Lozenges are typically hard and solidified. Typically, the base consists of refined sugar and an edible gum like gum acacia. The necessary medicaments are combined with sugar and powdered gum, then bound using a mixture of distilled water and pre-wetted gum. From this point on, the procedure resembles that of crafting pastry shapes. A cylindrical roller is used to roll the combined ingredients out to a consistent thickness, after which one piece is cut out with a lozenge cutter. To verify that a single lozenge holds the right amount, this item is weighed. If this is not the case, the rolling-out and cutting process is repeated. Once the thickness is accurate, as many lozenges as feasible are cut. The rest of the mass is once more rolled to the same thickness, additional lozenges are cut and this procedure is repeated until there is no more base left. A mixture of sugar and starch can be used to dust the mass in order to avoid sticking.¹ The rolling process can be performed on a tile or wooden base, but in the 1800s, an adjustable device known as a lozenge board was introduced to help guarantee that the mass rolled evenly. Lozenge cutters (or punches) evolved from a single metal tube into machines

capable of cutting multiple lozenges at once. The lozenges are thoroughly dried after being cut by placing them in an oven at 4000°C for forty minutes. (**Figure 1**)

Lozenges are a type of solid medication designed to dissolve in the mouth or pharynx. The intraoral administration route is the most favoured because of its ease of use and quick onset of action. Intraoral dosage forms have developed as an alternative to traditional tablets, capsules, and liquid formulations. Many intraoral dosage forms are designed to disintegrate, dissolve, or release the medication in the oral cavity, allowing for local absorption, either partially or fully, and they may also be swallowed for subsequent absorption in the gastrointestinal tract (GIT). The term "Lozenge" is derived from the French word "Lozenge," which denotes a diamond-shaped four-sided geometric figure. Lozenges and pastilles have been created in pharmacies since the twentieth century and continue to be produced commercially. Lozenges are solid formulations that include one or more active ingredients.

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2. History

Early in the millennium BC, the Egyptians found several candies that were prepared from honey and certain types of herbs. Learn more about the 19th-century drug that was primarily used to control coughing at its source and was manufactured from morphine and heroin. Cough drop, sore throat sweet, troche, throat lozenge, cachou, pastille, and cough sweet are other names for a lozenge.¹ It is frequently used to treat influenza and the common cold. Because of its diamond-like shape, it is nicknamed lozenges. Typically, medication is consumed directly from a spoon or measure. Prolonged medication release is more effective for certain conditions. These conditions would include oral thrush, sore throats, coughs, and so on. Lozenges, which are derived from the French word for a diamond-shaped figure of four equal sides), and as palatable preparations that would meet this criterion, pastilles (also known as jujubes) were created. The medication is mixed into a base that releases the medication gradually when sucked.² To improve palatability, flavourings and sweeteners might be given concurrently with the medication. Although they are currently produced commercially, lozenges and pastilles were created in pharmacies until far into the 20th century. The French word "Lozenge," which refers to a diamond-shaped geometry with four equal sides, is where the word "Lozenge" originates. Since the 20th century, pharmacists have been creating lozenges and pastilles, which are still produced commercially today.¹ Solid concoctions called lozenges are meant to dissolve in the mouth or throat.



Figure 1: Lozenges strip²

3. Types of Lozenges: (Fig.2)

- Medicated Lozenges- This type of lozenges used for medicinal purpose. Ex- Strepsils.¹²
- Non-medicated Lozenges- this type of lozenges doesn't have medicinal use. It basically used for soothe a dry sore throat. Ex- Candies.

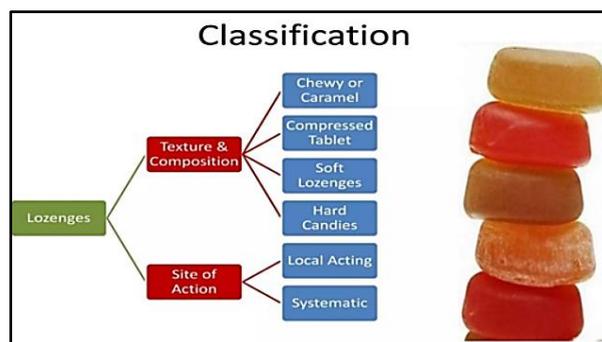


Figure 2: Classification of lozenges²¹

3.1. Chewy or caramel based medicated lozenges

Chewy lozenges are the dosage form in which medicament is incorporated into a caramel base which is chewed instead of being dissolve in mouth. These are especially used for paediatric patient. Lozenges also Contain Vitamin D3 and Biotin for oestopenia and hairfall. (Figure 3)



Figure 3: Chewy or caramel based medicated Lozenges

3.2. Compressed tablet lozenges-

This type of lozenges is helpful for thermo-labile substance. The lozenges tablet different from conventional tablets in terms of non-disintegrating characteristics and slower dissolution profile. (Figure 4)



Figure 4: Compressed tablet lozenges²¹

3.3. Soft lozenges

This type of lozenges basically for chewing into mouth for slow dissolution. It mainly made up from Poly ethylene glycol (PEG), sugar acacia and silica gel. One form of these soft lozenges is pastille, it is soft variety of lozenges.⁹ (Figure 5)



Figure 5: Soft candy lozenges²¹

4. Hard candy lozenges

Hard candy lozenges are mixture of sugar and carbohydrates in non-crystalline solid. In this type of lozenges moisture

5. Review on Patent Lozenges (Table 1)

Table 1: Review on patent lozenges³

Sr. No.	File No.	Chemical Constituents	Manufacturing	Published Date
1	US20150096575 [3]	Maltodextrin (soluble-fibre)	Altria Client Services Inc.	04/09/2015
2	4967773	Nicotine containing lozenges	Shaw; Alec S. W.	11/06/1990
3	5614207	Dry mouth lozenges	McNeil-PPC, Inc.	03/25/1997
4	11241413	cannabinoids	NordicCan A/S (Vejle, DK)	02/08/2022
5	8343533	amorphous carbohydrate polymer with radiofrequency	McNeil-PPC, Inc.	01/01/2013
6	US20170232048	symbiotic lozenge	Renuzoral LLC	08/17/2017
7	US20080107728	eleuthero, St. John's Wort, Valerian, and Passion flower.	Christopher I. Calpito	05/08/2007
8	US20050238695	Dextromethorphan	Linda A. Vag	10/27/2005
9	US20130034649	erythritol and isomalt	Cargill, Incorporated (Wayzata, MN, US)	02/07/2013
10	11400047	micronized benzocaine and polyethylene glycol	Johnson & Johnson Consumer Inc. (Skillman, NJ, US)	08/02/2022

Table 2: Ingredient in lozenges and roles.⁴

Sr.no	Ingredients	Examples	Role
1.	Candy base Sugar ^{Error! Reference source not found.}	Sucrose, Dextrose, Maltose, Sorbitol,	These are the used as sweetening agent and impart the taste masking properties.
2.	Fillers	calcium sulphate, calcium carbonate, lactose, microcrystalline cellulose	These are the used to Improve the flowability
3.	Lubricants	Magnesium stearate, calcium stearate, stearic acid and PEG, vegetable oils and fats	These are the used to avoid sticking of candy to the teeth
4.	Binders	Binders Acacia, corn syrup, sugar syrup, polyvinyl pyrrolidine, gelatine, tragacanth, andmethylcellulose.	These are the used to hold the particles
5.	Colouring Agents	FD & C colours, orange colour paste, red colour cubes, etc.	These are the used to enhance appearance and organoleptic properties of dosage form
6.	Flavouring agents ⁴	Menthol, eucalyptus oil, spearmint	These are the used to give a taste.
7.	Whipping agent	Milk Protein, gelatine, Starch, align, pectin.	These are the used in toffee-based confection
8.	Humectant	Glycerine, propylene glycol and sorbitol	They improve chew mouthfeel properties

content and weight between 0.5 to 1.5% and 1.5 to 4.5g respectively. (Figure 6)



Figure 6: Hard candy lozenges²¹

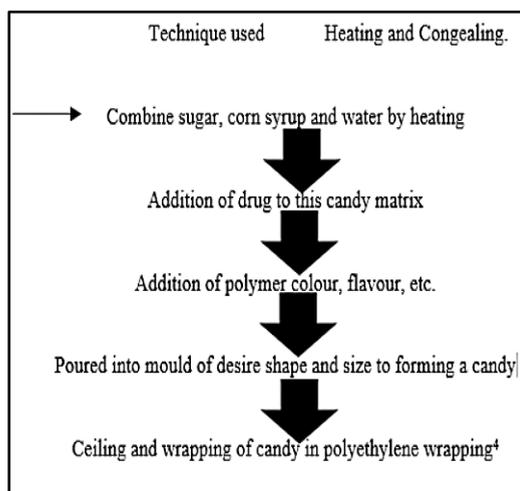
6. Formulation of Lozenges

6.1. Ingredients: (Table 2)

Lozenges may contain benzocaine an anaesthetic, or eucalyptus oil.⁸ Non-menthol throat lozenges generally use either zinc gluconate glycine or pectin as an oral demulcent several brands of throat lozenges contain dextromethorphan.¹⁰ Other varieties such as hall contain menthol, peppermint oil and mint oil as their active ingredient. Honey lozenges are also available.

The purpose of the throat lozenge is to calm the irritation that may be felt in the throat while swallowing, breathing, or even drinking certain fluids. However, one study found that excessive use of menthol cough drops can prolong coughs rather than relieve them.

6.2. Method of preparation



6.3. Strategies for formulation of effective lozenges (

Figure 7)

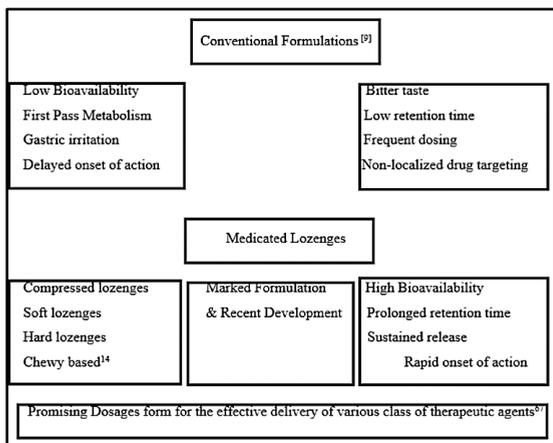


Figure 7: Strategies for formulation of effective lozenges⁹⁾

7. Lozenges Market Outlook

Worldwide revenue from sale of lozenges is approximately at US\$ 5.97 billion in 2024 and is rise at a 5.1% of CAGR to reach US\$ 9.8 billion by the end of this year 2034.⁹

Some comparative analysis of market show that forecasted market value (2034F) for throat lozenges market is approx US\$ 9.80 billion.

For natural cold, cough and sore throat remedies market value (2034F) approx US\$12 Billion.

Cough, Cold and allergy market value (2034F) approx. US\$ 70Billion. (Table 3)

Table 3: Market outlook of lozenges

Sr. no	Report Attributes	Details
1	Throat lozenges market Size (2024E)	US\$ 5.97 Billion
2.	Forecasted Market Value (2034F)	US\$ 9.8 Billion
3.	Global Market Growth Rate (2024 to 2034)	5.1% CAGR
4.	South Korea market Value (2034F)	US\$ 408.3 Million

7.1. Major companies marketing lozenges

1. JB Pharma
2. Helenz Pharmaceutical Pvt Ltd.
3. Bliss GVS Pharma Ltd
4. Glaxo smith kline (GSK)
5. Himalaya Wellness
6. Cipla Pvt Ltd
7. Johnson & Johnson

7.2. Upcoming brand of Lozenges

1. Dabur Honitus
2. Himalaya Koflet
3. Multani Kuka
4. Orac 99k Turmaric
5. Recofast orange
6. Gls Cotrimazole

7.2. Brand of lozenges in market

1. Strepsils
2. Cofsils
3. Turmgel (Turmeric Lozenges)
4. Vicks
5. Amrut Tulsi Lozenges
6. Multani KuKa
7. Zinda Tilismath
8. Kofol
9. Multi-vitamin Lozenges

8. Lozenges Related to Oral Disease

Patient compliance, quick start of action, extended retention period, improved bioavailability, convenience of

manufacture, localized medication targeting, sustained or regulated effect, and fewer doses are just a few of the benefits that lozenges offer.⁹ In order to treat a variety of oral cavity-related conditions, such as gingivitis, dental plaque, mouth ulcers, throat pain, oral thrush, throat infection, periodontitis, and pharyngitis, they can also combine medications from other therapeutic classes. Its use is not restricted to localized action, though; it has also been used to provide the medication systemically for ailments like cough, runny nose, decongestion, nausea, vomiting, allergy, low immunity, fever, body aches, worm killing, quitting smoking. They were found to have had a significant impact. Lozenges are used all over the world. It is primarily used to stop gastric juice and first-pass metabolism.¹ It is also a classic Chinese dosage form. Boots Healthcare first released Strepsils as a mouthwash in 1950. Reckitt introduced throat lozenges in 1958. Since the expense of developing a new chemical entity was quite high at the time, pharmaceutical companies are now concentrating on creating novel drug delivery methods for their current medications that have better bioavailability and efficacy as well as lower dosage frequency to lessen side effects. Some probiotic lozenges are utilized because of their effects.

Probiotics play a major role in controlling oral microbiota and lowering the incidence of oral illness. Probiotics were the subject of certain clinical studies, and in vitro screening of possible oral protective probiotics was conducted in order to assess their ability to preserve oral health.

Numerous clinical studies at the time demonstrate that using lozenges to treat dental-related diseases also has too many important side effects because many oral and parent formulations do not reach the site too early. However, research on dental-related issues like tooth decay and gum disease also shows that lozenges can help treat these conditions because they reach the site of effect earlier than oral dosage and maintain the drug's concentration at the site of effect.

Overall, we need to enhance the clinical research on probiotics because it enhance more oral immunity, improve oral health and also modulate oral microbiota.

8.1. Key drives and trends

1. Increasing health awareness
2. Growing Disposable Income
3. Preference for OTC Medicine
4. Ayurvedic Remedies

8.2. Indian Scenario on lozenges

1. The medicated lozenge market in India is currently estimated at Rs. 55-60 crore, and is growing at a healthy 15% per annum, despite competition from

home remedies at the primary level and mouth fresheners at the secondary level.

2. Nestle recently launched Acti-V in the lozenges segment with two flavors, honey lemon and menthol, but has not been very active in promoting the brand¹¹.
3. The Rupees 21-crore brand, Strepsils, has grown by about 15% over the past 12 months while the growth of brands like Smyle and D"cold have slowed. Last year, Boots Piramal launched Strepsils Pain Relief, which has also helped the brand. Strepsils is available in five flavours- orange, regular, ginger-lemon, lemon and menthol.
4. Halls is leading cough lozenge brand and compete with other on 6.2 Crore throat drops market in India.
5. Many Indian manufacturing Pharmaceutical have global takeover of the cough lozenges and view the past 12 months analysis it maintains the approx. 30%growth rate.¹⁰

$$\text{Weight Variation} = \frac{\text{average weight} - \text{Average weight}}{\text{Average weight}} * \text{Initial weight}$$

Equation No.1 Weight Variation

$$\text{Friability} = \frac{\text{Initial Weight of tablet} - \text{Initial Weight of tablet} * \text{Weight of tablet}}{\text{Initial Weight of tablet}}$$

Equation No.2 Friability

9. Evaluation of Lozenges

9.1. Physical and chemical testing

1. **Diameter and thickness:** For the lozenges to be uniform in size, their diameter is crucial. Vernier Calliper's can be used to measure it. The degree of deviation of the lozenges' diameter from $\pm 5\%$ of the reference value.
1. **Hardness:** It was determined by using tablet hardness tester. It test was performed by using three lozenges and standard deviation was calculated. The hardness of lollipops can be measured by using Monsanto hardness tester. The hardness was measured in terms of kg/cm².
2. **Weight Variation:** The USP weight variation test is done by weighing 20 lozenges. individually, calculating the average weight and comparing the individual weights to the average.
3. **Drug excipients interaction studie:** Determined by FTIR.
4. **Friability:** Determined by Friabilator operated at 25rpm for 4min.
5. **In-vitro drug release:** This is carried out in USP II paddle type dissolution apparatus.
6. **Drug content:** In a 50 ml volumetric flask, lozenges were ground into powder, dissolved in 5 ml of an appropriate solvent, and then the volume was increased to 50 ml using pH 6.8 phosphate buffer. In a 50 ml volumetric flask, 1 ml of this solution is taken,

diluted with pH 6.8 phosphate buffer, sonicated for 30 minutes, filtered through filter paper, and the absorbance of the mixture is determined using spectrophotometry.

7. **In vitro mouth Dissolving Time:** Each batch formulation's mouth dissolving time was calculated using a USP disintegration apparatus. Lozenges were put in each tube of the apparatus, and the amount of time it took for the lozenges to dissolve entirely was recorded using 100 milliliters of pH 6.8 phosphate buffer at 37 degrees Celsius. Three duplicates of this test were conducted. Lozenges' average dissolving time was computed and displayed together with the standard deviation.
8. **In vitro buoyancy studies:** The pace at which the drug dissolved from the lozenges was used to calculate the rate of drug absorption. Therefore, the effectiveness of the lozenge may be directly correlated with its rate of dissolution and bioavailability. 100 ml of the dissolution media, pH 6.8 phosphate buffer, was added to the beaker containing the lozenges and agitated at 100 rpm using magnetic stirrers. At 5-minute intervals, 5 ml aliquot samples were taken out and promptly replaced with an equivalent volume of brand-new fluid, such as simulated saliva. A UV visible spectrophotometer was used to analyze each diluted aliquot.

9.2. Stability testing

9.2.1. Stability Testing of lozenges before packaging-

Lozenges are carried for stability testing under following conditions⁵⁶-

- 1-2 months at 60°C.
- 3-6 months at 45°C.
- 9-12 months at 37°C.
- 36-60 months at 25°C and 4°C.

9.2.2. Stability testing of lozenges after packaging-

Lozenges after final packing is carried for stability testing under following conditions-

- 25°C at 80%RH for 6-12 months.
- 37°C at 80%RH for 3 months.
- 25°C at 70%RH for 6-12 months.

10. Discussion

The preparation of lozenges is a straight forward and time-efficient procedure. This is a formulation that is more organoleptically favourable, especially among paediatric patients. Medicated lozenges will serve as optimal dosage forms for paediatric patients. They will provide extra benefits including patient adherence, convenience, and comfort for effective treatment, such as lower doses, rapid onset of action, decreased dosage frequency, and cost-effectiveness. This will present a superior innovative dosage form. Lozenges hold a significant place in pharmacy and will persist in offering more benefits in the future.

11. Conclusion

Lozenges are therapeutic sweets that were created approximately 20th century ago and continue to be manufactured commercially. Lozenges hold a significant place in pharmacy and are expected to maintain this status in the future. Lozenges are an effective and convenient over-the-counter remedy for temporary relief of throat discomfort, coughing, and mouth irritations. They work by delivering soothing agents and sometimes mild anesthetics directly to the affected area. While generally safe when used as directed, excessive consumption can lead to side effects, especially in products containing menthol or other active ingredients. They should not replace medical treatment for more serious conditions, but they are a helpful tool for managing mild symptoms. The majority of these formulations are accessible over the counter and represent very cost-effective dosage forms. They are intended for both local and systemic treatment. A diverse array of active ingredients can be included in their composition.

12. Source of Funding

None.

13. Conflict of Interest

None.

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