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# Lozenges are Trends in Oral Mucosal Drug Delivery- Brief Review

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**ABSTRACT:** Lozenges are well-accepted solid oral dosage forms intended to dissolve slowly in the mouth, allowing the drug to come into prolonged contact with the oral and pharyngeal mucosa. Primarily utilized as a dosage form intended for the treatment of a sore throat, cough, oral infections, and other related conditions, it also holds the promise of systemic drug delivery as a consequence of buccal absorption. Placed on the utilization of excipients in the form of sweetening agents, binders, flavouring substances, and humectants that play a crucial part in the enhancement of palatability, shelf life, and patient compliance. Special consideration shall also be placed on the advancements of taste masking, controlled drug delivery, and the use of natural substances in the preparations of these dosage forms.

Finally, regulatory aspects in general, and the related quality control tests and criteria that are pertinent to the promotion and assurance of the product's safety and efficacy will also be covered. It might be noted that the utilization of lozenges as a dosage form, owing to its masticatory appeal, shall continue to be a reality and shall play a greater part in the pharmaceutical world.

The recent market outlook regarding lozenges at a global and Indian level have been discussed. lozenges assume greater importance as a convenient, economical, and patient-friendly drug dosage form.

**KEYWORDS:** lozenges, Intraoral drug delivery, Controlled release, Market trends, Patient compliance

## I. INTRODUCTION

Lozenges are the solid oral dosage forms that are designed to be retained in the mouth, dissolving slowly to prolonged contact of active ingredients with the mucosa of the mouth and pharynx for either local or systemic therapeutic effects.(1,2) Lozenges have their origin in ancient times where early forms of medicinal confections, the advancement in pharmaceutical sciences, these traditional forms evolved into a standardized dosage form and commercially manufactured products. In the nineteenth century, lozenges gained widespread acceptance for the management of cough and throat irritation; (3,4) in the twentieth century, they were made into an industrial-scale pharmaceutical product with better quality, safety, and acceptability by the patients. (4)

Lozenges have certain advantages from a pharmaceutical point of view, such as ease of administration without water, bypassing first-pass metabolism, suitability for patients with swallowing difficulties, and an increase in patient compliance through taste masking and attractive formulations. (1,5)

Lozenges are differentiated on the basis of the action site, texture, and composition and range from hard candy, soft lozenges, compressed lozenges, and chewy ones to sophisticated centre-filled ones. Recent developments with increased focus on market demand for lozenges can now be addressed through cutting-edge materials such as mucoadhesive polymers, Nano carrier based ones, stimuli-sensitive materials, glycosaminoglycan matrices, and three-dimensional printing technology. Thus, with increased market focus and development in formulation, the importance and development in the dosage form of lozenges have unfolded to invoke significant development in the current pharmacological scene.(6)  
History

Throat-soothing lozenges have been used since ancient civilizations. Records show that around the second millennium BC, people in Egypt created basic medicinal confections. Using natural ingredients like honey and herbs to relieve throat discomfort. As Understanding of medicine improved over the centuries, these preparations became more Refined. During the 1800s, lozenges gained widespread popularity as remedies for coughs And throat irritation. At that time, some cough

lozenges included powerful substances such as morphine and heroin, which were then considered effective for controlling cough symptoms. (7,8)

Lozenges are also referred to by several other names, such as cough drops, troches, Pastilles, and cachous. The term lozenge is derived from a French word meaning “diamond,” reflecting their traditional shape that remains common today. These products are designed to dissolve slowly in the mouth so that the active ingredients are released over time. Because of this gradual action, lozenges are helpful in easing sore throat, calming coughs, treating minor mouth infections, and reducing common cold symptoms. While they were once made mainly by pharmacists, lozenges began to be manufactured on a large commercial scale in the 20th century. (7,8)

### **Advantages**

- a. Lozenges are produced in uniform shapes and sizes, which makes dosing convenient for elderly patients as well as children. They are particularly attractive to children because they can be molded into playful designs such as animals, hearts, or toy-like figures.
- b. Sugar-free formulations allow people with diabetes to use lozenges without affecting blood sugar levels. (9,10)
- c. Drugs with an unpleasant smell or taste can be made easier to tolerate by incorporating suitable flavouring and tastemasking agents.
- d. The manufacturing process for lozenges is straightforward, requiring minimal equipment and relatively little preparation time.
- e. Lozenges avoid first-pass metabolism, which can improve drug effectiveness, reduce gastric irritation, and enhance absorption.
- f. You don't need to give them with water, which makes them easy to use and non-invasive. (9,10)
- g. They are useful for patients who have trouble swallowing.

### **Disadvantages**

- a. Because lozenges resemble sweets, they may attract children and pose a risk if accidentally consumed; therefore, they must be stored safely out of reach.
- b. The production of hard lozenges involves the use of high temperatures, which can be challenging during manufacturing.
- c. Hard lozenges may develop a gritty or crystalline texture if not prepared or stored properly. (9,10)

## **II. CHALLENGES**

### **1. Salivary Washout**

Continuous saliva production (~0.5–1.5 L/day) rapidly dilutes and clears the drug from the mucosal surface. This reduces contact time and can significantly lower drug uptake through the mucosa, especially for poorly permeable drugs.

### **2. Enzymatic Degradation**

Saliva contains enzymes such as proteases and amylases that can degrade sensitive drug molecules (e.g., peptides/proteins) before absorption. This enzymatic activity reduces effective drug concentration and bioavailability.

### **3. Permeability Barrier**

The oral mucosa is lined with stratified squamous epithelium, which is an effective barrier against many drugs—especially large or hydrophilic molecules. Penetration enhancers or specialized carriers are often needed to improve uptake. (12)

### **4. Taste & Palatability**

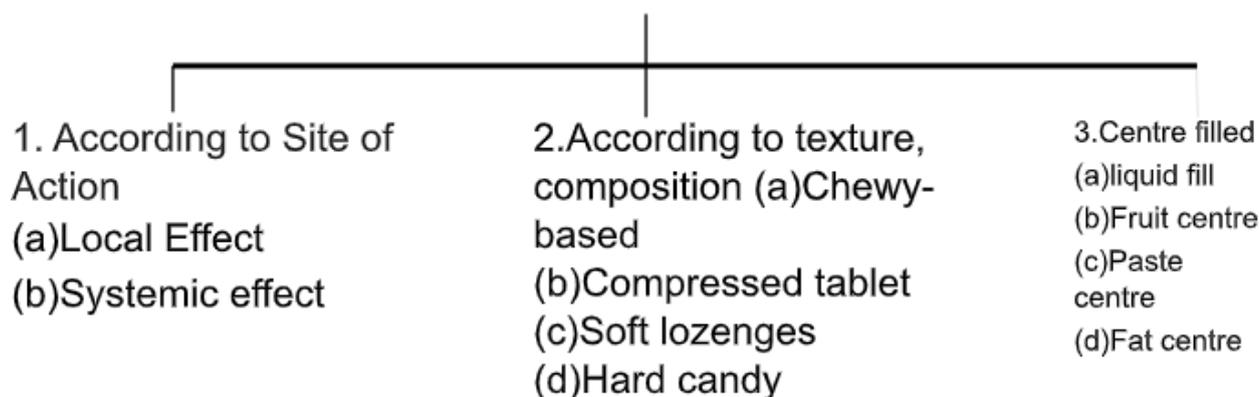
Many drugs have bitter or unpleasant tastes.

Formulations that fail to mask or modify taste can lead to poor patient compliance, especially with frequent dosing or paediatric use.

### **5. Dosing Accuracy & Compliance**

Lozenges rely on dissolution in the oral cavity over time. Elderly patients, children, or individuals with reduced manual dexterity may have difficulty properly placing and keeping lozenges in position, leading to inconsistent dosing. (11,12)

## Classification



### (a) Local effect

These lozenges act locally in the oral cavity and pharyngeal region. They are primarily used to relieve conditions such as sore throat, oral infections, and nasal congestion. Examples: Antiseptics, local anaesthetics, decongestants.(13,14)

### (b) Lozenges for Systemic Effect

Systemic lozenges are designed to allow the drug to be absorbed through the oral mucosa into the systemic circulation, thereby avoiding first-pass hepatic metabolism. Examples: Vitamins, nicotine, certain analgesics.(13)

## 2. Classification According to Texture and Composition

### (a) Chewy-Based Medicated Lozenges

Chewy lozenges are prepared by incorporating the medicament into a caramel or gummy-like base. Unlike conventional lozenges, they are chewed rather than slowly dissolved in the mouth. They are commonly used for absorption and circulation drug delivery.(14,15)

### (b) Compressed tablet

Compressed lozenges are prepared by tablet compression techniques, making them suitable for drugs that are heat-sensitive. The granulation process is similar to that used for conventional tablets, including: Improved organoleptic properties Non-disintegrating nature slower dissolution rate (13,14)

### (c) Soft Lozenges

Soft lozenges have gained popularity due to their ease of preparation and suitability for a wide range of drugs. The base typically consists of polyethylene glycols (PEGs), acacia, or similar polymers. One common form is the pastille, defined as a soft, often transparent lozenge containing medication dispersed in a gelatine or acacia–sucrose base. (15,16)

### (d) Hard Candy Lozenges

Hard candy lozenges consist of sugars or other carbohydrates in an amorphous or glassy state and may be considered solidified sugar syrups. The typical moisture content ranges from 0.5–1.5%, and the weight usually lies between 1.5–4.5 g.(13,14)

### Types of centre filled lozenges

Centre-filled lozenges are an advanced presentation of hard candy lozenges where a solid external shell encloses a different inner core, with improved palatability, drug loading, and release characteristics. **Categorized as liquid fill, fruit**

### **centre, paste centre, and fat centre types.**

Liquid-filled lozenges have a core that consists of a solution of fruit juice, sugar syrup, hydroalcoholic solutions, or sorbitol solution, usually occupying about 10–20% of the whole lozenge weight, which is promoted for rapid soothing and immediate flavour release. (28,29)

Fruited-center lozenges are represented by jams or jellies whose viscosity is altered by the addition of corn syrup or liquid sucrose to form a semi-solid, gel-like core that occupies usually 20–25% of the whole lozenge weight and provides prolonged flavour retention and acceptability by the patient. (27,28)

Paste-center lozenges consist of granules or crystals of the active ingredients prepared in a paste. This enables a higher core percentage of around 40%, which is very useful when a larger quantity of the drugs or the sensitive components needs to be incorporated.(27,28) Fat Centre Lozenges consist of drugs or flavors dissolved in hydrogenated vegetable

oils. The fill weight of these preparations varies from 25-32%. The results have shown these to be effective in masking the flavors very effectively and providing a better controlled release mechanism. From a pharmaceuticals standpoint, the advantages of lozenges include easy intake in the absence of water, elimination of first pass metabolism, ease of intake in patients suffering from difficulty in swallowing, and increased patient compliance due to masking of taste and pleasant dosage units. (27,28,29)

### III. TRENDS IN ADVANCED LOZENGES

#### 1. Mucoadhesive Approaches

Mucoadhesive strategies have gained significant importance in the design of next-generation lozenges because they enhance the duration of contact between the dosage form and the oral mucosal surface. The use of mucoadhesive polymers slows the rate of lozenge erosion, extending drug exposure and enabling sustained or controlled drug release. Consequently, lozenges are transitioning from simple symptomatic remedies to sophisticated drug delivery platforms. (17,18)

#### 2. Nanocarrier-Based and Novel Formulations

Nanocarriers, including lipid-based nanoparticles, polymeric nanoparticles, and dendrimers, improve drug solubility, stability, and penetration through the mucosal barrier. These systems are particularly beneficial for safeguarding fragile therapeutic agents, such as peptides and genetic materials, from degradation within the oral cavity. (19,20) Moreover, lozenges incorporating nanocarriers can be engineered to provide sustained drug release, thereby enhancing treatment precision and decreasing the need for frequent dosing.

3. Stimuli-Responsive (“Smart”) Drug Delivery Systems innovative smart delivery systems are being investigated to achieve sitespecific and controlled drug release triggered by conditions present in the oral environment. These systems employ responsive polymers that react to changes in pH, temperature, enzymatic activity, allowing drug release specifically at diseased sites. (19,20) This responsive mechanism improves therapeutic efficiency, reduces unnecessary drug exposure, and minimizes adverse effects, positioning smart lozenges as a promising option for targeted oral treatment.

#### 4. Three-Dimensional Printed Lozenges

Recent developments in three-dimensional (3D) printing technology have made it possible to produce customized lozenges with precise control over drug dose and release behaviour. This technique allows adjustment of formulation parameters such as drug concentration, dissolution rate, and adhesive properties to suit individual patient requirements. (19,20) In the future, 3D-printed lozenges may provide flexible drug release patterns and improved clinical effectiveness. (19)

#### Targeted population

**Adults:** The target patient population for hard-boiled lozenges is comprised of adults  $\geq 18$  years of age with acute, uncomplicated oropharyngitis, especially those with moderate sore throat pain of recent onset  $\leq 72$  hours. Clinical assessments on adults within this specific age group reflect gradual progression of pain reduction and assessment of overall product efficacy, underlining supplementary mouth-soothing, salivation, and symptomatic relief factors provided by lozenge preparations. Hence, hardboiled lozenges are specifically targeted to adults  $\geq 18$  years with self-limiting URTS, thereby validating supportive oral mucosal drug delivery devices rather than definitive treatment modalities. (21,22)

**Pediatric patients :** The target population for lozenge formulation extends to children as well, particularly healthy children aged 6-12 years, who may have acute self-limiting sore throat conditions. Clinical acceptability studies for children underscore the need for taste, mouthfeel, and ease of administration, where these parameters can have a significant effect on compliance. (21,22) In these acceptance and taste studies, children were shown lozenge experiments including the preference for taste and willingness to repeat usage of lozenge formulation. These observations indicate that children find flavoured lozenge formulation satisfactory since a high percentage of children rated lozenge formulation taste as good or better and were willing to repeat usage of lozenge formulation. These observations indicate that lozenge formulation can work effectively for children aged 6-12 years.

#### Disease base lozenges :

To deliver therapeutic agents locally to the oral cavity and pharynx for specific pathological conditions, including sore throat, viral upper respiratory tract infections, chronic pharyngitis, and general oral and respiratory health maintenance. Lozenges designed for sore throat conditions offer rapid symptomatic relief by incorporating analgesic, anesthetic, and antiseptic agents that reduce pain, inflammation, and mucosal irritation due to their long period of contact

with the tissues of the pharynx. Such formulations have focused on controlled dissolution and stimulating saliva to increase drug availability in the affected area. Conversely, lozenges being developed for the inactivation of respiratory viruses target prolonged retention on the mucous membranes and incorporate agents with virucidal activity; this not only minimizes viral load at the site of infection but may also limit the transmission of the disease. (23,24,25)

In addition, lozenges meant for oral as well as respiratory wellness also have a supporting role, which could include mild antimicrobials, herbs, or nutraceuticals for maintaining microbial equilibrium, facilitating saliva secretion, as well as providing support to mucosa. In light of this, disease-based lozenges vary significantly from others in terms of development intent, rate of disintegration, as well as excipients. Disease-based lozenges differ in formulation objectives, dissolution characteristics, and excipient selection.(26,27)

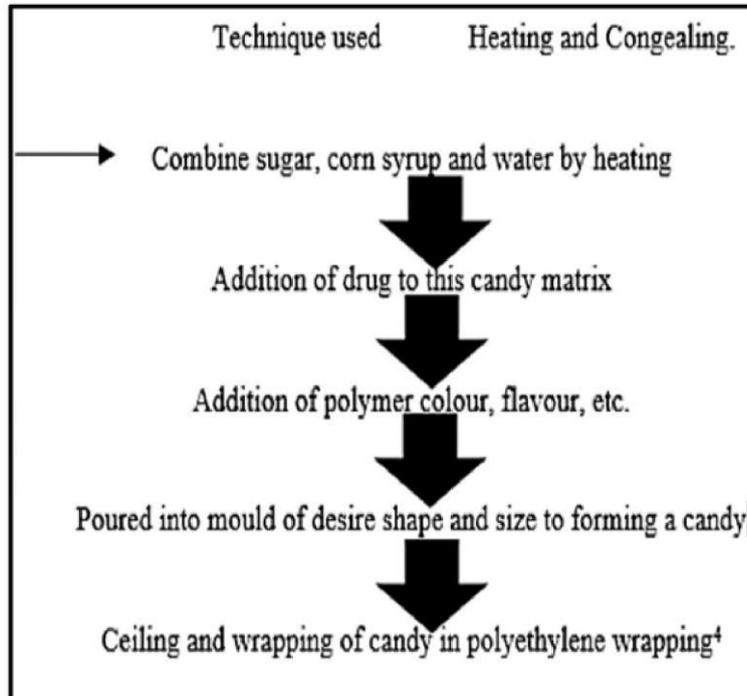
#### **IV. FORMULATION OF LOZENGES**

1. Sugar: Sucrose, which is a disaccharide of glucose and fructose, can be derived either from sugarcane or beet roots. The choice will depend on accessibility and geological considerations related to beet sugar and beet sweetener. Sucrose, as well as sucrose-based articles, find application in cured capsules due to its importance as a neutral sugar, its properties regarding solvability, as well as its capacity as “drier” to reduce the weight of sweet by crystallization. (28,29,30)
2. Corn syrup: Corn syrup is used in all kinds of candies for the regulation of sucrose and dextrose crystallization, which can cause the candy to disintegrate. Corn syrup in proportion along with sucrose and dextrose helps in the formation of an amorphous glass and the formation of the candy with an attractive look. Sucrose crystallization occurs in various food and pharmacological uses. (29,30)
3. Binders: Binders are usually employed compressed tablets that are designed to retain the particles of mass as discrete granules comprising acacia, corn syrup, sugar syrup, gelatin, polyvinylpyrrolidone, tragacanth, methylcellulose , etc., (29)
4. Lubricants: These include magnesium stearate, calcium stearate, stearic acid, and PEG, among others, which are used to avoid the sticking of candies to the teeth and improve flow of the final troche mixture. (29,30)
5. Colouring agents: Coloring agents are Colourants are incorporated into medicated lozenges for product identification, good appearance, and masking of physical degradation. Dyes and other organic colourants may deteriorate by heat or light through oxidation, hydrolysis, photo-oxidation, etc., and their compatibility with the drug, excipients, and process conditions should be studied before selection. (29,30)



6. Flavouring agents: Flavour is a combined sensation of taste, touch, smell, sight and sound. Flavours consist of various organic chemicals, like hydrocarbons, alcohols, aldehydes, ketones, acids, esters or lactones. The low volatility and low molecular weight, usually below 400 Daltons, is responsible for a range of sensorial sensations attributed to the flavours. (29,30)
7. Preservatives: Since hard candy lozenges are hygroscopic, the water content may increase and bacterial growth may occur if they are not properly packed. The presence of water would dissolve some sucrose; the resulting highly concentrated sucrose solution is bacteriostatic in nature and would not support bacterial growth.(28)

Method of preparation of lozenges



**Current Business Review**

Worldwide revenue raised by the sale of lozenges is approximately US\$ 5.97 billion in 2024 and will increase at the rate of 5.1% CAGR to reach US\$ 9.8 billion by the end of this year.

“Some relative comparison of the market shows that the predicted market value for the “throat” market in 2034F will be approximately 12 Billions (32,33) US\$.

Cough, Cold & Allergy Market Value (2034F) US\$

<p>1. Lozenge Marketing by</p> <ul style="list-style-type: none"> <li>• JB Pharma • Helenz Pharmaceutical Pvt Ltd</li> <li>• Bliss GVS Pharma Ltd • Glaxo Smith Kline</li> <li>• Himalaya Wellness</li> <li>• Cipla Pvt Ltd</li> <li>• Johnson &amp; Johnson</li> </ul> <p>2. Upcoming brand of lozenges</p> <ul style="list-style-type: none"> <li>• Dabur Hon</li> <li>• Himalaya Kof</li> <li>• Multani Kuka</li> <li>• Orac 99K Tur</li> <li>• Recofast Orange</li> <li>• Gls Cotrim</li> </ul>		
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<p>3. Brands of lozenges</p> <ul style="list-style-type: none"> <li>● Streps</li> <li>● Turmgel</li> <li>● Vicks</li> <li>● Ashok Deshpandi</li> <li>● Zinda Tilism</li> <li>● KOFO</li> <li>● Multi-Vitamin Lo</li> <li>● Fungilin</li> <li>● Cold-EEZE Zinc Gluconate Lozenge</li> <li>● Zinc supplement</li> <li>● Strepfen Anti-inflammatory Lozenges (32,33)</li> </ul>		
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#### IV. LOZENGE EVALUATION

**1. Analysis of moisture** 1. Gravimetric method- 1gm of testing sample is to be placed in vaccum oven at 60-70° for 12-16 hrs.

Sample is to be weighed after a definite given period of time, and moisture content is Worked out as under:-

Water Content = Initial weight – Final weight

**2. Karl fisher titration-** A sample calculated so that to contain 10-250 mg water, is taken in

Titration flask! And karl fisher reagent is used and titrated

**3. Determination of sugar and corn syrup ratio-** These can be done by using “Dextrose this is an equivalent method, otherwise known as the Lane eyvon titration method.(31,33,34)

**4. Percentage of reducing sugar-** 3gm of anhydrous dextrose is dissolved in 500 ml of water and 2 drops of methylene Blue is added which is then boiled for 2 min and titrated against 25 ML of Fehling solution, and the end is yellowish red.

#### **2. Physical And Chemical Tests:**

1. Diameter and thickness – Lozenge uniformity is based on its diameter. It can depends on the vernier caliper. The value of the extent limit for the diameter of lozenges was varying from ±5% of the standard value.

2.Hardness- Resistance to lozenge shipment, storage, and breakage, Transport handling, which depends upon the hardness. It is therefore necessary to calculate hardness for checking the threshold capacity, which may be established through the Monsanto hardness tester for kg/csq. (31,33,34)

3.Weight variation- The weight variation testing done by USP involves weighing 20 lozenges individually and then by taking average comparatively as follows:

Weight variation = (Average weight - Initial Weight) / Average Weight

4.Friability- This is done for same as hardness testing. It is performed as Friability testing done by using Roche Friabilator running at a specific speed for a specific time like 25 rpm for 4 minutes.

5. In-vitro drug release- This test is also known as the “dissolution test” and carried out in the USP paddle type dissolution apparatus . (31,33,34)

#### V. CONCLUSION

Lozenges started as conventional medicines and developed into modern dosage forms with advanced capabilities to release drugs for both topical and systemic purposes. The slow release of lozenges in the oral cavity provides extended

mucosa-surface contact and overcomes the first-pass effect. Though lozenges possess vast therapeutic capabilities, their uses are restricted due to some drawbacks like salivary washout, enzymatic degradation, permeability barriers, and intersubjective variations.

The broader classification of lozenges are involved. Advancements made using mucoadhesive polymers, Nanocarrier, and stimulus-responsive systems combined with 3D printing technology have greatly improved the stability and release of the lozenge dosage form. Lozenges appear as a promising platform for the oral mucosal delivery of drugs and future research and development would be aimed at enhancing bioavailability, accuracy of dosing, and personal dosing responses.

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