MEDICATED LOZENGES AS AN EASY TO USE DOSAGE FORM

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ABSTRACT

Lozenges are solid preparations that contain one or more medicaments, usually in a flavoured, sweetened base, and are intended to dissolve or disintegrate slowly in the mouth or these are medicated candy intended to be dissolved slowly in the mouth to lubricate and soothe the irritated tissues of throat. Lozenges are one of the widely used dosage forms. The benefits of the medicated lozenges is they increase the retention time of the dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. Lozenges provide a palatable means of dosage form administration and enjoy its position in pharmaceutical market owing to its several advantages but it suffers from certain disadvantages too. This dosage form can be adopted for local as well as systemic therapy and a wide range of active ingredient can be incorporated in them lozenges or troches are experiencing a renewed popularity as a means of delivering many different drug products. Lozenges have various advantages and disadvantages. Different types of lozenges and their methods of preparation along with ingredients used in their preparation are discussed. Drug candidates which can be incorporated in lozenges include antiseptics, local anesthetics, antibiotics, antihistamines, antitussives, analgesics, decongestants and demulcents. The selection criteria for flavouring agents are mentioned, quality control tests of lozenges have been reviewed. The present review covers more or less all aspects associated with lozenges and also throws light on the development criteria of the lozenges dosage form.

KEYWORDS: Lozenge, medicaments, flavouring agent.
INTRODUCTION

Oral drug delivery is the most flavoured route for the administration of various medications and tablets are the most widely accepted dosage form. Solid dosage forms are popular because of the ease of administration, accurate dosage, self-medication, pain avoidance, and most importantly patient compliance. Among the major problems faced by many patients with conventional tablet dosage form is difficulty in swallowing. This problem is more apparent when drinking water is not easily available to the patient taking medicine. Dispersible tablet delivery system is characterized by fast disintegration, quick dissolving, rapid release and improved patient compliance. Difficulty in swallowing (dysphagia) is a common problem of all age groups, especially the elderly and paediatrics, because of physiological changes associated with those groups. Other categories that experience problems in using conventional oral dosage forms include the mentally ill, uncooperative and patients suffering from nausea, motion sickness, sudden episodes of allergic attack or coughing. Sometimes it may be difficult to swallow conventional products due to non-availability of water. These problems led to the development of a novel type of solid oral dosage form hence, an attractive, taste masking formulations are the need of the hour.

Lozenges are the flavoured medicated dosage forms intended to be sucked and held in the mouth or pharynx containing one or more medicaments usually in the sweetened base. Lozenges are intended to relieve oropharyngeal symptoms, which are commonly caused by local infections and also for systemic effect provided the drug is well absorbed through the buccal linings or when it is swallowed. Lozenges are used for patients who cannot swallow solid oral dosage forms as well as for medications designed to be released slowly to yield a constant level of drug in the oral cavity or to bathe the throat tissues in a solution of the drug. Drugs often incorporated into lozenges include analgesics, anaesthetics, antimicrobials, antiseptics, antitussives, aromatics, astringents, corticosteroids, decongestants, and demulcents. However, this is by no means an exhaustive list as many other drugs may lend themselves to delivery by a lozenge. As well, both single and multi-ingredient lozenges can be compounded, depending on the particular patient’s needs.

Today they are used for drugs like analgesics, anesthetics, antimicrobials, antiseptics, antitussives, aromatics, astringents, corticosteroids, decongestants, and demulcents and other classes and combinations. They are easy to handle, the dose has been apportioned, and the excipients have a demulcent effect on throat since the ingredients are released slowly and
spread uniformly over the affected mucosal membrane. Lozenges, which may consist of one or more pharmaceuticals into a candy carrier, have been used to deliver medications, either topically within the buccal cavity of the patient or by swallowing the pharmaceutical after it has dissolved in saliva. Generally, each lozenge includes a quantity of one or more pharmaceuticals sufficient to deliver an effective dose to the average patient when the entire lozenge is consumed. However, many patients are affected differently by that dose, with some being more sensitive and some being less sensitive to the effects. Further, lozenges for administering medicine may be inappropriate in some circumstances because there is a chance a patient may choke on the lozenge.

Sore throats, sores, and other irritations in mouth and pharynx are common ailments that can cause pain. Although a variety of pharmaceuticals are available, both prescription and over-the-counter, to treat the pain, these pharmaceuticals can be sometimes difficult to administer to patients who are unwilling and/or unable to take conventional oral medications. For example, children and adults may have difficulty swallowing tablets or capsules. Patients may resist taking medicine in liquid form due to the medicine’s unpleasant taste or texture or difficulty in swallowing. Moreover, there may be a significant time delay, sometimes twenty minutes or longer, between ingesting many oral medications and the onset of a therapeutic effect because the medications must be absorbed into the bloodstream from the digestive system after the medicine is swallowed.

**Medicaments**

Drug candidates which can be incorporated in lozenges, belong to one of the following categories:

1. Antiseptics
2. Local anesthetics
3. Antibiotics
4. Antihistaminics
5. Antitusives
6. Analgesics
7. Decongestant
8. Antifungal
Classification of Lozenges
Lozenges can be classified into various classes based on various methods like

A. According to the site of action
   a. Local effect
      Ex. Antiseptics, Decongestants.
   b. Systemic effect
      Ex. Vitamins, Nicotine.

B. According to texture and composition
   a. Chewy or caramel based medicated Lozenges
   b. Compressed tablet lozenges
   c. Soft lozenges
   d. Hard lozenges

According to Site of Action
Lozenges can be classified into various classes based on various methods such as according to the site of action which can either be local and systemic effects. Examples of local effects are antiseptics, decongestants, while vitamins and nicotine are examples of systemic effect.

According to Texture and Composition
Chewy or Caramel Based Medicated Lozenges
Chewy or caramel based medicated lozenges are the dosage form in which medicament is incorporated into a caramel base which is chewed instead of being dissolved in mouth. Most formulations are based on the glycerinated gelatine suppository formula which consists of glycerine, gelatine, and water. These lozenges are often highly fruit flavoured and may have a slightly acidic taste to cover the acrid taste of the glycerine. Its constituent ingredients are the candy base, whipping agent, humectants, lubricants, flavour and of course medicaments incorporated into the lozenges. The candy base consists of a mixture of sugar and corn syrup in a ratio of 50:50 to 75:25 sugar to corn syrup. The whipping agents are used to incorporate air in toffee-based confections to obtain the desired degree of soft chew. These are exemplified by milk protein, egg albumin, gelatin, xanthan gum, starch, pectin, algin and carageenan. The humectants improve chew and mouth feel properties and include glycerin, propylene glycol and sorbitol. Lubricants are added to avoid sticking of candy to the teeth while chewing. It includes vegetable oils and fats. Medicaments up to 35-40% can be incorporated. Seeding crystal involves addition of fine powdered sugar at 3-10% to warm
candy mass to speed up the crystallization and allow the base to be formed into tablets in a much shorter time. Seeding crystals involves addition of fine powdered sugar at 3-10% to warm candy mass to speed up the crystallization and allow the base to be formed into tablets in a much shorter time.

**Manufacturing of Chewy or Caramel Based Medicated Lozenges**
The candy base is cooked at 95-125°C and transferred to planetary or sigma blade mixer. Mass is allowed to cool to 120°C. This is followed by the addition of whipping agent below 105°C. The medicaments are then added between 95-105°C. Colour is dispersed in humectant and added to the above mass at a temperature above 90°C. Seeding crystals and flavour are then added below 85°C. followed by lubricant addition above 80°C. Candies are then formed by rope forming.

**Compressed Tablet Lozenges**
If the active ingredient is heat labile, it may be made into lozenge by compression. The granulation is prepared in a manner similar to that used for any compressed tablet. The lozenge tablets differ from conventional tablets in terms of organolepticity, non-disintegrating characteristics and slower dissolution profiles. The lozenge is made using heavy compression equipment to give a tablet that is harder than usual, as it is desirable for the troche to dissolve slowly in mouth. They are usually flat faced with sizes, weight, hardness, and erosion time ranging between, 5/8-3/4 inch, 1.5-4 g, 30-50 kg inch2 and 5-10 min, respectively. The ingredients for compressed tablet lozenges are tablet based or vehicles which are sugar such as dextrose, sucrose. Other vehicles are sugar free vehicles such as mannitol, sorbitol, polyethylene glycol (PEG) 6000 and 8000. Some commercially available sugar based vehicles include- Emdex, Nu-tab, Sweetrex, Mola-tab, Hony-tab, Sugartab. Other fillers include dicalcium phosphate, calcium sulphate, calcium carbonate, lactose and microcrystalline cellulose. Binders are also included to hold the particles of mass as discrete granules and include acacia, corn syrup, sugar syrup, gelatin, polyvinyl-pyrrolidone, tragacanth and methylcellulose. Lubricants are used to improve flow of final troche mixture and include magnesium stearate, calcium stearate, stearic acid and PEG. The colours used include water soluble and lakolene dyes.

**Manufacturing of Compressed Tablet Lozenges**
Manufacturing of compressed tablet lozenges can either be direct compression and wet granulation. In direct compression, ingredients are thoroughly mixed and then compressed. In
wet granulation, sugar content is pulverized by mechanical comminution to a fine powder (40-80 mesh size). Medicament is added and thoroughly blended. The blended mass is subjected to granulation with sugar or corn syrup and screened through 2-8 mesh screen. This is followed by drying and milling to 10-30 mesh size. Flavour and lubricant are then added prior to compression.

**Soft Lozenges**

They are either meant for chewing or for slow drug release in mouth. They can be made from PEG 1000 or 1450, chocolate or sugar-acacia base while some soft candy formulations can also contain acacia and silica gel. Acacia is used to provide texture and smoothness and silica gel is used as a suspending agent to avoid settling of materials to the bottom of the mould cavity during the cooling. The formulation requires heating process at about 50°C, hence is only suitable to heat resistant ingredients. These are mixtures of sugar and other carbohydrates in an amorphous (non crystalline) or glassy state. They can also be regarded as solid syrups of sugars. The moisture content and weight of hard candy lozenge should be in between, 0.5 - 1.5% and 1.5-4.5 g respectively. These should undergo a slow and uniform dissolution or erosion over 5-10 min., and they should not disintegrate. The disadvantage of this method is that the temperature required for their preparation is high hence heat labile materials cannot be prepared.

**Manufacturing of Soft Lozenges**

On the account of the soft texture of these lozenges, they can be hand rolled and then cut into pieces or the warm mass can be poured into a plastic mould. Mould cavity should be overfilled if PEG is used, as PEG’s contract as they cool. This is not required in case of chocolate as it does not shrink. Phaechamud and Tuntarawongs fabricated clotrimazole soft lozenges by molding method and evaluated the factors that affect the physical properties of lozenge. They found that increasing amounts of PEG 1500, xanthan gum or xylitol increased the hardness of the lozenge. And also disintegration time was found to be increased on increasing amount of actives and hardness.

**Hard Candy Lozenges**

Hard candy lozenges are mixtures of sugar and other carbohydrates in an amorphous (noncrystalline) or glassy state. They can also be regarded as solid syrups of sugars. The moisture content and weight of hard candy lozenge should be between, 0.5 to 1.5% and 1.5-4.5g respectively. These should undergo a slow and uniform dissolution or erosion over 5-
10 min., and should not disintegrate. The temperature requirements for their preparation is usually high hence heat labile materials cannot be incorporated in them. The ingredients for hard candy lozenges include body agent or base which is corn syrup that is available on Baume basis. A 43° Baume corn syrup is preferred in hard candy lozenges. Sweetening agents such as sucrose, dextrose, maltose and lactose are added. Acidulents are added to candy base to strengthening the flavour characteristics of the finished product. Commonly used acids are citric, tartaric, fumaric and malic acid. Colours include FD & C colours, orange colour paste, red colour cubes etc while flavours used include menthol, eucalyptus oil, spearmint, cherry flavour etc. Medicaments up to 2-4% can be incorporated in the hard candy lozenges. Salvage solution can be liquid or solid.

**Manufacturing of Hard Candy Lozenges**

The candy base is cooked by dissolving desired quantity of sugar in one third amount of water in a candy base cooker. This is continued till the temperature rises to 110°C. Corn syrup is added and cooked till the temperature reaches 145-156°C. The candy mass is removed from the cooker and transferred to a lubricated transfer container mounted onto a weight check scale where the weight of the mass is checked. This is followed by colour addition in form of solutions, pastes or colour cubes. The mass is then transferred to a water-jacketed stainless steel cooling table for mixing and the flavour, drug and ground salvage is added. The mass is either poured in mould or pulled into a ribbon while cooling and then cut to desired length. The obtained lozenges are packaged. Cocaine voice tablet lozenges and pastilles were developed in late 1800's and were indicated in Extra Pharmacopoeia, 1888. They were used by singers and public speakers for the remedy of vocal huskiness and hoarseness.

**Table 1: Type of hard candy lozenges.**

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Type of Centre filled lozenges</th>
<th>Composition</th>
<th>Fillweight(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Liquid fill</td>
<td>Fruit juice, sugar syrup, hydroalcoholic solutions or Sorbitol solution.</td>
<td>10-20</td>
</tr>
<tr>
<td>2.</td>
<td>Fruit center</td>
<td>Jams and jellies whose viscosity has been modified with corn syrup or liquid sucrose</td>
<td>20-25</td>
</tr>
<tr>
<td>3.</td>
<td>Paste center</td>
<td>Granules and crystals formulated as paste Medicament or flavor being suspended or dissolved in hydrogenated vegetable oil</td>
<td>40</td>
</tr>
<tr>
<td>4.</td>
<td>Fat center</td>
<td></td>
<td>25-32</td>
</tr>
</tbody>
</table>
Table 2: Formulation of medicated Lozenges.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) <strong>Sugar</strong></td>
<td>Dextrose, sucrose, maltose, lactose.</td>
</tr>
<tr>
<td>b) Sugar free vehicles</td>
<td>Mannitol, sorbitol, polyethylene glycol (PEG) 600 and 800.</td>
</tr>
<tr>
<td>c) Fillers</td>
<td>Di calcium phosphate, calcium sulfate, calcium carbonate, lactose, microcrystalline cellulose.</td>
</tr>
<tr>
<td><strong>Lubricants</strong></td>
<td>Magnesium stearate, calcium stearate, stearic acid and PEG, vegetable oils and fats.</td>
</tr>
<tr>
<td><strong>Binders</strong></td>
<td>Acacia, corn syrup, sugar syrup, gelatin, polyvinyl pyrrolidone, tragacanth and methylcellulose.</td>
</tr>
<tr>
<td><strong>Coloring agents</strong></td>
<td>Water soluble and lakolene dyes, FD &amp; C colors, orange color paste, red color cubes, etc.</td>
</tr>
<tr>
<td><strong>Flavorings agent</strong></td>
<td>Menthol, eucalyptus oil, spearmint, cherry flavor, etc.</td>
</tr>
<tr>
<td><strong>Whipping agent</strong></td>
<td>Milk protein, egg albumin, gelatin, xanthan gum, starch, pectin, algin and carrageenan.</td>
</tr>
<tr>
<td><strong>Humectants</strong></td>
<td>Glycerin, propylene glycol and sorbitol.</td>
</tr>
</tbody>
</table>

**Formulation of Lozenges**

Lozenges are formulated in such a way that they are stable; provide a good medium for administration of drugs. The ingredients which are used for formulation of Lozenges are as shown in table 2.

**Criteria for preparation of medicated Lozenges**

- Selection of Drug Candidate
- Selection of Drug Carrier

**Method of preparation of medicated Lozenges**

Technique used → heating and congealing.

Combine sugar, corn syrup and water by heating

Addition of drug to this candy matrix

Addition of polymer, colour, flavour etc.

Poured into mould of desired shape and size to forming a candy

Sealing and wrapping of candy in polyethylene wrapping
Flavoring agent

For hard lozenges, the emphasis is on the slow, uniform release of the medication directly onto the affected mucous membrane. This presents an additional challenge to the compounding pharmacist to develop flavor blends that effectively mask any unpleasant principles contributed by the medications, while maintaining a smooth lozenge surface texture as the tablet slowly dissolves. If the incorporated medication has no significant taste, flavoring will not be a problem. However, if the medication has a strong, disagreeable taste, special emphasis should be placed on minimizing the taste in order to enhance patient compliance. Flavor is a very complex phenomenon that is a combination of the senses of taste, touch, smell, sight and sound. The first of these, taste, is made of four primary tastes: sweet, bitter, sour and salty. We are generally more sensitive to odors than to tastes and the level of odor required for the elderly may be 3-5 times greater than that required for young people. Females tend to have a greater sensitivity to odors than do males. Taste and smell are altered in many disease states. Some correlations can be made between flavors/odors and chemical structure. For example, a sour taste is associated with hydrogen ions, saltiness with both anions and cations present, bitterness with high molecular weight salts, sweet with polyhydroxyl compounds/polyhalogenated compounds and alpha amino acids, a sharp, biting taste with unsaturation, a camphoraceous odor with a tertiary carbon atom, a fruity odor with esters and lactones, and a pleasant odor with ketones. The causative factors for taste include the following: a hot taste is due to a mild, counterirritant effect, an astringent taste is due to tannins and acids, coarseness/grittiness is due to texture, and coolness is due to a negative heat of solution. In flavor formulation development, there are usually the requirements for an immediate flavor identity, a rapid full flavor development, compatible mouth feel, no “off” notes, and a short aftertaste.

Some techniques commonly used in flavoring include blending, overshadowing, physical methods, chemical methods, and physiological methods. A flavor selection guide is shown in table No.3. Blending: blending incorporates the use of a characteristic common to both the flavor and drug, for example the use of a fruit flavor to blend in with a sour/acid taste (orange flavor to blend with ascorbic acid). Salty/sweet/sour flavors can be used to blend with a bitter taste. Also, the use of a slight salty taste will actually decrease sourness and increase sweetness. It has also been found that adding a sour flavor may help overcome a bitter taste. Overshadowing: methyl salicylate and glycyrrhiza, with their strong essences, can overshadow or overpower many products.
Table no. 3: flavor selection guide.

<table>
<thead>
<tr>
<th>Flavored</th>
<th>Natural Flavors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salty</td>
<td>Butterscotch, Maple, Nutty, Buttery</td>
</tr>
<tr>
<td>Bitter</td>
<td>SpiceWild Cherry, Licorice, Chocolate Mint, Grapefruit, Coffee, Cherry, Peach</td>
</tr>
<tr>
<td>Acid</td>
<td>Raspberry, Orange, Lemon, Lime</td>
</tr>
<tr>
<td>Sour</td>
<td>Raspberry, Fruits, Berries, Acacia</td>
</tr>
<tr>
<td>Oily</td>
<td>Syrup</td>
</tr>
<tr>
<td>Sweet</td>
<td>Peppermint, Anise, Wintergreen</td>
</tr>
<tr>
<td>Acid</td>
<td>Fruit, Berry, Vanilla</td>
</tr>
<tr>
<td>Metallic</td>
<td>Citrus, Berries, Mint, Grape, Marshmallow</td>
</tr>
</tbody>
</table>

**Physical methods:** physical methods include the formation of insoluble compounds, emulsification of oils, effervescence, high viscosity fluids and the coating of tablets. Insoluble compounds can be formed and result in a minimal taste due to the drug. The drug must be in solution for it to be “tasted”; therefore, drugs in suspension usually do not impart taste. Poorly tasting oils can be incorporated into the internal phase of an oil-in-water emulsion and the external aqueous phase can be sweetened and flavored. This is the principle behind products such as cod liver oil emulsion, castor oil emulsion, etc., where the patient primarily tastes the sweetened, flavored external aqueous phase upon administration.

**Chemical Methods:** Chemical methods include adsorption and complexation of the active drug to a material, resulting in a loss of the undesirable taste characteristics. Physiological Methods: Physiological Methods include utilizing the anesthetic effect imparted by menthol and mint, which can be used to assist in making a taste more palatable. Flavoring materials are very complex mixtures. The following table illustrates the number of separate chemicals that may be contained in both natural and artificial flavors.

**Evaluation of medicated Lozenges**

(A) Quality Control

1. **Candy base** – It has to be checked for the following parameters-Corn syrup, sugar delivery gears, temperature, steam pressure and cooking speed of pre-cookers and temperature, steampressure, cooking speed and vacuum of candy base cookers.

2. **Moisture analysis**
   a. **Gravimetric method** - 1 g of sample is placed in vacuum oven at 60-70oC for 12-16hrs. After a specified period of time, weigh the sample and moisture content is calculated by subtraction of final weight from initial weight.
Moisture Content =Initial weight – final weight

b) Karl Fisher titration- A sample calculated to contain 10-250mg water is taken in titration flask and titrated with Karl Fischer reagent.

c) Azeotropic distillation method

10-12g pulverized candy placed in 500ml flask (to which 150-200ml toluene is added) flask is connected to a reflux condenser (reflux for 1-2 hrs ) water collected gives the amount water present in the sample

(3) Determination of sugar and corn syrup ratios- This is done by "Dextrose equivalent method: Lane Eynon Titration method".

(4) Percentage reducing sugars

3g anhydrous dextrose dissolved in 500ml water add 2 drops of methylene blue and (boiled for 2mins) titrated against 25ml of fehling solution to a yellowish red end point percent reducing sugar = reducing sugar factor × 100 sample weight 250× vol. of sample soln consumed by fehling’s soln

(5) Salvage solutions- Determined using a refractometer.

(6) Forming checks- Involves a check on candy rope diameter.

(7) Cooling checks- Visual inspection is performed in order to analyze any stress cracking due to rapid cooling, air bubble formation, surface cracking and black specks.
(B) Physical and Chemical Testing

(1) Diameter and thickness- Diameter of the lollipop is important for uniformity of lozenges size. It can be measured using Vernier Calipers. The extent to which the diameter of the lozenges deviated from ± 5% of the standard value.

(2) Hardness- The resistance of lozenges to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of lollipops can be measured by using Monsanto hardness tester. The hardness was measured in terms of kg/cm².

(3) 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.

\[
\text{Weight Variation} = \frac{\text{Average weight} - \text{Initial weight}}{\text{Average weight}}
\]

(4) Drug excipients interaction studies- Determined by FTIR.

(5) Friability - Determined by Roche Friabilator operated at 25rpm for 4min.

(6) In-vitro drug release- This is carried out in USP II paddle type dissolution apparatus.

(7) Drug content- Appropriate number of lollipop are crushed and dissolved in an appropriate solvent and the absorbance of the solution is measured spectrophotometrically.

Table 4: Therapeutic applications of medicated Lozenges.

<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Therapeutic uses</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Anesthetic</td>
<td>Lidocaine, benzocaine</td>
</tr>
<tr>
<td>2.</td>
<td>Analgesic</td>
<td>Fentanyl, codeine, ketamine</td>
</tr>
<tr>
<td>3.</td>
<td>Antifungal</td>
<td>Clotrimazole, miconazole, amphoteresin</td>
</tr>
<tr>
<td>4.</td>
<td>Smoking cessation</td>
<td>Nicotine</td>
</tr>
<tr>
<td>5.</td>
<td>Nausea relief</td>
<td>Ondansetron, promethazine, ginger root</td>
</tr>
</tbody>
</table>

(C) Microbial check

In this, the presence of any bacterial, mold or spore contamination is checked in raw materials, finished products, machinery, cooling tunnels, environmental conditions and storage drums.
Laboratory microbial testing should include the following counts:

- Total plate
- Total coliform
- Yeast and mold
- E.coli
- Staphylococcus
- Salmonella

(D) Stability testing

Lozenges are subjected to stability testing under following conditions-

- 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.

Stability testing of product in package-

Lozenges in their final packs are subjected to following conditions for stability testing:

- 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.

Recent advances

The USP currently recognizes Cetyl pyridinium chloride Lozenges and Nystatine lozenges. Sublingual Zolpidem tartarate lozenge for the treatment of Insomnia was developed.

Bacitracin was developed in the form of lozenge for the treatment of infections caused after burns, scars etc.

Nicotine lozenges

These are the newest form of Nicotine replacement therapy on the market. The FDA recently approved the first Nicotine-containing lozenge as an over-the-counter aid in smoking cessation.

These are available in 2 strengths: 2 mg and 4 mg.
Applications of lozenges

Antifungal lozenges: Oral lozenges, such as clotrimazole and nystatin, are used to treat fungal infections.

Nicotine lozenges: Nicotine lozenges are used as a method to quit smoking. The lozenges release nicotine into bloodstream when you suck on the lozenges, according to the Mayo clinic. Nicotine smoking is intended to be used as often as necessary, until the craving to smoke ceases.

Zinc lozenges: Zinc is used as an antioxidant to help your body fight infections. When contained in lozenges, zinc is thought to help reduce the duration of colds and symptoms. Yet, the Mayo clinic notes that there are conflicting studies on whether those zinc claims are accurate.

Throat/cough lozenges: Sore throat lozenges contain an anesthetic, such as benzocaine, to soothe your throat. The anesthetic works by numbing the affected area to provide temporary relief. Some throat lozenges also might contain an antibiotic to treat diseases of the throat, including strep throat. Cough lozenges which suppress coughing, can contain ingredients, such as menthol or eucalyptus.

Erectile dysfunction lozenges: According to the New Zealand men’s clinic, lozenges are available to treat erectile dysfunction. The lozenges are administered up to the 30 minutes before intercourse erectile dysfunction lozenges have less side effects than tablet forms.

Morning sickness lozenges: Prenatal lozenges contain pyridoxine, or vitamin B6 helps to relieve nausea and vomiting symptoms. The use of prenatal lozenges should be taken as directed by your physician, since high doses of B6 during pregnancy can cause side effects in your newborn.

Marketed products

<table>
<thead>
<tr>
<th>Type</th>
<th>Ingredients</th>
<th>Effects</th>
<th>Uses</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amylmetacresol 2,4 dichlorobenzylalcohol lozenges</td>
<td>Corn syrup mixed with mucoadhesive polymers</td>
<td>Rapid release of the drug in the mouth</td>
<td>Acute sore throat and as analgesics</td>
<td>Wade et al 2011</td>
</tr>
<tr>
<td>Salbutamol sulphate lozenges</td>
<td>Isomalt a tooth friendly sugar substitute mixed with corn syrup</td>
<td>Extended drug release profile for 60 min</td>
<td>Asthma</td>
<td>Rajesh kini 2011</td>
</tr>
<tr>
<td>Medicine Type</td>
<td>Ingredients</td>
<td>Effect/Use</td>
<td>Author(s)</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td>Ketoconazole lozenges</td>
<td>Sucrose, citric acid, HPMC, HEC</td>
<td>Reduces gastric irritation by passing first pass metabolism</td>
<td>Nagobas.n 2011</td>
<td></td>
</tr>
<tr>
<td>Paracetamol lozenges</td>
<td>Paracetamol, sucrose, sodium CMC, methyl cellulose</td>
<td>Slow release of medicaments</td>
<td>Dhrmajitpattanayak 2011</td>
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<tr>
<td>Clotrimazole lozenges</td>
<td>Sugar base, acacia/guar gum/methyl cellulose, citric acid, artificial flavours and colours</td>
<td>Prolonged oral retension time</td>
<td>Shivappa N Nagoba 2012</td>
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<tr>
<td>Artesunate oral retentive lozenges</td>
<td>Mucoadhesive polymer like sodium hydroxyethyl cellulose is used</td>
<td>Prolonged retension of the lozenges</td>
<td>Edward K Kamamia</td>
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<tr>
<td>Montelukast sodium lozenges</td>
<td>Montelukast sodium glucose HPMC</td>
<td>Prolonged retention in the mouth</td>
<td>Waliamandee, purushottamrao 2013</td>
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<tr>
<td>Marshmallow root extract lozenges</td>
<td>Xanthum gum as a gummy base</td>
<td>Increased the disintegration time over 30 min and retained in vitro drug release rate 40% for 30 min of the lozenges</td>
<td>Bistrakostova 2013</td>
<td></td>
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<tr>
<td>Garlic and ginger lozenges</td>
<td>Sucrose, sodium chloride, pvp, SCMC</td>
<td>Taste masking with good release matrix type lozenges</td>
<td>Charlie o. esimone 2013</td>
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<tr>
<td>Itroconazole topical delivery lozenges</td>
<td>Rolled into lozenges using PEG base</td>
<td>90% drug release by the end of 60 min and remain stable</td>
<td>Deepikamodyala 2014</td>
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<tr>
<td>Ondansetron HCl lozenges</td>
<td>Sucrose as a base and eudragit E100 SCMC, HPMC K 4M, methyl cellulose as a binder used</td>
<td>Increased in bioavailability reduction in gastric irritation by passing of first pass metabolism and increased in onset of action</td>
<td>Suchitapundhir 2014</td>
<td></td>
</tr>
<tr>
<td>Fluconazole tablet Lozenges</td>
<td>Maize starch, acacia, HPMC, E50, Sucrose as base and</td>
<td>Increased bioavailability. Reduction in Oral thrush</td>
<td>V.B.Bharkad</td>
<td></td>
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</tbody>
</table>
CONCLUSION
Lozenges are organoleptically accepted formulations by the pediatric patients and patients having dysphasia. Lozenges as medicated confections both for systemic and local delivery of drugs are growing more popular. They are expected to acquire more demand in pharmaceutical production as innovative dosage forms for potent drugs which seem to be an ideal dosage form. Lozenge provide easy administration, convenience to patient, large patient compliance and efficient treatment of low drug dosing, immediate onset of action, reduced dosage regimen and cost effectiveness. New drug design in this area always benefit for the patient, physician and drug industries. This will offer better innovative dosage form. Lozenges enjoy an important position in pharmacy and will continue to remain at the same future.

REFERENCES
7. Loyd V. Allen, J1r.,1 Ph.D11111111. troches and lozenges Current & Practical Compounding Information for the Pharmacist. 4(2).


