INTRODUCTION

Lozenges dissolve slowly in the mouth or throat which is a favored delivery system particularly for drugs meant for relieving sore throats and cold symptoms. The name “troche” can be applied to compressed lozenges but the term lozenge and troches are used interchangeably. Lozenges are intended to be held in the mouth or pharynx containing one or more medicaments either dissolved or dispersed in a sweetened base. Lozenges are used for patients who have difficulty swallowing. Solid oral dosage forms as well as for the drugs which should be released slowly to yield a constant amount of drug in the oral cavity or to coat the throat tissues with the solution of drug. The lozenge tablets differ from conventional tablets in terms of slower dissolution profiles. Commercially lozenges are made by moulding or by compression they slowly dissolve or disintegrate in the mouth sometime they are chewed. Lozenges made by compression are harder than ordinary tablets. Lozenges prepared using sugars to form a hard lozenges, polyethylene glycol (PEG) to form a soft lozenges and gelatin to form a chewable type of lozenges. A throat lozenge includes cough drop, troche, cachou, or cough sweet which is a small, medicated tablet intended to be dissolved slowly in the mouth to temporarily arrest coughs, to lubricate and to soothe the irritated tissues of the throat infections (sore throat) caused due to common cold or influenza. Several brands of throat lozenges like halls contain menthol, peppermint oil, eucalyptus oil and/or spearmint as their active ingredient(s) and some honey lozenges. Non-menthol throat lozenges generally use either zinc gluconate glycine or pectin as an oral demulcent. Chewable lozenges are popular among the pediatric and geriatric populations.

A number of innovative technologies have been developed to improve the conventional forms of lozenges which include the use of novel ingredients and techniques to enhance taste, reduce calorie content, facilitate quick manufacture and modify the drug release characteristics. The benefits of the medicated lozenges is to increase the retention time of the dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. The predilection of lozenge can be attributed mainly to their ability to keep the naso-pharyngeal mucosa moist, enhance the swallowing reflex and to provide longer contact time of the drug on the mucosal layer.

Lozenge tablets are loaded with analgesics like Codeine, Ketamine, Fentanyl and Paracetamol; antifungal like Ketoconazole, Miconazole, Clotrimazole, Amphotericin B; anesthetics like lidocaine, benzocaine; antimicrobials like Artesunate; anti-emetic like Ginger root extract, Ondanestron and Promethazine; and Antihistamines like Chlorpheniramine maleate, Phenyltolaxamine DihydrogenCitrate, Diphenhydramine HCI; Anti-asthmatics like Salbutamol, Theophylline; antimicrobial action egitraconazole, and Thryrothrinic; demulcents action e.g. Zinc gluconate; antiseptics action e.g. Chloraseptic; having astringent action e.g herbal pastilles; and having antitussive properties like Dextromethorphanhydrobromide, Besides, Decongestants like Phenyl propanolamineHCI, d-pseudo ephedrine HCI. steroid like corticosteroids; smoking cessation e.g. Nicotine and some aromatics. Traditional drugs used in lozenge dosage form are Phenol, Sodium phenolate, and Cetylpyridinium chloride etc.

Lozenge exerts local effect at a particular site in the oral cavity and some systemic effect for which the drug undergoes circulation in the bloodstream and exhibits its pharmacological action eg. Some vitamins C and D lozenges and multivitamin lozenge tablets contains B-Complex and lozenges containing nicotine for smoking cessation. More recently it is proved that single or multiple ingredients lozenges may be formulated for
chronic ill patient, making a patient’s friendly lozenge dosage form.

Types of Lozenges

1. Based on Site of Action: Local and systemic action lozenges
2. Based on Texture: Medicated type compressed lozenge tablets, hard candy lozenges, chewy or caramel based medicated lozenges, soft lozenges and center filled lozenges and non-medicated type lozenge include sugar candies and lollipops.

Advantages of Lozenges

1. Ease of administration to paediatric and geriatric patients
2. Local and systemic effect through oral cavity
3. Increased contact time of the drug
4. Prolonged drug action
5. Avoid first pass metabolism of drugs
6. Do not require water for intake
7. Suitable for patients having difficulty swallowing (Dysphagia)
8. Lozenge can be withdrawn if dose is not needed
9. Modification of formula as per the patient’s need
10. Less production time
11. Cost of production is less
12. Provides flavour and pleasant taste to the mouth
13. Better patient compliance

Disadvantages of Lozenges

1. Non-uniform distribution of drug in the saliva for local therapy
2. Possible draining of drug into the stomach
3. Accidental swallowing of entire dosage form

Table 1: Ingredient used in lozenge formulation

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candy Base</td>
<td>Candy Base</td>
</tr>
<tr>
<td>1. Sugar</td>
<td>Sucrose, Maltose, Lactose, Dextrose, Polyethylene Glycol (PEG) 600 and 800, Mannitol and Sorbitol.</td>
</tr>
<tr>
<td>2. Sugar free vehicles</td>
<td>Calcium Sulphate, Calcium Carbonate, Dicalcium Phosphate, Microcrystalline Cellulose,</td>
</tr>
<tr>
<td>3. Fillers</td>
<td>Candy Base</td>
</tr>
<tr>
<td>Binders</td>
<td>Acacia, Corn Syrup, Sugar Syrup, Gelatin, Polyvinyl Pyrrolidone, Tragacanth and Methylcellulose (MC).</td>
</tr>
<tr>
<td>Lubricants</td>
<td>Stearic Acid, Magnesium Stearate, Calcium Stearate, Polyethylene Glycol, vegetable oils and fats.</td>
</tr>
<tr>
<td>Flavouring Agents</td>
<td>Menthol, Eucalyptus Oil, Cherry flavour, Spearmint etc.</td>
</tr>
<tr>
<td>Colouring Agents</td>
<td>Water soluble and Lakolene dyes, Food Drug and Cosmetic Colours, Orange Colour paste and Red Colour cubes and etc.</td>
</tr>
<tr>
<td>Whipping agents</td>
<td>Milk protein (Casein), Egg Albumin, Gelatin, Xanthan gum, Starch, Pectin, Algin and Carrageenan.</td>
</tr>
<tr>
<td>Humectants</td>
<td>Glycerin, Propylene Glycol and Sorbitol.</td>
</tr>
</tbody>
</table>

Various ingredients of lozenge formulations

Figure 1: Steps Involved in Manufacturing of Lozenges

Sugar, Corn Syrup and water are mixed by heating → Incorporation of the drug to the candy base → Polymers, colors and flavours are added → The candies are sealed, wrapped in polyethylene sheets → Mixture is poured into the mould of required size and shape to form a candy
Manufacturing of Lozenges

LOZENGE FORMULATIONS

The lozenges are aimed to formulate into a stable dosage form and to provide a more promising means of administration of variety of drugs.

Criteria for the formulation of lozenges includes 8,10

1. Selection of suitable drug candidate
2. Selection of appropriate drug carrier excipients
3. Selection of appropriate type of lozenge formulation

Compressed Lozenge tablets 10,11

Compressed lozenges tablets are manufactured either by direct compression or wet granulation method. Thermoldable drugs can be made into a compressed lozenge tablets. The granulation method used for making lozenge tablets is as similar to that used for normal compressed tablet. The compressed lozenge is harder enough so that it dissolves slowly in the mouth. They have flat faced with sizes of 5/8 - 3/4 inch, weight 1.5 - 4 g, hardness 30 - 50 kg inch² and erosion time ranges between 5 -10 min. In direct compression, the compressed lozenge tablets contain sugar based vehicle like dextrose or sucrose including some sugar free vehicles like mannitol, sorbitol, polyethylene glycol (PEG) 6000 and 8000 for the benefit of diabetic patients if anti-diabetic drug are loaded as drug in the lozenge formulation. There are some commercially available sugar based vehicles used lozenge formulation in their brand name like Nu-tab, Sweetrex, Endex, Honey-Tab, Mola-tab and Sugar tab. In direct compression of medicated lozenges, dicalcium phosphate, calcium sulphate, calcium carbonate, lactose and microcrystalline cellulose are used as diluents in order to facilitate the formulation of lozenges. Acacia, corn syrup, sugar syrup, gelatin, polyvinyl-pyrrolidone, tragacanth and methylcellulose are used as binders to hold the particles as discrete granules to make free flow during compression into lozenge tablets. In the direct compression process, the free flow of mixture is aided by using lubricants like magnesium stearate, calcium stearate, stearic acid and PEG to make lozenges of the required weight. The water soluble colors and lake dyes are usually used to impart color to the lozenge tablets. All the selected ingredients are mixed homogenously and compressed into lozenge tablets. In wet granulation method sugar is ground into a fine powder by mechanical agitation and passed through sieve 40 -80 mesh size. Medicament is now added to the sugar mass and uniformly mixed. These homogenously mixed mass is granulated using sufficient amount of sugar syrup or corn syrup and passed through 2-8 mesh screen to get wet granules. These wet granules are dried and once again passed through 10-30 mesh size. Suitable flavor and lubricant are then added before compression into required size lozenge tablets.

Hard Candy Lozenges 10,11

Hard candy lozenges are manufactured by cooking process by dissolving desired quantity of sugar to prepare the candy base and other carbohydrates if any are then added to get an amorphous, non-crystalline glassy state in one third amount of water in the candy cooker at the temperature at about 110°C. If Baume base, a corn syrup if used in manufacturing of hard candy lozenges, the temperature should be kept in between 145 - 156 °C. Medicaments up to 2-4% can be incorporated in the hard candy lozenges. Sucrose, dextrose, maltose and lactose are added as sweeteners. citric, tartaric, fumaric and malic acid etc are added as acidulents to strengthening the candy base. Colours approved by FD & C are added with shades like orange, red, green or yellow. Flavours used include menthol, eucalyptus oil, spearmint, and cherry flavor etc. The moisture content should be between 0.5 to 1.5% and weight of hard candy lozenge lie between 1.5-4.5g. They undergo slow and uniform dissolution or erosion over 5-10 min. and it should not undergo disintegration. The temperature required for the preparation is usually high hence heat sensitive ingredients cannot be incorporated into them. Then the color is added to it in the form of solutions or pastes or cubes which is then mixed homogenously to get uniformly coloured mass. The weight of candy mass is checked by mounting the lubricated vessel containing the candy mass. This mass is then transferred to a water-jacketed stainless steel cooling table for mixing of drug and the flavor. The mixed mass is either poured into mould to get desired and uniform size lozenge. The mass may also be pulled into a ribbon and after cooling it is cut into desired length to obtain lozenges which are packed as single units using wrappers.

Chewy or Caramel based medicated lozenges 12

Chewy or caramel based medicated lozenges contains medicament incorporated into a caramel base which is chewed instead of being dissolved in mouth. These are made by using glycerinated gelatin suppository formula containing gelatin, gelatin, and water. The other ingredients incorporated are candy base, whipping agent, humectants, lubricants, flavour and the selected medicaments. Caramel based medicated lozenges are manufactured by allowing the caramel base to cool to 120 °C. This is followed by the addition of whipping agent at temperature 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 at about 90 °C. Seeding crystals and flavour are then added below 85 °C followed by lubricant, added at above 80 °C. These lozenges are fruity flavoured and have a slightly acidic taste to mask the acrid taste of drug. The candy base contains sugar and corn syrup in two ratios either 50:50 or 75:25. The whipping agents used to aerate the toffee-based confections to obtain the desired degree of softness to chew. The humectants improves mouth feel includes gelatin, propylene glycol and sorbitol. Lubricants are added to avoid sticking of candy to the teeth while chewing which include 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 more quickly. Candies which are formed in the form a long rope of suitable thickness cut to a desired size and then packed using wrappers.

Soft Lozenges 13,14

Soft lozenges are made by using polyethylene glycol 1000 or 1450, chocolate or sugar-acacia base which gives soft texture to the lozenges. They are made by hand roll method to a desired size and thickness and cut into pieces or the warm mass can be poured into a plastic mould to get soft lozenges. The soft candy lozenge contains silica gel which acts as a suspending agent to prevent sedimentation of particles in the moulds during cooling. The formulation requires heating to about 50 °C and it should not undergo overfilling is required since itself provides a soft texture. Soft lozenges containing Cotrimazole is made by moulding method in which the increasing amount of PEG, Xanthan gum or Xylitol
increases the hardness of the lozenge and hence the disintegration time, care must be taken in the quantity of these agents.

**Center Filled Hard Lozenges**

Center filled hard lozenge tablets are hard candy type with a soft or liquid filled center containing the active medicament. There are various types of centre filled lozenges like liquid filled containing fruit juice, sugar syrup, sorbitol solutions or hydroalcoholic solutions at about 10-20 % of fill weight. Fat filled centre containing medicament or flavour being suspended or dissolved in hydrogenated fats with a fill weight of 25-32%. Paste centre filled lozenge contains crystals and granules formulated as paste with a 40% of fill weight. Fruit centre Jellies and jams where corn syrup or liquid sucrose had modified into a viscous gel form with a fill weight at about 20-25%. Center filled hard lozenges are manufactured by forming a candy base or vehicle comprising sugar, corn syrup and water; the candy base or the vehicle was heated to remove water therefrom to obtain a cooked candy base having a residual moisture content ranging from about 0.02% to about 5.0%. Then, subsequent cooling the candy base or vehicle to a soft state and forming the candy base into a rope. The rope is wrapped around a filling pipe and a powder or semi-liquid center film was prepared containing medicament in a stabilizing base including vegetable oil, and optionally sugar and/or gelatin. The semi-liquid or the powder center filler was dispensed into the center of the candy base or vehicle in a ratio of about 2 to 50% by weight of the medicament.

**Table 2: Medicated lozenges and their proven facts**

<table>
<thead>
<tr>
<th>Type</th>
<th>Ingredients</th>
<th>Effects produced</th>
<th>Uses</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin agar pastilles</td>
<td>Gelatin and agar</td>
<td>Retention time was found to be 4-5hrs</td>
<td>Spirochaetal infection and for hemolytic streptococcal infection of throat</td>
<td>Greer et al 1945&lt;sup&gt;15&lt;/sup&gt;</td>
</tr>
<tr>
<td>Multi-layered Pastilles</td>
<td>Enteric coated controlled and pulsatile release polymer like Polyethylene Glycol added with colloidal silicon dioxide</td>
<td>Delayed in vivo drug release</td>
<td>Asthma, chronic obstructive pulmonary disease, (COPD) and for chrono-therapeutic management of nocturnal asthma</td>
<td>Shukla et al 2009&lt;sup&gt;16&lt;/sup&gt;</td>
</tr>
<tr>
<td>Amylmetacresol and 2,4 – dichlorobenzyl alcohol Lozenge</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 analgesic</td>
<td>Wade et al 2011&lt;sup&gt;17&lt;/sup&gt;</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 minutes</td>
<td>Asthma</td>
<td>Rajesh Kini 2011&lt;sup&gt;18&lt;/sup&gt;</td>
</tr>
<tr>
<td>Ketoconazole lozenges</td>
<td>Sucrose, Citric Acid, Hydroxy Propyl methyl cellulose and Hydroxy Ethyl Cellulose</td>
<td>Reduces gastric irritation by passing first pass metabolism</td>
<td>Fungal infections in pediatric and geriatrics.</td>
<td>NagobaS.N 2011&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
<tr>
<td>Paracetamol lozenges</td>
<td>Paracetamol, Sucrose, Sodium Carboxy Methyl Cellulose, Methyl Cellulose</td>
<td>Slow release of medication</td>
<td>Fever and pain</td>
<td>Dharmajit Pattanayak 2011&lt;sup&gt;20&lt;/sup&gt;</td>
</tr>
<tr>
<td>Clotrimazole lozenges</td>
<td>Sugar base, acacia/ Guar Gum/ Methyl Cellulose citric acid artificial flavours and colours</td>
<td>Prolonged oral retention time</td>
<td>Pediatric and geriatric dysphagia</td>
<td>Shivappa N. Nagoba, 2012&lt;sup&gt;21&lt;/sup&gt;</td>
</tr>
<tr>
<td>Artesunate oral retentive lozenges</td>
<td>Mucoadhesive polymer like sodium hydroxyl ethyl cellulose is used</td>
<td>Prolonged retention of the lozenges</td>
<td>Malaria in paediatric patient</td>
<td>Edward K kamamia 2013&lt;sup&gt;22&lt;/sup&gt;</td>
</tr>
<tr>
<td>Montelukast Sodium lozenges</td>
<td>Montelukast Sodium, glucose, Hydroxy Propyl Methyl Cellulose (HPMC)</td>
<td>Prolonged retention in the mouth</td>
<td>Asthma</td>
<td>Walia Mandep, K. PurushothamRao, 2013&lt;sup&gt;23&lt;/sup&gt;</td>
</tr>
<tr>
<td>Marshmallow root extract Lozenges</td>
<td>Xanthan gum as a gummy base</td>
<td>Increased the disintegration time over 30 min and retain in vitro drug release rate 40% for 30 min of the lozenges</td>
<td>Irritated oropharyngeal mucosa and associated dry cough</td>
<td>Bistra Kostova 2013&lt;sup&gt;24&lt;/sup&gt;</td>
</tr>
<tr>
<td>Garlic and ginger Lozenges</td>
<td>Sucrose, sodium chloride, poly vinyl pyrrolidone, sodium carboxy methyl cellulose</td>
<td>Taste masking with good release matrix type lozenge</td>
<td>Inhibitory activity against non-resistant C. albicans infections, non-resistant oral thrush</td>
<td>Charles O.Esimo 2013&lt;sup&gt;25&lt;/sup&gt;</td>
</tr>
<tr>
<td>Itraconazole 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>Topical application</td>
<td>Deepika Modyala 2014&lt;sup&gt;26&lt;/sup&gt;</td>
</tr>
<tr>
<td>Ondansetron hydrochloride lozenges</td>
<td>Sucrose as base and Eudragit E100, sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose K4M and methyl cellulose as binder are used</td>
<td>Increase in bioavailability, reduction in gastric irritation by passing of first pass metabolism and increase in onset of action</td>
<td>Chemotherapy induced nausea and vomiting.</td>
<td>Sachita Pandir 2014&lt;sup&gt;27&lt;/sup&gt;</td>
</tr>
<tr>
<td>Fluconazole tablet lozenges</td>
<td>Maize starch, acacia, HPMC E50. sucrose as base and gelatin as a binder</td>
<td>Increased bioavailability, reduction in gastric irritation, by passing first pass</td>
<td>Oral thrush</td>
<td>V.B. Bharkad 2014&lt;sup&gt;28&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Formulations proved to be effective as Lozenges

Table 3: List of marketed lozenges

<table>
<thead>
<tr>
<th>S.N.</th>
<th>Products</th>
<th>Ingredients</th>
<th>Other Ingredients</th>
<th>Indication</th>
<th>Marketed By</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cepacol</td>
<td>Menthol, Benzoic acid</td>
<td>Cetylpyridinium Chloride, glucose, peppermint oil, propylene glycol, sucrose, yellow 10</td>
<td>Sore Throat</td>
<td>Combe incorporated</td>
</tr>
<tr>
<td>3.</td>
<td>Clostrimazole lozenges</td>
<td>Clostrimazole</td>
<td>Croscarmellose Sodium Dextrates, magnesium stearate, Cellulose Microcrystalline, Povidone</td>
<td>Oral thrush</td>
<td>Perrigo company</td>
</tr>
<tr>
<td>4.</td>
<td>Koflet-h</td>
<td>Madhu Haritaki, Trikatu, Kalanjana (Alpinia galanga) Khadira (Acacia catechu) Oils. Lavanga, Sukshmalia (Elettaria cardamomum), Darusita (Cinnamomumzeylanicum), Sugar base</td>
<td>Alleviate cough and quickly relieves throat irritation</td>
<td>Himalaya Herbal Healthcare</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Lockets</td>
<td>Eucalyptus and menthol</td>
<td>Sugar, Glucose syrup, Honey, Glycerol, Citric Acid, Vitamin C, Monopropylene Glycol, Colors E122 and E142</td>
<td>Nasal congestion and sore throat</td>
<td>Wrigley Company</td>
</tr>
<tr>
<td>6.</td>
<td>Nicorette</td>
<td>Nicotine</td>
<td>Aspartame, calcium polycarbophil, flavor, magnesium stearate, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum</td>
<td>Smoking cessation</td>
<td>Perrigo company</td>
</tr>
<tr>
<td>7.</td>
<td>Strepsils</td>
<td>Amylmetacresol, dichlorobenzyl alcohol</td>
<td>Hexylresorcinol, sucrose, glucose, levmethonol, blackcurrant flavour (contains propylene glycol), carmoisine edicol (E122), patent blue V (E131)</td>
<td>Sore throat and blocked nose</td>
<td>Reckitt Benkiser</td>
</tr>
<tr>
<td>8.</td>
<td>Sualin</td>
<td>Glycyrrhiza Glabra</td>
<td>Adhatovasav, Ocimum sanctum, Menthaarvensis, Pimpinellaanum, Eucalyptus Citriodora, Cinnamom zeylanicum, Piper cubeba.</td>
<td>Influenza, bronchitis, sore throat, cold and cough, congestion of head and lungs</td>
<td>Hamdard (WAKF) Laboratories</td>
</tr>
<tr>
<td>9.</td>
<td>Sucrets</td>
<td>Dextromethorphan Hydrobromide</td>
<td>Corn Syrup, D&amp;C Yellow, Hydrogenated Palm Oil, Menthol, N&amp;A Honey Lemon Flavor, Sugar</td>
<td>Sore throat</td>
<td>Insight Pharmaceuticals</td>
</tr>
<tr>
<td>10.</td>
<td>Therazine</td>
<td>Zinc Gluconate</td>
<td>Vitamin A (Acetate) 500 IU, A proprietary blend of Slippery Elm Bark of Ulmus Fulva (4:1), Propolis, Elderberry, Larch and Mullein, natural flavors.</td>
<td>Common cold and flu</td>
<td>Quantum Healthcare</td>
</tr>
<tr>
<td>11.</td>
<td>Vicks</td>
<td>Menthol</td>
<td>Ascorbic acid, eucalyptus oil, FD&amp;C Blue No. 1, FD&amp;C Red No. 40, flavor, liquid glucose, sucrose.</td>
<td>Sore throat</td>
<td>Procter and Gamble</td>
</tr>
<tr>
<td>12.</td>
<td>Vigroids</td>
<td>Liquorices</td>
<td>Maize starch, menthol, kaolin, tragacanth, eucalyptus oil, peppermint oil, tolu tincture</td>
<td>Expectorant</td>
<td>Ernest Jackson</td>
</tr>
</tbody>
</table>

Few lozenge formulations available in the market

EVALUATION TEST FOR LOZENGES

Quality Control

Candy Base- For the candy base it is essential to check for corn syrup and sugar delivery gears; temperature, steam pressure, cooking speed, temperature and vacuum of candy based cooker.

Moisture Analysis

Gravimetric method: Weigh 1g of sample and noted as its initial weight, it is then placed in a vacuum oven at 60-70°C for 12-16 hours. After specified intervals of time, once again weigh the sample and moisture content can be calculated using the following formula.

Moisture Content = Initial weight – final weight

Moisture Analysis
Azeotropic Distillation Method

Figure 2: Azeotropic distillation method - Moisture Analysis

Karl Fisher titration - A sample of the prepared lozenge is calculated to obtain 10-250mg of water which is then titrated with Karl Fischer reagent.

Determination of sugar and corn syrup ratio
The test is carried out by Lane Eynon Titration method which is a Dextrose equivalent method.
1. Percentage Reducing Sugar

Figure 3: Percentage Reducing Sugar

\[
\text{Percent Reducing Sugar} = \frac{\text{Reducing Factor} \times 10}{(\text{Sample weight/250}) \times \text{volume of sample consumed by Fehling's solution}}
\]

1. Determination of salvage solutions using a refractometer.
2. Rope forming test involves checking of the rope diameter of the candy.
3. Cooling checks is done on visual inspection to analyze any stress cracking occurs due to rapid cooling, bubble formation, surface cracking and black spots.

Physical and Chemical Testing

1. Hardness of the lozenges is determined by Pfizer or Monsanto hardness tester.
2. Diameter and thickness of the lozenges are determined by using Vernier callipers.
3. Friability of the prepared lozenges can be determined by Roche Friabilator operated at 25rpm for 4mins.
4. Weight variation test is done on 20 lozenges, initially they are weighed and average weight is determined. Individual weight is compared with the calculated average weight.
5. Drug and the excipients interaction can be determined by FTIR.
6. In vitro drug release is carried out using USP II paddle type dissolution apparatus.
7. Drug content is done by taking an appropriate number of lozenges being crushed and dissolved in a suitable solvent and the resultant absorbance of the solution is measured spectrophotometrically.

**Microbiological Test For Lozenges**

The presence of bacteria, mold or spore in the formulated Lozenges is checked on raw materials, finished products, machinery used, cooling tunnels, environmental conditions and storage drums etc. Laboratory microbial tests include the counts on total plate, total coliform, yeast and mould, E.coli, staphylococcus species and salmonella.

**Stability Testing for Lozenges**

Lozenges soon after prepared is subjected to stability testing as per the prescribed conditions either 1-2 months at 60°C or 3-6 months at 45°C or 9-12 months at 37°C and or 36-60 months at 25° and 4°C. The lozenges in their final pack should be stored either at 25°C at 80% RH for 6-12 months or 37°C at 80% RH for 3 months and or 25°C at 70% RH for 6-12 months for its stability study as per ICH guidelines.

**PACKAGING OF LOZENGES**

Lozenges are usually hygroscopic in nature hence an involute and multiple packing system should be used in order to maintain its stability during marketing. The single unit of lozenge is to be wrapped in a moisture impervious liner. These wrapped lozenges are then placed in a tamper proof or water resistant glass, polyvinyl chloride or metal container. Finally, these are over-wrapped using aluminum foil or by a cellophane sheet.

**STORAGE**

Lozenges should be stored from extremes of temperature or humidity condition. Refrigerator or room temperature is generally specified on the label of the product depending on the storage requirements of both the drug and the base used in the lozenge formulation. Lozenges should be kept out of reach by the children as per the label instruction.

**CONCLUSION**

Lozenges are organoleptically accepted formulations by the pediatric patients and patients having dysphagia. Lozenges as medicated confections both for local and systemic 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. Lozenges 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. Lozenges surely will enjoy the most wanted position in pharmacy in the very near future.

**ACKNOWLEDGMENT**

The authors wish to convey gratitude to our respectful Dean, SRM College of Pharmacy, SRM University, who gave us constant support to complete this review article.

**REFERENCES**

3. The Pharmaceutics & Compounding Laboratories at the UNC Eshelman School of Pharmacy. [Cited 2015 December 29]; [about 1p.].
6. The Pharmaceutics and compounding Laboratory, Lozenges and medication sticks. [Cited 2015 December 29]; [about 3p.].
17. Wade AG et al., A multicenter randomized, double blind, single-dose study assessing the efficacy of AMC/DCBA Warm lozenge or AMC/DCBA Cool lozenge in the relief of acute sore throat. BMC FamPract.2011; 12(6).
34. Lozenges and medication sticks. The Pharmaceutics and compounding Laboratory. UNC ESHEL MAN/school of pharmacy

Cite this article as:

Source of support: Nil, Conflict of interest: None Declared

Disclaimer: IRJP is solely owned by Moksha Publishing House - A non-profit publishing house, dedicated to publish quality research, while every effort has been taken to verify the accuracy of the content published in our Journal. IRJP cannot accept any responsibility or liability for the site content and articles published. The views expressed in articles by our contributing authors are not necessarily those of IRJP editor or editorial board members.