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## **Review Article**

#### CHEWABLE LOZENGE FORMULATION- A REVIEW

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#### ABSTRACT

Development of lozenges dated back to 20<sup>th</sup>century and is still remain popular among the consumer and hence it has continued commercial production. Lozenges are palatable solid unit dosage form administrated in the oral cavity. They meant to be dissolved in mouth or pharynx for its local or systemic effect. Lozenge tablets provide several advantages as pharmaceutical formulations however with some disadvantages. Lozenge as a dosage form can be adopted for drug delivery across buccal route, labial route, gingival route and sublingual route. Multiple drugs can also be incorporated in them for chronic illness treatments. Lozenge enables loading of wide range of active ingredients for oral systemic delivery of drugs. Lozenges are available as over the counter medications in the form of caramel based soft lozenges, hard candy lozenges and compressed tablet lozenges containing drugs for sore throat, mouth infection and as mouth fresheners. The rationale behind the use of medicated lozenges as one of the most favored dosage form for the delivery of antitussive drugs. This review focuses various aspects of lozenge formulation providing an insight to the formulation scientist on novel application of lozenge drug delivery system.

Keywords: Lozenges, antitussive, mucosal effect, local and systemic drug delivery

#### 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<sup>1</sup>, <sup>2</sup>. Lozenges are used for patients who have difficulty swallowing of 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<sup>3</sup>. The lozenge tablets differ from conventional tablets in terms of organolepticity, non-disintegrating characteristics and with 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, Amphoterisin B; anesthetics like lidocaine, benzocaine; antimicrobials like Artesunate; anti-emetic like Ginger root extract, Ondansetron and Promethazine; and Antihistamines like Chlorpheniramine maleate. Phenyltolaxamine Dihydrogencitrate, Diphenhydramine HCl; Anti-asthmatics like Salbutamol, Theophylline; antimicrobial action egItraconazole, Thyrothricin; demulcents action e.g. Zinc gluconate; antiseptics action e.g. Chloraseptic; having astringent action e.g herbal pastilles; and having antitussives properties Dextromethorphanhydrobromide, Besides, Decongestantants like Phenyl propanolamineHCl, d-pseudo ephedrine HCl. steroid like corticosteroids; smoking cessation e.g. Nicotine and some aromatics 5. 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 Lozenge

- 1. Based on Site of Action: Local and systemic action lozenges
- 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 lollypops.

# Advantages of Lozenges<sup>4-7</sup>

- Ease of administration to paediatric and geriatric patients
- 2. Local and systemic effect through oral cavity
- 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<sup>4-7</sup>

- Non-ubiquitous 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

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

#### Various ingredients of lozenge formulations

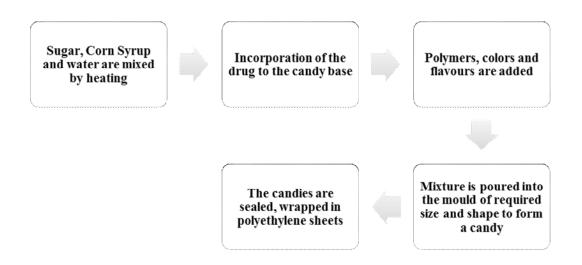


Figure 1: Steps Involved in Manufacturing of Lozenges 9,10

#### **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<sup>8, 9,10</sup>

- 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 be direct compression or wet granulation method. Thermolabile 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, Emdex, 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, polyvinylpyrrolidone, tragacanth and methylcellulose are used as binders to held 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 thorough 10-30 mesh size. Suitable flavor and lubricant are then added before compression into required size lozenge tablets.

# Hard Candy Lozenges<sup>10, 11</sup>

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. 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<sup>12</sup>

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 glycerin, gelatin, and water. The other ingredients incorporated are candy base, whipping agent, humectants, lubricants, flavour and the selected medicaments. Caramel based medicated lozengesare manufactured by allowing the caramel base to cool to 120 This is followed by the addition of whipping agent at temperature below 105 . The medicaments are then added between 95-105 . Colour is dispersed in humectant and added to the above mass at a temperature at about 90 . Seeding crystals and flavour are then added below 85 followed by lubricant, added at above 80. 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 glycerin, 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<sup>13, 14</sup>

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 rollmethod 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 it is suitable for heat resistant ingredients. The soft lozenges are meant for chewing and to provide a slow release of drug in the mouth. Soft lozenges contain polyethylene glycol are made by moulding method. The mass is poured over filling into the mould cavity as the polyethylene glycol shrinks on cooling gives spongy texture to the lozenge tablets in case of chocolate base no overfilling is required since itself provides a soft texture. Soft lozenge containing Clotrimazole 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<sup>14</sup>

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

Type	Ingredients	Effects produced	Uses	References
Penicillin agar pastilles	Gelatin and agar	Retention time was found to be 4-5hrs	Spirochaetal infection and for hemolytic streptococcal infection of throat	Greey et al 1945 <sup>15</sup>
Multi-layered Pastilles	Enteric coated controlled and pulsatile release polymer like Polyethylene Glycol added with colloidal silicon dioxide	Delayed in vivo drug release	Asthma, chronic obstructive pulmonary disease, (COPD) and for chrono-therapeutic management of nocturnal asthma	Shukla et al 2009 <sup>16</sup>
Amylmetacresol and 2,4 – dichlorobenzyl alcohol Lozenge	Corn syrup mixed with mucoadhesive polymers	Rapid release of the drug in the mouth	Acute sore throat and as analgesic	Wade et al 2011 <sup>17</sup>
Salbutamol sulphate lozenges	Isomalt a tooth friendly sugar substitute mixed with corn syrup	Extended drug release profile for 60 minutes	Asthma	Rajesh Kini 2011 <sup>18</sup>
Ketoconazole lozenges	Sucrose, Citric Acid, Hydroxy Propyl methyl cellulose and Hydroxy Ethyl Cellulose	Reduces gastric irritation by passing first pass metabolism	Fungal infections in pediatric and geriatrics.	NagobaS.N 2011 <sup>19</sup>
Paracetamol lozenges	Paracetamol, Sucrose, Sodium Carboxy Methyl Cellulose, Methyl Cellulose	Slow release of medicament	Fever and pain	Dharmajit Pattanayak 2011 <sup>20</sup>
Clotrimazole lozenges	Sugar base, acacia/ Guar Gum/ Methyl Cellulose citric acid artificial flavours and colours	Prolonged oral retention time	Pediatric and geriatric dysphagia	Shivappa N. Nagoba, 2012 <sup>21</sup>
Artesunate oral retentive lozenges	Mucoadhesive polymer like sodium hydroxyl ethyl cellulose is used	Prolonged retention of the lozenges	Malaria in paediatric patient	Edward K kamamia 2013 <sup>22</sup>
Montelukast Sodium lozenge	Montelukast Sodium, glucose, Hydroxy Propyl Methyl Cellulose (HPMC)	Prolonged retention in the mouth	Asthma	Walia Mandeep, K. PurushothamRao, 2013 <sup>23</sup>
Marshmallow root extract Lozenges	Xanthan gum as a gummy base	Increased the disintegration time over 30 min and retain in vitro drug release rate 40% for 30 min of the lozenges	Irritated oropharyngeal mucosa and associated dry cough	Bistra Kostova 2013 <sup>24</sup>
Garlic and ginger Lozenges	Sucrose, sodium chloride, poly vinyl pyrollidone, sodium carboxy methyl cellulose	Taste masking with good release matrix type lozenge	Inhibitory activity against non-resistant C. albicans infections, non- resistant oral thrush	Charles O.Esimone 2013 <sup>25</sup>
Itraconazole topical delivery Lozenges	Rolled into lozenges using PEG base	90% drug release by the end of 60 min. and remain stable	Topical application	Deepika Modyala 2014 <sup>26</sup>
Ondansetron hydrochloride lozenges	Sucrose as base and Eudragit E100, sodium carboxy methyl cellulose, hydroxy propyl methyl cellulose K4M and methyl cellulose as binder are used	Increase in bioavailability, reduction in gastric irritation by passing of first pass metabolism and increase in onset of action	Chemotherapy induced nausea and vomiting.	Suchita Pundir 2014 <sup>27</sup>
Fluconazole tablet lozenge	Maize starch, acacia, HPMC E50. sucrose as base and gelatin as a binder	Increased bioavailability, reduction in gastric irritation, by passing first pass	Oral thrush	V.B. Bharkad 2014 <sup>28</sup>

		metabolism, provide slow release medicament		
Joshanda, polyherbal lozenge	Conventional decoction form of Joshanda	Slow dissolution in the mouth, prolonged effect	Cold, cough and associated allergic	Monika Bansal, July 2015 <sup>29</sup>
Č		1 5	reactions	

#### Formulations proved to be effective as Lozenges

Table 3: List of marketed lozenges<sup>30,31</sup>

S.N.	Products	Ingredients	Other Ingredients	Indication	Marketed By
1.	Cepacol	Menthol, Benzocaine	Cetylpyridinium Chloride, glucose, peppermint oil, propylene glycol, sucrose,	Sore Throat	Combe incorporated
		Benzoeume	yellow 10		meorporated
2.	Chloraseptic	Benzocaine	Corn Syrup, FD&C Red #40, Flavor, Glycerin, Soy Lecithin, Sucrose, Water	Relief of minor sore throat and mouth pain	Prestige Brands Inc.
3.	Clotrimazole lozenge	Clotrimazole	Croscarmellose Sodium Dextrates, magnesium stearate, Cellulose Microcrystalline, Povidone	Oral thrush	Perrigo company
4.	Koflet-h	Madhu	Haritaki, Trikatu, Kulanjana (Alpiniagalanga) Khadira (Acacia Catechu) Oils. Lavanga, Sukshmaila (Elettaria cardamomum), Darusita (Cinnamomumzeylanicum), Sugar base	Alleviate cough and quickly relieves throat irritation	Himalaya Herbal Healthcare
5.	Lockets	Eucalyptus and menthol	Sugar, Glucose syrup, Honey, Glycerol, Citric Acid, Vitamin C, Monopropylene Glycol, Colors E122 and E142.	Nasal congestion and sore throat	Wrigley Company
6.	Nicorette	Nicotine	Aspartame, calcium polycarbophil, flavor, magnesium stearate, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum	Smoking cessation	Perrigo company
7.	Strepsils	Amylmetacr esol, dichlorobenz yl alcohol	Hexylresorcinol, sucrose, glucose, levomenthol, blackcurrant flavour (contains propylene glycol), carmoisineedicol (E122), patent blue V (E131)	Sore throat and blocked nose	Reckitt Benkiser
8.	Sualin	Glycyrrhiza Glabra	Aadhatodavasica, Ocimum sanctum, Menthaarvensis, Pimpinellaanisum, Eucalyptus Citriodora, Cinnamon zeylanicum, Piper cubeba.	Influenza, bronchitis, sore throat, cold and cough, congestion of head and lungs	Hamdard (WAKF) Laboratories
9.	Sucrets	Dextrometho rphan Hydrobromide	Corn Syrup, D&C Yellow, Hydrogenated Palm Oil, Menthol, N&A Honey Lemon Flavor, Sugar	Sore throat	Insight Pharmaceuticals
10.	Therazinc	Zinc Gluconate	Vitamin A (Acetate) 500 IU, A proprietary blend of Slippery Elm Bark of UlmusFulva (4:1), Propolis, Elderberry, Larch and Mullein, natural flavors	Common cold and flu	Quantum Health care
11.	Vicks	Menthol	Ascorbic acid, citric acid, eucalyptus oil, FD&C Blue No. 1, FD&C Red No. 40, flavor, liquid glucose, sucrose.	Sore throat	Procter and Gamble
12.	Vigroids	Liquorices	Maize starch, menthol, kaolin, tragacanth, eucalyptus oil, peppermint oil, tolu tincture	Expectorant	Ernest Jackson

## Few lozenge formulations available in the market

## **EVALUATION TEST FOR LOZENGES**

# Quality Control<sup>32, 33</sup>

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

## Azeotropic Distillation Method

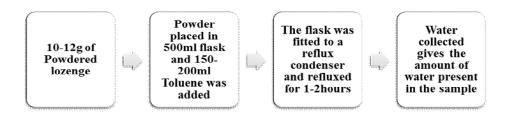


Figure 2: Azeotropic distillation method - Moisture Analysis

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.

Percentage Reducing Sugar

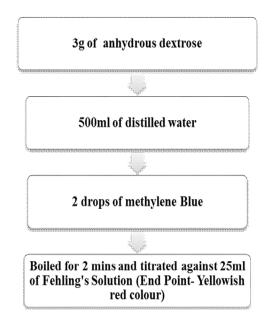


Figure 3: Percentage Reducing Sugar

# $\begin{aligned} \textbf{Percent Reducing Sugar} &= \frac{\textbf{Reducing Factor} \times 10}{(\textbf{Sample weight/250}) \times \textbf{volume of sample consumed by}} \\ &\quad \textbf{Fehling's solution} \end{aligned}$

- 1. Determination of salvage solutions using a refractometer.
- Rope forming test involves checking of the rope diameter of the candy.
- 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<sup>34, 35</sup>

- 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.
- 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.

- Drug and the excipients interaction can be determined by FTIR.
- In vitro drug release is carried out using USP II paddle type dissolution apparatus.
- 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<sup>36</sup>

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

#### PACKAGING OF LOZENGES<sup>37</sup>

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<sup>37</sup>

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.

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