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Review Article

MEDICATED CHEWABLE LOZENGES: A REVIEW

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ABSTRACT

Oral solid dosage form vary and have advantages over other dosage form. Lozenges are one of the widely used oral solid dosage form. They contain one or more medicament, usually in a flavored, 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 sooth the irritated tissues of throat. They are the most natural and easiest route of drug administration. They are design for local as well as systemic therapy. Lozenges have various advantages and disadvantages. Different types of lozenges and their method of preparation along with the ingredient used in their preparation are discussed. Examples of different synthetic and herbal lozenges with their proven facts and different marketed products can be known from these reviews. The selection criteria for flavoring agent are mentioned, quality control tests of lozenges have been reviewed. The acceptance for lozenges as a dosage form is high by adults and also more by children.

INTRODUCTION

Lozenges are solid, single dose preparation intended to be sucked to obtain, usually, a local effect in the oral cavity and the throat. They contain one or more active substances, usually in a flavored and sweetened base, and are intended to dissolve or disintegrate slowly in mouth when sucked. [1] Lozenges are used for patient who have difficulty in swallowing of solid oral dosage form 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 throat tissues with the solution of drug. A throat lozenge includes cough drop, troche, cachou or cough sweet which is small, medicated tablet intended to be dissolved slowly in mouth to temporarily arrest coughs, to lubricate and to soothe the irritated tissues of the throat infections (sore throat) caused due to common cold and influenza. Chewable lozenges are popular among the pediatric and geriatric population. [2]

They are intended to treat local irritation or infection of mouth or pharynx and may also be used for systemic drug absorption. Lozenges are intended to achieve local effect as soothing and purging the throat. Lozenges are also used for systemic effect provided the drug is well absorbed through the buccal linings or when it is swallowed. Lozenges are placed in oral cavity. Since the sublingual lozenges may be impractical due to their size, buccal lozenges are formulated and have been extensively used and are intended to be placed between the cheek and the gums. Though the lozenge dissolution time is about 30 minutes, this depends on the patient; as the patient controls the rate of dissolution and absorption by sucking on lozenge until dissolves. Sucking and the subsequent production of saliva may also lead to increased dilution of the drug and accidental swallowing. [3] Lozenges can be prepared by molding (gelatin and/or fused sucrose and sorbitol base) or by compression of sugar-based tablets. Molded lozenges are sometimes referred to as pastilles, whereas compressed lozenges may be referred to as troches. They 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 bath the throat tissues in a solution of the drug. Lozenges historically have been used for the relief of minor sore throat pain and irritation and have been used extensively to deliver topical anesthetics and antibacterial. Today they are used for of drugs like analgesics, anesthetics, antimicrobials, antiseptics, antitussives, aromatics, astringents, corticosteroids, decongestants, and demulcents and other classes and combinations.[4]

Advantages of Lozenges [5, 6]

1. It can be given to those patients who have difficulty in swallowing.
2. Easy to administer to geriatric and pediatric population.
3. It extend the time of drug in the oral cavity to elicit a specific effect.

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4. Systemic absorption of drug can be possible through buccal cavity.
5. Taste of drug can be masked by sweeteners and flavors used in formulation
6. It can increase in bioavailability.
7. It can reduce dosing frequency.
8. No disintegration

Disadvantages of Lozenges [5, 6]

1. Some drug may not be suitable with aldehyde candy bases e.g. Benzocaine.
2. The non-ubiquitous distribution of drug within saliva for local therapy.
3. Possible draining of drug from oral cavity to stomach along with saliva.
4. The lozenges dosage form could be used as candy by children mistakenly.
5. A hard candy lozenges is a high temperature required for their preparation

Table 1 Ingredient used in Lozenge Formulation [2]

Ingredient	Example
Candy base 1. Sugar 2. Sucrose free vehicle 3. 3. Fillers	Dextrose, sucrose, maltose, lactose. Mannitol, sorbitol, polyethylene glycol (PEG) 600 and 800. Di calcium phosphate, calcium sulphate, calcium Carbonate, lactose, microcrystalline cellulose.
Lubricant	Magnesium stearate, calcium stearate, Stearic acid, PEG, vegetable oil, fats.
Binder	Acacia, corn syrup, sugar syrup, gelatine, polyvinyl pyrrolidone, tragacanth, methylcellulose.
Colouring agent	Water soluble and lakolene dyes, FD and C colour, orange colour paste, red colour cubes etc.
Flavouring agent	Menthol, eucalyptus oil, spearmint, cherry flavour.
Whipping agent	Milk protein, egg albumin, gelatine, xanthan gum, starch, pectin, align and carrageenan
Humectants	Glycerine, propylene glycol and sorbitol.

Types of Lozenges

According to Site of Action

1. Local effect.
Ex. Antiseptic, Decongestants
2. Systemic effect.
Ex. Vitamins, Nicotine

According to texture and Composition

1. Chewy or caramel based medicated lozenges
2. Compressed tablet lozenges
3. Soft lozenges
4. Hard candy lozenges

According to Site of Action

Lozenges are classified into various classes based on various methods such as according to the site of action which can either be local or systemic effect. Examples of local effect are antiseptic, decongestion, while vitamins, nicotine are example of systemic effect. [3]

According to Texture and Composition

Chewy or Caramel Based Medicated Lozenges

These are the dosage form in which medicament is incorporated into a caramel base which is chewed instead of being dissolved in mouth. These lozenges are especially used for pediatric patients and are a very effective means of administering medications for gastrointestinal absorption and systemic use. One of the more popular lozenges for pediatric use is the chewable lozenge, or "gummy-type" candy lozenge. These gelatin based pastilles were prepared by pouring the melt into molds or out onto a sheet of uniform thickness. [5]

Manufacturing of chewy or caramel based medicated lozenges

The candy base is cooked at 95-125℃ and transferred to planetary or sigma blade mixer. Mass is allowed to cool to 120℃. This is followed by the addition of whipping agent below 105℃. The medicaments are then added between 95-105℃. Color is dispersed in humectant and added to the above mass at a temperature above 90℃. Seeding crystals and flavor are then added below 85℃. Followed by lubricant addition above 80℃. Candies are then formed by rope forming. [7]

Compressed Tablet Lozenges

When the active ingredient is heat sensitive, it may be prepared by compression. The granulation method is similar to that used for any compressed tablet. These tablets differ from conventional tablets in terms of

1. Organoleptic property
2. Non disintegrating characteristics and
3. 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. Commercially, the preparation of lozenges by tablet compression is less important. [5]

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 commination 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 screens. This is followed by drying and milling to 10-30 mesh size. Flavor and lubricant are then added prior to compression. [7]

Soft Lozenges

Soft lozenges have become popular because of the ease of extemporaneous preparation and applicability to a wide variety of drugs. The bases usually consist of a mixture of various polyethylene glycols, acacia or similar materials. One form of these soft lozenges is the pastille, which is defined as a soft variety of lozenge, usually transparent, consisting of a medication in a gelatin, glycero-gelatin or acacia: sucrose base. They are easy to use, convenient to carry, easy to store (room temperature), and are generally pleasant tasting. Polyethylene

glycol-based lozenges may have a tendency to be hygroscopic and may soften if exposed to high temperatures. [5]

Table 2 Synthetic Lozenges

Type	Ingredient	Effect produced	Uses	References
Ondansetron hydrochloride lozenges	Sucrose as base and Eudragit E100, NaCMC, hydroxyl propyl methyl cellulose K4Mand 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	SuchitaPundir 2014[8]
Diphenhydramine hydrochloride	Mannitol, sucrose, dextrose, isomalt, sodium citrate	Improve bioavailability by avoiding hepatic first pass metabolism of drug	Cough	Dasharath M. Patel 2014 [9]
Fluconazole tablet lozenges	Maize starch, acacia, HPMC, E50, sucrose as base and gelatin as binder	Increased bioavailability, reduction in gastric irritation by passing first pass	Oral thrush	V. B. Bharkad 2015[10]
Hard and soft lozenges of Albendazole	Albendazole, sucrose, dextrose, NaCMC , methyl cellulose , sorbitol solution	99.37% drug release after 30 min for hard lozenges and 88.92% drug release after 50 min for soft lozenges	Worm infection	Aparna 2015 [11]
Cefixime lozenges	PEG, gelatin, glycerin , citric acid, xylitol, sorbitol	Increase onset of action	Throat infection	Kirti et el2015[12]
Miconazole lozenges	Maize starch dried, sucralose, citric acid, PEG400, PEG6000, methylene chloride	Good buccal resistance time	Fungal infection in pediatric and geriatric	Majumdar S., 2015[13]
Domperidone candy lozenges	HPMCK100M, HPMCE5, sucrose, dextrose, citric acid, menthol, amaranth	Increase bioavailability		B. Moulika Lakshmi 2017[14]

Table 3 Herbal Lozenges

Type	Ingredient	Effect produced	Uses	References
Garlic and ginger lozenges	Sucrose, sodium chloride , poly vinyl pyrollidone, NaCMC	Taste masking with good release matrix type lozenges	Inhibitory activity against non- resistant C. albicans infection, non-resistant oral thrush	Charles O. Esimone 2010 [15]
Marshmallow root extract lozenges	Xanthan gum as gummy base	Increase the disintegration time over 30min and retain in vitro release rate 40%for 30 min of lozenges	Irritated oropharyngeal mucosa and associated dry cough	Bistrakostova 2013[16]
Liquorice and catechu lozenges	Galen IQ 990, liquid glucose, liquorice powder extract, black catechu powder extract	Combination of both drug produced synergistic effect	Recurrent aphthous stomatitis	Kasha D., 2016 [17]
Polyherbal extract based linkus lozenges	Adhatodavasica, glycyrrhizaglabra, piper longum, viola odorata, hyssopusofficinalis, cordialatifolia, alpiniagalanga	Suitable dosage form in symptomatic relief	Sore throat and cough	Hina R., 2017[18]
Eucalyptus oil and coleus aromaticus oil lozenges	Magnesium stearate, lactose, mannitol, gelatin, sucrose	Inhibitory activity against non-resistance C.albicans infection	Antimicrobial activity	Binu A., 2018 [19]

Formulation Proved to be Effective as Lozenges

Table 4 Synthetic Lozenges

S.N	Product	Ingredient	Other ingredient	Indication	Marketed by
1	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.
2	Clotrimazolelozenge	Clotrimazole	Crosscarmellose, sodium dextrates, magnesium stearate, cellulose microcrystalline, povidone	Oral thrush	Perrigo Company
3	Nicorette	Nicotine	Aspartame, calcium polycarbophil, flavor, magnesium stearate, mannitol, potassium bicarbonate, sodium alginate, sodium carbonate, xanthan gum	Smoking cessation	Perrigo company
4	Strepsils	Amylmetacresol, dichlorobenzyl alcohol	Hexylresorcinol, sucrose, glucose, levomenthol, blackcurrant flavour (contain propylene glycol), carmoisineedicol (E122), patent blue V (E131)	Sore throat and block nose	Reckitt Benkiser
5	Sucrets	Dextro Metrphan Hydro bromide	Corn syrup, D&C yellow, hydrogenated palm oil, menthol, N&A honey lemon flavor sugar	Sore throat	Insight Pharmaceutical

Table 5 Herbal Lozenges

S.N	Product	Ingredient	Other ingredient	Indication	Marketed by
1	Cepacol	Menthol, Benzocaine	Cetylpyridinium chloride, glucose, peppermint oil, propylene glycol, sucrose, yellow 10	Sore throat	Combe incorporated
2	Koflet – h	Madhu	Haritaki, trikatu, kulanjana (Alpiniagalanga) khadira(Acacia catechu) oils, lavanga, sukshmaila (Elettariacardamomum), Darusita	Alleviate cough and quickly relieves throat irritation	Himalaya Herbal Healthcare
3	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
4	Sualin	Glycyrrhizaglabra	Aadhatodavasica, ocimum sanctum, menthaarvensis, pimpinellaanism, eucalyptus citriodora, cinnamon zeylanicum, piper cubeba	Influenza, bronchitis, sore throat, cold and cough, congestion of head and lungs	Hamdard (WAKF) Laboratories
5	Vicks	Menthol	Ascorbic acid, citric acid, eucalyptus oil, FD&C red no. 40. Flavor, liquid glucose, sucrose	Sore throat	Procter and Gamble

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 mold. Mold 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. [7]

Hard Candy Lozenges

Hard candy lozenges 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 between, 0.5 to 1.5% and 1.5-4.5g respectively. These should undergo a slow and uniform dissolution or erosion over 5-10min., and should not disintegrate. The temperature requirements for their preparation is usually high hence heat labile materials cannot be incorporated in them. These pastilles were prepared by Heating and congealing method. [5]

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℃. Corn syrup is added and cooked till the temperature reaches 145-156℃. 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 color addition in form of solutions, pastes or color cubes. The mass is then transferred to a water-jacketed stainless steel cooling table for mixing and the flavor, drug and ground salvage is added. The mass is either poured in mold or pulled into a ribbon while cooling and then cut to desired length. The obtained lozenges are packaged. [7]

Medicated Lozenges and Their Proven Fact

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 base cooker. [2]

Moisture Analysis [2]

Gravimetric Method: 1g sample is weighed and placed in vacuum oven at 60-70℃ for 12-16 hrs. After specific interval of time, once again weigh the sample and moisture content is calculated using the following formula.

Moisture content = initial weight-final weight

Azeotropic Distillation Method

10-12g of powdered lozenges
Powder placed in 500ml flask and 150-200ml toluene was added

The flask was fitted to a reflux condenser and refluxed foe 1-2 hours

Water collected gives the amount of water present in sample

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

Physical and Chemical Testing [5]

Hardness- This is determined by Pfizer or Monsanto hardness tester.

Diameter and thickness- This is determined by Vernier calipers.

Drug excipient interaction studies- Determined by FTIR.

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

Weight variation- 20 lozenges are weighed and average weight is determined. Individual weight is compared to the average weight.

In-vitro Drug Release- This is carried out in USP II paddle type dissolution apparatus.

Drug Content- Appropriate number of lozenges are crushed and dissolved in an appropriate solvent and the absorbance of the solution is measured spectrophotometrically.

Microbial Test for Lozenges [7]

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:

1. Total plate
2. Total coliform
3. Yeast and mold
4. E. coli
5. Staphylococcus
6. Salmonella
7. Stability Testing

Stability Testing of Product- Lozenges are subjected to stability testing under following conditions-

- 1-2months at 60℃
- 3-6months at 45℃
- 9-12months at 37℃
- 36-60months at 25 and 40℃
- Stability testing of product in package- Lozenges in their final packs are subjected to following conditions for stability testing:
- 25℃ at 80%RH for 6-12months
- 37℃ at 80%RH for 3 months
- 25℃ at 70%RH for 6-12 months

Packaging [5]

Since the lozenges are hygroscopic in nature a complex and multiple packaging is adopted. The individual unit is wrapped in polymeric moisture barrier material which are then placed in tight or moisture resistant glass, polyvinyl chloride or metal container that is over wrapped by aluminum foil or cellophane membrane.

Storage

Lozenges should be stored away from heat and out of reach of children. They should be protected from extremes of humidity. Depending upon the storage requirements of both, the drug and the base, either room temperature or refrigerator temperature is usually indicated.

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CONCLUSION

Lozenges are medicated confections that have been developed about 20th century ago and are still under commercial production. Lozenges are organoleptically accepted formulation by the pediatric patients and patients having dysphasia. They are the most natural and easiest route of drug administration. They are easy to prepare and store. Lozenges are adopted for both local and systemic administration and a wide range of active ingredients can be incorporated in them. Sweetened and flavored lozenges are today's demands. They are expected to acquire more demand in pharmaceutical production as innovative dosage form for the potent drugs which seem to be an ideal dosage form. Most of the preparations are available over the counter products and are very economic dosage form. Lozenges enjoy an important position in pharmacy and will continue to remain so in future.

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