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MEDICATED LOZENGES: A COMPRESHIVE REVIEW ON FORMULATION AND APPLICATION

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ABSTRACT

Lozenges are solid medicated dosage forms containing a drug along with flavoring and Sweetening agents and are intended to be sucked and held in mouth or pharynx which dissolve or disintegrate slowly in the mouth. Development of lozenges dated back to 20th century and is still remain in the commercial production and have a bright future as novel method of delivering drugs for local and systemic effect lozenges provides the several advantages as pharmaceutical formulations however with some disadvantages. Lozenges as a dosage form can be adapted for drug delivery across buccal route, labial route, gingival route and sublingual route. Lozenges are of different types and are manufactured by different methods. Different types of lozenges available in market are compressed lozenges, hard lozenges & soft lozenges and their methods of preparation along with ingredients used in their preparation are discussed. The acceptance for lozenges as a dosage form is high by adults and also more by children. The present review covers more or less all aspects associated with lozenges it includes various research performed till date, advantages, disadvantages, classification, evaluation parameters, packing and application of lozenges.

KEYWORDS: Lozenges, Oral Drug Delivery (ODD), dysphagia.

INTRODUCTION

Oral drug delivery is simple, convenient, safest, non-invasive, economical and preferential route of administration. It is the most popular route due to ease of ingestion, pain avoidance,

versatility and most importantly, patient compliance. The most facing challenges in oral drug delivery are to overcome problems like pill-swallowing difficulty, delivery of unpalatable drugs and reducing dosing frequency. Pill swallowing difficulty primarily affects the patients having dysphagia, geriatric and pediatric populations.[1]

The ODD is the most preferred due to its convenience and rapid onset of action. ODD dosage forms have evolved as an alternative to conventional tablets, capsules and liquid preparations. Most of the ODD dosage forms are intended to disintegrate, dissolve or release the drug in the oral cavity, where it has opportunity to be locally absorbed, in part or whole alternatively may be swallowed and subsequently absorbed along the gastro-intestinal tract (GIT).[2]

The word "Lozenge" comes from the French word "Lozenge" which refers to a four-sided geometric diamond shape. Lozenge and pastille have been produced in pharmacies during the twentieth century and are still manufactured commercially.[3]

Lozenges are solid preparations that contain one or more medicaments, usually in a flavored, sweetened base, that are intended to dissolve or disintegrate slowly in the lubricate and sooth the irritated tissues of throat. They can be prepared by molding or by compression of sugar-based tablets. Molded lozenges are sometimes referred to as ‘pastilles. More amount of the drug will be absorbed from the buccal cavity and less will be swallowed and lost in GI Tract. Most of the lozenge formulations are available as Over the Counter (OTC) products where there is no need of prescription from a medical practitioner while some are prescribed by the medical practitioners.[4]

Medicated lozenges are designed to increase retention of dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. Lozenges should dissolve slowly in mouth and possess some degree of smoothness with their shape being without corners. Lozenges are formulated with various shapes like flat, circular, octagonal, biconvex, rod shaped etc.

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.[5]

ADVANTAGES[6,7]

- It Can be given to those patients who have difficulty swallowing.
- Easy to administer to the Geriatric and Pediatric.
- Pleasant taste.
- It extends the time of the drug in the oral cavity to elicit a specific effect.
- Easy to prepare with a minimum amount of equipment and time.
- Do not require water intake for administration.
- Can reduce gastric irritation and onset of action.
- Bypass first-pass metabolism.
- Improved patient compliance.
- Can Increase the bioavailability
- Can Reduced dosing frequency.
- Less production cost and times.

DISADVANTAGES[8]

- Some drugs may not be suitable with aldehyde candy bases eg; benzocaine.
- Children having above 6 years of age can use lozenges safety.
- The non-ubiquitous distribution of drug within saliva for local therapy.
- Possible draining of drug from oral cavity to stomach along with saliva.
- The lozenge dosage form is that it mistakenly could be used as candy by children.
- A hard candy lozenge is the high temperature required for their preparation.
- Hard lozenges become grainy.

Medicaments[9]

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

Antiseptic

Local anesthetics Antibiotics Antihistamines Antitussives Analgesics Decongestants Demulcents

Classification of lozenges[10]

Lozenges can be classified into various classes based on various method like.

A. According to the site of action

a. Local effect

Ex: Antiseptics, Decongestants.

b. Systemic effects

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

A. 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: Antiseptics, Decongestants, vitamins and nicotine

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. These lozenges are often highly fruit flavored 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. These are exemplified by milk protein, egg albumin, gelatin, xanthan gum, starch, pectin. 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.

Compressed Tablets 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 organoleptic, 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. Some commercially available sugar-based vehicles include- Emdex, Nu-tab, Sweeter, Mola-tab, Hony- tab, Sugar tab.

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. The formulation requires heating process at about 50℃ hence is only suitable to heat resistant ingredient. 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.

Hard Candy Lozenges

Hard candy lozenges are mixtures of sugar and other carbohydrates in an amorphous (noncrystalline) or glassy state. The moisture content and weight of hard candy lozenge should be between, 0.5 to 1.5% and 1.5-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. Medicaments up to 2-4% can be incorporated in the hard candy lozenges.

Table no 1: Types of Hard Candy Lozenges.[11]

Sl. No	Types of Centers filled lozenges	Composition	Fill Weight (%)
1	Liquid fill	sugar syrup, hydroalcoholic solutions or Sorbitol solution	10-20
2	Fruit center	Jams and jellies whose viscosity has been modified with corn syrup or liquid sucrose	20-25
3	Paste center	Granules and crystals formulated as paste	40
4	Fat center	Medicament or Flavour being suspended or dissolved in hydrogenated vegetable oil	25-32

Method or Preparation of Lozenges[12]

a. Chewy or caramel based medicated lozenges
b. Compressed tablet lozenges

c. Soft lozenges

d. Hard candy lozenges.

a. Chewy or caramel based medicated lozenges

The candy is cooked at 95- 125℃ and transferred to planetary/ sigma blade mixer. Mass is allowed to cool to 120℃. This is followed by addition of whipping agent below105℃. Then medicaments are added between 95- 105℃.Colour is dispersed in humectants and added below 85℃ followed by lubricant addition above 80℃.

b. Compressed tablet lozenges

Method used for manufacturing of compressed tablets of lozenges are direct compression method and wet granulation method.

Manufacturing processes

a. Direct compression

In this method all the ingredients are thoroughly mixed and directly compressed in to lozenges tablets.

b. Wet granulation

Wet granulation method involves grinding of sugar into by mechanical agitation and passed through sieve 40-80 mesh size. Medicament is added to sugar mass and then mixed uniformly. Sufficient amount of sugar syrup or corn syrup is added to homogeneously mixed mass for the granulation and then passed through 2- 8 mesh size to obtain wet granules. These wet granules are dried and once again passed through 10- 30 mesh size. Suitable flavour and lubricant are the added before compression into required size of tablet lozenges.

c. Soft lozenges

Soft lozenges are manufactured by hand rolled and then cut in to pieces by maintaining desired size and thickness. Another method involves heating of all ingredients along with medicament at about 50℃ and poured into a plastic mould.

d. Hard candy lozenges

Hard candy lozenges manufactured by cooking processes by dissolving desired quantity of sugar to prepare the candy base and other carbohydrates in one third amount of water in the candy cooker at temperature about 110℃. If corn syrup is used for the manufacturing of hard candy lozenges, the temperature should be kept in between 145-156℃. 2-4%

medicaments are incorporated in hard candy lozenges. The weight of candy mass is checked by mounting the lubricated vessel containing candy mass. This mass is then transferred to a water- jacketed stainless-steel cooling table for mixing of drug and flavour. The mixed mass is poured into mould to get desired and uniform lozenge as well as 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 unit wrappers.

Table No. 2: Material of lozenges and their function.[13]

SL.NO	Ingredients	Examples	Role
1	Candy base sugar, sugar free	Dextrose, sucrose, maltose, lactose, Mannitol, sorbitol, PEG 600.	These are the used as sweetening agent and impart the taste masking properties
2	Fillers	Dicalcium phosphate, calcium carbonate, microcrystalline cellulose.	These are the used to Improve the flowability
3	Lubricants	Magnesium stearate, calcium stearate, PEG, vegetable oils and fats	These are the used to avoid sticking of candy to the teeth.
4	Binders	Acacia, corn syrup, sugar syrup, gelatin, tragacanth and methylcellulose	These are the used to hold the particles.
5	Coloring agents	FD & C colors, orange color paste, red color cubes etc.	These are the used to enhance appearance and organoleptic properties.
6	Flavouring agents	Menthol, eucalyptus oil, cherry flavor etc.	These are the used to give a taste
7	Whipping agents	Milk protein, egg albumin, gelatin, xanthan gum etc.	These are the used in toffee-based confection

Components of lozenges[14]

Sucrose

It is disaccharide of glucose and fructose is obtained from sugarcane or beet. Medicated lozenges are prepared by using sucrose products because of their value as neutral sweeteners, their ready solubility and their function as a drier to reduce the weight of the confection through crystallization

Invert sugar

Invert sugar is derived from sucrose, possesses the very desirable physical property of controlling the crystallization of concentrated sugar solutions and maintaining freshness of the finished product through its humectant's properties.

Corn syrup

It is used in almost every type of confection to control sucrose and dextrose crystallization, which may lead to crumbling. Some physical properties of corn syrup are essential in the preparation of medicated candies: density, dextrose equivalent (DE) Hygroscopicity, sugar crystallization, viscosity, freezing point depression and osmotic pressure.

Isomalt

It has properties like a binding agent, i.e., to a certain extent it is capable of establishing binding between the individual particles in the composition and further in the binding during the kneading step in the process of preparing a lozenge. Isomalt is beyond being a binding agent also a suitable softener.

Binder

These are generally intended for compressed tablet that are used to hold the particles of mass as discrete granules and include acacia, corn syrup, sugar syrup, gelatin, tragacanth and methylcellulose.

Lubricants

These are used to avoid sticking of candy to the teeth and improve flow of final troche mixture and include magnesium stearate, calcium stearate and PEG.

Colorants

Appearance product identification, and masking of physical degradation. Dyes and other organic colorants may degrade by heat or light via oxidation, hydrolysis, photo oxidation etc. Suppliers of colors are excellent sources of information on current regulatory status of colorants.

Acidulants

Acidulants are generally added to medicated lozenges to fortify and strengthen their flavor profile. Organic acids such as citric, malic, fumaric and tartaric acids are most commonly used. Citric acid alone or in combination with tartaric acid is the most common. Another use of acids in medicated lozenges is to alter the pH to maintain the integrity of the drug.

Preservatives

These are solid dosage forms, there usually is no need to incorporate preservatives. However, since hard candy lozenges are hygroscopic, the water content may increase and bacterial

growth may occur if they are not packaged properly. Since the water that is present would dissolve some sucrose, the resulting highly concentrated sucrose solution is bacteriostatic in nature and would not support bacterial growth.

Flavours

Flavors used in medicated lozenges must be compatible with the drug and excipients and capable of withstanding the rigors of the manufacturing conditions. Flavors consist of numerous chemicals that may interact with excipients or medicaments and that degrade by heat and light. Aldehydes, Ketones and esters may react with drugs. A classic example of flavor–drug interaction is that of a primary amine drug (benzocaine, phenylpropanolamine) with aldehyde containing.

Flavor components like cherry, banana, etc., resulting in the formation of a Schiff base, drug decomposition, and loss of efficacy.

Table No. 3: Flavor selection guide.[10]

Salty	Butterscotch, Maple, Nutty, Buttery's
Bitter	Spice wildcheery, Licorice, Chocolate, Mint, Grapefruit, Coffee, Cherry, Peach
Acrid	Raspberry, Fruit, Beeris, Lime
Sour	Raspberry, Fruits, Berries, Acacia
Oily	Syrup
Sweet	Peppermint, Anise, Wintergreen
Acid	Fruit, Berry, Vanilla
Metallic	Citrus Berries, Mint, Grape, Marshmallow

LOZENGES-FORMULATION[9]

Lozenges can be formulated into a stable dosage form and to provide a better mode of administration of many drugs.

Criteria for the formulation

1. Selecting the suitable drug molecules.
2. Selecting appropriate drug carrier excipients.
3. Selecting appropriate type of lozenge formulation.

METHOD OF PREPARATION[9]

Medicated lozenges are prepared by heating and congealing technique

Step1: Combine sugar, corn syrup and water by heating.

Step 2: Adding drug to the candy matrix.

Step 3: Addition of polymers, colouring agents, flavoring agents etc.

Step 4: It is poured into moulds of desired shaped and size to form a candy.

Step5: Seal and wrap the candy in polyethylene.

Evaluation of lozenges[14]

Physical and Chemical testing Hardness

Hardness of the lozenges is determined by Pfizer or Monsanto hardness tester. The resistance of lozenges to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness.

Diameter and Thickness

A Vernier caliper is the instrument used for the determination of diameter and thickness of the lozenges.

Friability test

Friabilator is used for the determination of friability of lozenges. Apparatus is rotated at 25 rpm for 4 min. Initial weights of lozenges are taken and they are placed in friabilator. After the revolution the lozenges were de-dusted and weighed again. The observed value not be more than 1%.

Friability is calculated by following formula

$$\% \text{ friability} = (1- Wt / W) \times 100$$ Where, W= Initial weight of lozenges

Wt= Weight of lozenges after revolution

Weight variation

Twenty lozenges were randomly selected and individually weighed using an electronic balance. The average weight and standard deviation of 20 lozenges was calculated or initial weight is compared with the calculated average weight.

Drug Excipients interaction studies

Fourier Transform InfraRed analysis i.e., FTIR is used to study the Drug-Excipients interactions.

Disintegration test

USP Disintegration apparatus is used to determine the disintegration time of lozenges.

Disintegration time is noted in pH 6.8 phosphate buffer or artificial saliva at 37ºC.

***In-vitro* drug dissolution study**

Rate of drug absorption is determined by the rate of drug dissolution of the lozenges. Rate of dissolution and bioavailability is directly related to efficacy of lozenges. This study is carried out by using USP II dissolution type apparatus (paddle type) dissolution study was carried out in 900 ml of buffer pH 6.4 or use artificial saliva by USP II paddle method at 100 rpm. Samples were withdrawn at 5 min time interval and replaced immediately with an equal volume of fresh buffer or artificial saliva and were analyzed spectrophotometrically. Temperature 37℃ ± 2℃ maintain between dissolution studies.

Drug content

Drug content is done by taking an appropriate number of lozenges being crushed and dissolved in a suitable solvent and the absorbance of the solution is measured spectrophotometrically.

Moisture Analysis

Gravimetric, Karl Fisher titration and Azeotropic distillation methods are used to determine the moisture content of lozenges.

Gravimetric method

Weigh accurately about 1g of sample and note the initial weight. It is then placed in a vacuum oven at 60-70 ℃ for 12- 16 hours. After specific period of time, once again weigh the sample and moisture content can be calculated by subtraction of initial weight from initial weight.

Formula used for calculation moisture content is Moisture content = Initial weight – Final weight.

Karl Fischer titration

A sample of the prepared lozenges is calculated to contain 10- 250 mg water is taken in titration flask and then it is titrated with Karl fisher reagent

Azeotropic distillation method

In azeotropic distillation method, 10- 12g candy is pulverized and placed in 500ml flask to which 150-200ml toluene is added. Flask is connected to a reflux condenser and is refluxed for 1- 2hrs. Water collected gives the amount of water present in the sample.

Microbial Test for Lozenges[15]

Microbial test for lozenges is performed to check the presence of any bacterial, mold or spore contamination in raw materials, cooling tunnels, finished products, machinery, environmental conditions and storage drums. Laboratory microbial testing should include the various counts such as total plate, total coliform, yeast and mold, E. coli, Staphylococcus and Salmonella. Stability Testing Stability testing of lozenges is carried out under following conditions:

→1-2months at 60℃

→ 3-6months at 45℃

→9-12months at 37℃

→ 36-60months at 25 and 40℃

Stability testing of packed products

The final packs of lozenges are subjected for stability testing under following conditions:

→25℃ at 80% RH for 6-12months

→ 37℃ at 80% RH for 3 months

→ 25℃ at 70% RH for 6-12 months

Storage

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

Packaging

Hard candies are hygroscopic and frequently prone to absorption of atmospheric moisture. Considerations must include the hygroscopic nature of the candy base, storage conditions of the lozenges, length of time they are stored and the potential for drug interactions. These products should be stored in tight containers to prevent drying. This is especially true of the chewable lozenges that may dry out excessively. If a disposable mold with a cardboard sleeve is used, it is best to slip this unit into a properly labelled, sealable plastic bag. Packaging should be proper and attractive.

APPLICATION OF LOZENGES[16]

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 suck on the lozenges according to the Mayo clinic. Nicotine smoking's are 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.

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.

Table no 4: Lozenges Available in marketed and its application.[17]

Marketed Brand	Drug	Uses
Sore throat lozenges	Menthol and benzocaine	Oral anaesthetics
Codral	Sour throat lozenges	Antibacterial &anaesthetics
Prospan	Hrdera helix extract	Chesty cough relief
ORAC99k	Turmeric	Ayurvedic proprietary medicines
Equate	Nicotine	Stop smoking aid
Zinc lozenges	Vitamin Echinacea	Dietary, Supplement
Difflamplus	Benzydiamine, Hydrochloride	Anesthetics

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