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MEDICATED LOZENGES: AS AN EASY TO USE FOR PEDIATRIC AND GERIATRIC PATIENTS

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Abstract

Lozenges are one of the most widely used and revolutionary dosages and oral confectionary items in the world. Lozenges have been in use since the 20th century and are still being produced commercially. As a new way of transmitting medications for local action and systemic effect in the oral cavity, Lozenges has a promising future. Lozenges are flavored medicated dosage formulations that are sucked and kept in the mouth or pharynx. They normally contain one or more medicaments inside a sweetened base. The advantages of medicated lozenges are that they improve the retention time within the mouth of the drug type, increasing bioavailability, reducing gastric discomfort, and bypassing the metabolism of the first pass. The acceptance of lozenges as a form of dosage is high for adults and also high for children. Compressed lozenges, hard lozenges & soft lozenges are various types of lozenges available on the market and their preparation methods and ingredients used in their preparation are discussed. The present analysis covers more or less all things relevant to lozenges and also sheds light on lozenge applications. This includes numerous studies undertaken to date, parameters of formulation and evaluation, packaging, and lozenge applications.

Keywords: Lozenges, Medicaments, Excipients

1. Introduction

Oral drug delivery is the most flavored route for the administration of various medications and tablets are the most commonly used dosage form. Solid dosage types are common because they are easy to administer, provide accurate dosage, allow for self-medication, reduce discomfort, and most importantly, ensure patient compliance. Among the main problems faced by many patients with conventional tablet dosage form is difficulty in swallowing. This problem is more apparent when a beverage isn't easily available to the patient taking medicine. Dispersible tablets are distinguished by rapid disintegration, rapid breakdown, rapid release, and increased patient compliance. Dysphasia (difficulty swallowing) is a common problem in people of all ages, particularly the elderly and children, due to physiological changes in those groups. Other categories that experienced problems inducing conventional oral dosage forms include the mentally ill, uncooperative, and patients suffering from nausea, motion sickness, sudden episodes of allergic attack, or coughing. Sometimes it may be difficult to swallow conventional products due to the non-availability of water. These problems led to the event of a unique sort of solid oral dosage form hence, beautiful, taste masking formulations are the necessity of the hour.[1, 2]

Lozenges are flavored medicated dosage formulations that are sucked and kept in the mouth or pharynx. They normally contain one or more medicaments inside a sweetened base. Lozenges are used to treat oropharyngeal symptoms that are mostly caused by local infections, as well as to have a systemic effect if the drug is well absorbed through the buccal linings or swallowed. Lozenges are also used for drugs intended to be released slowly to create a consistent amount of medication in the mouth or to wash the throat tissues during a drug solution for patients who cannot swallow solid oral dosage types.[3]

Lozenges also include analgesics, anesthetics, antimicrobials, antiseptics, antitussives, aromatics, astringents, corticosteroids, decongestants, and demulcents. Sore throats, sores, and other irritations in the mouth and pharynx are common ailments that will cause pain. While there are a variety of pharmaceuticals available to relieve pain, both prescription and over-the-counter, these pharmaceuticals can be difficult to prescribe to patients who are reluctant or unable to take traditional oral drugs. Moreover, many oral drugs have a considerable time interval, often up to twenty minutes, between ingestion and the onset of a therapeutic effect. Because the medications must be absorbed into the bloodstream from the digestive system after the medicine is swallowed.[4]

1.1) Advantages

- Ease of administration to pediatrics and geriatrics patients.
- Easy to organize, with a minimum amount of kit and time.
- The local and systemic effect through the mouth.
- Increased contact time of drug.
- Prolonged drug action.
- Avoid the first-pass metabolism of medicine.
- Do not require water for intake.
- Suitable for patients who have trouble swallowing (dysphagia).

1.2) Disadvantages

- Accidental swallowing of the entire dosage form.
- Possible draining of drug into the stomach.
- A high temperature is needed for the preparation of hard candy lozenges.[5,6]

2) Classification

2.1) According to the site of action

1) Local effect Ex. Antiseptics, Decongestants.
2) Systemic effect Ex. Vitamins, Nicotine.

2.2) According to texture and composition

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

These are the dosage forms in which the medication is mixed with a caramel base and chewed rather than dissolved in the mouth. These lozenges are frequently fruit-flavored and should have a slightly acidic flavor to mask the acrid glycerin taste. These lozenges are particularly used in pediatric patients and are a very effective means of administering drugs for gastrointestinal absorption and systemic usage. The chewable lozenge, or 'gummy type candy lozenge, is one of the more popular lozenges for pediatric use. These gelatin-based pastilles were prepared by pouring the melt into molds or out onto a sheet of uniform thickness.

b) Compressed tablet Lozenges

When the active ingredient is heat-sensitive, it can be prepared by compression. The process of granulation is identical to that used by any tablet that is compressed. In terms of tablets, these tablets are distinct from traditional tablets.

- Organoleptic properties
- Non-disintegrating features and characters
- Profiles with the slower dissolution

Since the troche should dissolve slowly in the mouth, the lozenge is shaped using heavy compression equipment to provide a tablet that is tougher than normal. The preparation of lozenges by tablet compression is less relevant commercially.

c) Soft Lozenges

Due to the ease of extemporaneous preparation and applicability to a broad variety of drugs, soft lozenges have become common. Typically, the bases consist of a combination of different acacia, polyethylene glycols, or similar materials the pastille, which is characterized as a soft type of lozenge, typically transparent, consisting of medicine in gelatin, glycerogelatin, or acacia: sucrose base is one of these soft lozenges. Soft lozenges are similar to a historical form of a drug called "confection," which is making a comeback. Confections are highly saccharine, soft masses containing medicinal agents. The increase in their current usage is primarily due to the use of polymers as the matrix for the dosage form (polyethylene glycols). They are easy to use, convenient to carry, easy to store (room temperature), and are generally pleasant tasting. Polyethylene glycol-based lozenges may appear to be hygroscopic and, if exposed to elevated temperatures, may soften.

d) Hard Candy Lozenges

Hard candy lozenges in amorphous (noncrystalline) or glassy states are mixes of sugar and other carbohydrates. They can even be considered solid syrups of sugars. The moisture content and weight of the hard candy lozenge should be between, 0.5 to 1.5 % and 1.5 - 4.5 g respectively. These should undergo a slow and uniform dissolution or erosion over 5 - 10 min., and will not disintegrate. Since the temperature requirements for their preparation are typically high, heat-labile materials cannot be used. Heating and congealing is used to make these pastilles.[7, 8]

3) Methods of preparation

Candy Based Lozenges

3.1) Heating and Congealing Technique

Lakshmi, B et al. (2017) was prepared a Syrupy base in a beaker by dissolving the required amounts of sugar in water and kept for heating on a hot plate. The temperature was maintained at 105-110 °C till it became thick. The drug and other excipients (except plasticizer) were added manually and mixed thoroughly after 30 min with a continued process of healing. The prepared mass was further heated for 45 min and then a plasticizer was added to it. Then above syrupy base was poured into a pre-cooled and pre-lubricated mold and the mold was kept aside for 10-15 min. Lozenges were removed from the mould and were kept for air drying. In the case of batches without plasticizer, a step of plasticizer addition was omitted from the procedure.

3.2) Melting and Mold Technique

Pothu, R et al (2014) prepared by melting and mold technique, Polyethylene glycol (PEG) was melted on a water bath and mixed with the other ingredients to form a homogeneous mixture. Subsequently, the blend was poured into the desired shape & size stainless steel mold to forming a candy.

3.3) Compressed Tablet lozenges

Mishra, K (2017) was prepared compressed tablet lozenges by using the following technique.

(a) Direct compression technique

Ingredients may be thoroughly combined and compressed directly.

(b) Wet granulation technique

Sucrose is pulverized by mechanical combinations to a fine powder then add binder solution and mass is formed and pass through # sieve no.16 Granules formed & dried then add lubricant, flavor before the compression.

4) Formulation of medicated lozenges

table 1: excipients used

Sr.No	Ingredients	Example
01	a) sugar b) sugar-free vehicle c) filers	dextrose, sucrose, maltose, lactose. mannitol,sorbitol,polyethylene glycol(peg)600&800, di calcium phosphate, calcium sulfate, calcium carbonate lactose, microcrystalline cellulose.
02	lubricants	magnesium stearate, calcium stearate, stearic acid and peg, vegetable oils, and fats.
03	binders	acacia, corn syrup, sugar syrup, gelatin, polyvinyl pyrrolidone, tragacanth, and methylcellulose.
04	coloring agents	water-soluble and lakolene dyes, fd & c colors, orange color paste, red color cubes, etc.
05	flavoring agents	menthol, eucalyptus oil, spearmint, cherry flavor, etc.
06	whipping agents	milk protein, egg albumin, gelatin, xanthan gum, starch, pectin, algin, and carrageenan.
07	humectants	glycerin, propylene glycol, and sorbitol.

4.1) Sugar

Sucrose, glucose, and fructose disaccharide is a sugarcane or beet derivative. Availability and geographical considerations are the basis for selecting beet or cane sugar. Sucrose and sucrose products are utilized in medicated lozenges due to their value as neutral sweeteners, their ready solubility, and their function as a ‘‘drier’’ to scale back the load of the confection through crystallization.

4.2) Corn syrup

In almost any kind of confection, corn syrup is used to regulate the crystallization of sucrose and dextrose, which may contribute to crumbling. Corn syrup makes the creation of an amorphous glass in sufficient proportion with sucrose and dextrose and creates a candy with the desired appearance.

The following physical properties of syrup are extremely important within the preparation of medicated candies: density, dextrose equivalent, hygroscopicity, sugar crystallization, viscosity, melting point depression, and pressure.

4.3) Sugar bases

Sucrose or compressible sugar, dextrose, mannitol, and sorbitol are popular sugar bases used in lozenge tablets and are available in a variety of tableting grades from a variety of excipient manufacturers. Generally intended for applications requiring direct compaction, they can also be used in wet-granulation systems with the above binders.

A nonnutritive sweetener may be a synthetic or natural sugar substitute whose sweetness is above or like sucrose. Examples of nonnutritive sweeteners like xylitol, mannitol, sorbitol, invert sugar, etc.

4.4) Binders

These are commonly intended for compressed tablets that are used as discrete granules to retain particles of mass which include acacia, corn syrup, sugar syrup, gelatin, polyvinyl-pyrrolidone, methylcellulose tragacanth.

4.5) Lubricants:

These are used to prevent the candy from sticking to the teeth and boost the flow of the final troche mixture and contain stearate of magnesium, stearate of calcium, stearic acid, and PEG.

4.6) Colorants

For appearance, product recognition, and masking of physical deterioration, colorants are introduced into medicated lozenges. Dyes and other organic colorants may degrade in the presence of heat or light by oxidation, hydrolysis, photo-oxidation, and other processes, so their compatibility with drugs, excipients, and process conditions should be investigated before use.

4.7) Acidulants

Acidulants are commonly used to enhance and reinforce the taste profile of medicated lozenges. Citric, malic, fumaric, and tartaric acids are the most widely used organic acids.

The most popular is citric acid alone or in combination with hydroxy acid. Acids are often used to change the pH in medicated lozenges to keep the drug's credibility.

4.8) Preservatives

Since these are solid dosage types, preservatives are typically not needed. However, since hard candy lozenges are hygroscopic, if they are not packed correctly, the particle size can increase and bacterial growth may occur. Since the present water may dissolve some sucrose, the resulting highly concentrated sucrose solution will be bacteriostatic and will not help bacterial development. A few words about the tastes and effects of preservatives are in order.

4.9) Flavors

Flavors in medicated lozenges must be consistent with the medication and excipients, as well as able to endure the rigors of production. Flavors are made up of a variety of chemicals that interfere with excipients or medications and degrade when exposed to heat or light. Drugs can react with aldehydes, ketones, and esters. 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. Adjustment of lozenge base pH to accentuate certain flavors (e.g., citrus) may also result in incompatibility with some medicaments (e.g. benzocaine).[12, 13, 15]

5) EVALUATION OF MEDICATED LOZENGES

The prepared lozenges were evaluated for parameters like drug content uniformity, hardness, thickness and diameter, weight variation, friability and in vitro dissolution test, drug content, moisture content analysis, and stability studies by pharmaceutical standard methods.

5.1) Diameter

The thickness and diameter of lozenges were determined using vernier calipers. Three lozenges were used from each batch and mean values were determined. .[3,14,25]

5.2) Weight variation

The weight variation was conducted by weighing 20 lozenges individually and calculating the typical weight and comparing the individual lozenge's weight to the typical value. .[3,14,25]

$$\text{Weight Variation} = \frac{average\ weight - initial\ weight}{average\ weight} \times 100$$

5.3) Hardness

The hardness of the lozenges was decided by using the Monsanto Hardness tester, where the force required to interrupt the lozenges was noted. The hardness was measured in terms of (kg/cm^2). .[3,14,25]

5.4) Friability

The friability of the lozenges was decided using Roche Friabilator. Weighed lozenges were placed within the friability and operated for 4 min at 25 rpm. .[3,14,25]

5.5) Moisture content analysis

Moisture content within the final candy is decided by using the Helium moisture balance apparatus. The sample was weighed and crushed during a mortar from this one gram of the sample was weighed and therefore the moisture content is decided by the moisture balance apparatus. .[3,14,25]

5.6) Mouth dissolving time test:

The USP Disintegration apparatus was used to determine how long it took the candy to dissolve fully. Hard-boiled candy lozenges were put in each tube of the apparatus, and the time it took for the lozenges to dissolve completely was measured using phosphate buffer pH 6.8 at 37 ºC. .[3,14,25]

5.7) In-vitro drug dissolution studies

The speed of dissolution possibly is said to be the efficacy of the tablet lozenge. The dissolution study was administered in 800 ml of phosphate buffer of pH 6.8 at 150 rpm; use the USP II paddle system. Samples were taken every 5 minutes and immediately replaced with an equivalent volume of fresh buffer before being analyzed with a UV spectrophotometer.

5.8) Drug content

An appropriate number of lozenges are crushed and dissolved in an appropriate solvent and therefore the absorbance of the answer is measured spectrophotometrically. .[3,14,25]

5.9) 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 a total plate, total coliform, yeast and mould, E.coli, staphylococcus species, and salmonella.[3,14,25]

510) Stability studies

An accelerated stability study was conducted as per ICH guidelines (zone IV) at 45°C and 75% ratio over seven weeks. A sufficient number of optimized formulations were packed in amber-colored screw-capped bottles and kept in an incubator maintained at 37°C. Samples were taken at intervals of 15 days to estimate the drug content and to gauge organoleptic properties [3, 14, 25]

5.11) Storage

These preparations 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.[3]

5.12) Packaging

Hard candies are hygroscopic and usually prone to absorption of atmospheric moisture. The hygroscopic design of the candy base, the storage conditions of the lozenges, the length of time they are processed, and the potential for drug reactions must all be taken into account. To avoid drying, store these items in airtight containers. This is especially true of chewable lozenges, which can become difficult to chew if they dry out too much. If you're using a disposable mould with a cardboard sleeve, it's safer to put it in a clearly labeled, sealable plastic container.[3]

6. Application of lozenges

Lozenges are employed for the treatment of local also as systemic disorders. They may include several drug candidates for the treatment and relief of oral and throat infections such as oral thrush, sore throat, cough, gingivitis, pharyngitis, decongestants, etc. Moreover, these even have been wont to deliver the drug systemically for smoking cessation and pain relief.[1]

Table 2: Medicated lozenges and their proven facts

Type	Ingredients	Effect Product	Uses	References
montelukast sodium lozenges	montelukast sodium, glucose, hydroxypropyl methylcellulose (HPMC)	prolonged retention in the mouth	asthma	waliamandeep, Lodha. r 2006[18]
salbutamol sulfate lozenges	isomalt a tooth-friendly sugar substitute mixed with corn syrup	the extended drug release profile for 60 minutes	asthma	Rajesh kini 2011[16]
ketoconazole lozenges	sucrose, citric acid, hydroxypropyl methylcellulose, and hydroxyethylcellulose	reduces gastric irritation bypassing the first-pass metabolism	Fungal infections in pediatric and geriatrics.	nagobas. n 2011[13]
paracetamol lozenges	paracetamol, sucrose, sodium carboxymethylcellulose, methylcellulose	slow release of medicament	fever and pain	Dharmajit pattanayak 2012[2]
clotrimazole lozenges	sugar base, acacia/ guar gum/ methylcellulose citric acid artificial flavors and colors	prolonged oral retention time	pediatric and geriatric dysphagia	shivappa n. nagoba, 2012[14]
artesunate oral retentive lozenges	mucoadhesive polymer like sodium hydroxyl ethyl cellulose is used	prolonged retention of the lozenges	malaria in a pediatric patient	Edward k kamamia 2013[17]
garlic and ginger lozenges	sucrose, sodium chloride, polyvinyl pyrrolidone, sodium carboxymethylcellulose	taste masking with good release matrix type lozenge	inhibitory activity against non-resistant c. Albicans infections, nonresistant oral thrush	Charles o.esimone2013[20]
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	bistrakostova 2013[19]
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[21]
ondansetron hydrochloride lozenges	sucrose as a base and eudragit e100, sodium carboxymethylcellulose, hydroxypropyl methylcellulose k4m, and methylcellulose as a binder are used	increase in bioavailability, reduction in gastric irritation bypassing of the first-pass metabolism, and increase in onset of action	chemotherapy-induced nausea and vomiting	Suchita pundir 2014[22]
fluconazole tablet lozenge	Maize starch, acacia, HPMC e50. sucrose as base and gelatin as a binder	increased bioavailability, reduction in gastric irritation, bypassing the first pass	oral thrush	v.b. bharkad 2014[23]
joshanda, polyherbal lozenge	conventional decoction form of joshanda	slow dissolution in the mouth, prolonged effect	cold, cough, and associated allergic reactions	Monika Bansal, July 2015[24]

Conclusion

Lozenges are medicinal confections that were invented around the turn of the century and are still in use today. The majority of the preparations are done ahead of time. They are offered over the running pace items and are highly cost-effective. dose types They are intended for both local and systemic use therapy. A wide range of activities might be included. their framework Lozenges play an important role in the diet pharmacy, and they will remain so in the future.

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Conflict interest

The other declares that there is no conflict of interest in the submission of these manuscripts.

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