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Medicated Lozenges as an effective dosage form

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ABSTRACT:

One of the most popular and innovative oral confections and dose forms in the world is lozenges. Lozenges are still made commercially and have been used since the 20th century. Lozenges have a bright future as a novel method of delivering drugs for both systemic and local action in the oral cavity. Lozenges are medicinal dose forms with flavors that are retained in the mouth or throat after being sucked. Typically they have a sweetened foundation with one or more medications inside. Medicated lozenges have the following benefits: they increase bioavailability, decrease gastrointestinal discomfort, improve retention duration in the drug type's mouth, and avoid the first pass metabolism. Lozenges are widely accepted as a dose form for both adults and children. The several kinds of lozenges that are on the market—compressed, firm, and soft—as well as the substances and procedures used to prepare them are covered. The current analysis clarifies lozenge applications and includes nearly everything pertinent to lozenges. This covers the aspects of preparation and assessment, packing, lozenge applications, and the numerous studies conducted thus far.

Keywords: Lozenges, Medicament, Excipients, Local and Systemic drug delivery, Prolonged release.

Introduction:

The dosage form that is most frequently used is tablets, and Oral medication administration is the most palatable method of administering a variety of drugs. Solid dosage forms are widely used because they are simple to use, give precise dosages, enable self-medication, ease discomfort, and above all guarantee patient compliance. Swallowing difficulties are one of the primary issues that many patients with traditional pill dose forms encounter. When a patient taking medication cannot readily access a beverage, this issue becomes more noticeable. Rapid disintegration, breakdown, release, and improved patient compliance are characteristics that set dispersible pills apart. Due to physiological changes in those groups, dysphasia, or trouble swallowing, is a prevalent issue in people of all ages, although it is especially common in youngsters and the elderly. The mentally ill, the recalcitrant, and patients with motion sickness, nausea, acute allergic reactions, or coughing were among the other groups that had trouble ingesting traditional oral dosage forms. When water is scarce, it can occasionally be challenging to swallow conventional items. Beautiful, taste-masking formulations are now essential because of these issues, which resulted in the development of a novel type of solid oral dosage form.[1,2]

Lozenges are medicinal dose forms with flavors that are trapped and sucked in the throat or mouth. Typically, they have a sweetened foundation with one or more medications inside. If the medication is well absorbed through the buccal linings or ingested, lozenges can have a systemic effect in addition to treating oropharyngeal symptoms that are mostly brought on by local illnesses. For patients who are unable to take solid oral dose forms, lozenges are also used for medications that are meant to be given gradually to produce a steady amount of medication in the oral cavity or to cleanse the tissues of the throat during a drug solution.[3]

In addition, lozenges contain corticosteroids, decongestants, aromatics, astringents, antimicrobials, antiseptics, antitussives, analgesics, anesthetics, and demulcents. Common conditions that cause pain include sore throats, sores, and various irritations in the mouth and pharynx. Although there are many prescription and over-the-counter medications available to treat pain, it can be challenging to recommend these medications to individuals who are unwilling or unable to use conventional oral medications. Furthermore, it frequently takes up to twenty minutes after ingesting an oral medication for a therapeutic impact to start. Because after being taken, the drugs must pass through the digestive tract and into the circulation.[4]

Advantages:

- Simplicity in administering to elderly and pediatric patients.
- Simple to put together, requiring little time or kit.
- The oral cavity's systemic and local effects.
- Longer drug interaction time.

- Extended duration of medication action.
- Avoid clear of the first-pass metabolism of medications.
- Water is not necessary for consumption.
- It is appropriate for patients with dysphagia, or difficulty swallowing.
- Patient compliance is higher.
- Tastes good.

Disadvantages:

- Possible medication seeping into the stomach.
- Accidentally eating the entire dosage form.
- The requirement for a high temperature to prepare hard candy lozenges.
- Lozenges that are hard get grainy. [5,6]

Types of lozenges:[7,8,9]

Lozenges are classified into various methods classes based on various methods like

A) According to the site of action

a) Local effects E.g. decongestants, antiseptics.
b) Systemic effects E.g. Vitamins, Nicotine.

B) Based on composition and texture

a) Medicated lozenges with a chewy or caramel basis
b) Compressed tablet lozenges
c) Soft lozenges
d) Hard candy lozenges

According to the site of action

One way to categorize lozenges is by their site of action, which can be either local or systemic. For example, antiseptics and decongestants are examples of local effects, whereas vitamins and nicotine are examples of systemic effects.[3]

According to texture and composition

a) Medicated lozenges with a chewy or caramel basis:[9,10]

As "gummy type" lozenges, chewy lozenges are a popular choice among children because they contain medication in a caramel base that is chewed rather than dissolved in the mouth. They are made with a glycerinated gelatine suppository formula that contains glycerine, gelatine, and water, along with a candy base, whipping agent, humectants, lubricants, flavor, and the chosen medication.

Fig: 1

Manufacturing processes:

The candy is moved to a planetary/sigma blade mixer after being baked at 95–125 degrees Celsius.

⇩

Let the mass cool to 120 degrees Celsius. After that, whipping agent is added below 105°C.

⇩

Medication is then added at 95–105 degrees Celsius.

⇩

Humectants are used to disperse color, and lubricant is added below 85 °C and above 80 °C.

⇩

Long ropes of the appropriate thickness are cut to the appropriate length, then wrapped in wrappers to create chewable or caramel lozenges. We refer to this process as rope making.

b) Compressed tablet lozenges:[3,11,12,]

Direct compression and wet granulation techniques are employed in the production of compressed tablet lozenges. Compressed tablet lozenges can be made with thermolabile medications. The slower dissolution profile, non-disintegrating properties, and organolepticity of lozenges tablets set them apart from regular tablets. To make a tablet more durable than typical, lozenges are made with high compression machinery. Lozenges typically have a flat face, measure 5/8 to 3/4 inches, weigh 1.5 to 4 kg, have a hardness of 30 to 50 kg inch2, and erode over 5 to 10 minutes.

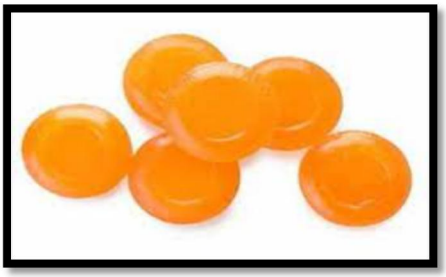


Fig: 2

Manufacturing process:

Direct compression:

All of the ingredients are combined in this technique and then crushed into lozenge tablets.

Wet granulation:

In the wet granulation procedure, sugar is ground by mechanical agitation and then sieved through a 40–80 mesh screen. After adding the medication to the sugar mass, it is well combined. Wet granules are obtained by passing a homogeneously mixed substance through a 2- to 8-mesh screen after adding a sufficient amount of sugar syrup or corn syrup. After drying, these moist granules are once more sieved through a 10- to 30-mesh screen. Before the tablet lozenges are compressed into the necessary size, the proper flavor and lubrication are added.

c) Soft lozenges:[13,14,15]

In the soft lozenges formulation, the bases of chocolate, sugar acacia, or polyethylene glycol 1000 or 1450 are employed to give the lozenges their soft texture. Certain soft lozenges contain silica gel and acacia. To keep parts from sinking to the bottom of the mold cavity during cooling, silica gel is used as a suspending agent. They are made by either pouring the heated material into a plastic mold to create soft lozenges or hand rolling them to the appropriate thickness and size before cutting them into pieces. Only heat-resistant ingredients can be used with this formulation because it needs to be heated to around 50ºC.

Fig: 3

Manufacturing process

In order to retain the appropriate size and thickness, hand-rolled soft lozenges are then divided into pieces. An alternative technique entails heating the components and the medication to around 50 degrees Celsius before filling a plastic mold with the mixture. If polyethylene glycol is utilized, the mold cavity should be overfilled because it contracts when it cools. Since chocolate does not shrink, this is not necessary.

Clotrimazole-containing soft lozenges are created using a molding technique that incorporates progressively more polyethylene glycol, xylitol or xanthan gum. Because this agent makes the lozenges harder, attention must be made in how much of these agents are used during the disintegration period.

d) Hard candy lozenges:[16,17]

Sucrose and other sugars and the amorphous or glassy state of carbohydrates make up hard candy lozenges. When the aqueous syrup is cooked during the production process to remove moisture, the water that was initially present evaporates. The weight of the hard candy lozenges should range from 1.5 to 4.5 g, and the moisture content should be between 0.5 and 1.5%. They dissolve gradually and evenly over the course of five to ten minutes. Heat-sensitive components are not appropriate for this formulation since a high temperature is needed to prepare hard lozenges.

Fig: 4

Manufacturing process:

To make hard candy lozenges, heat is used. a candy cooker to approximately 110 degrees Celsius, where a desired amount of sugar is dissolved to create the candy base and additional carbohydrates in a third of the water. When making hard candy lozenges with corn syrup, the temperature should be maintained between 145 and 156 degrees Celsius. Lozenges of hard candy contain 2-4% medication. Additional components are added, such as coloring agents, flavoring agents, sweeteners, and acidulents to strengthen the candy foundation. It is colored by adding it as a paste or solution and mixing it thoroughly. The lubricated vessel carrying the candy mass is mounted in order to determine its weight. After that, this mass is moved to a cooling table made of stainless steel that has been water-jacketed so that the medicine and flavor can mix. To create a uniform and desired lozenge, the combined mass is poured into a mold. Alternatively, the mass can be twisted into a ribbon and then cooled before being sliced into the appropriate length to create lozenges that are packaged as single unit wrappers.

Method of preparation of lozenges:

Method used :- Heating and congealing. [2,18,19]

Combined sugar, corn syrup, and water by heating

⇩

Addition of drug to this candy matrix

⇩

Addition of polymer, color, flavor etc.

⇩

Poured into mould of desired shape and size to forming a candy

⇩

Sealing and wrapping of candy in polyethylene wrapping

General consideration for designing Lozenges: [20,21,22,23]

In order to minimize side effects, pharmaceutical companies are now concentrating on developing new drug delivery systems for existing drugs that have improved efficacy and bioavailability along with a reduced frequency of dosing. Oral candidacies typically manifest as an conforming white, curd-like, encircling plaque anywhere in the oral cavity. For the treatment of these conditions, a variety of drug dosage forms, including lozenges, tablets, inhalers, and syrups, are available on the market. "Lozenges are flavored medicated dosage forms intended to be sucked and hold in the mouth/pharynx. These preparations are frequently used to provide either a systemic or local impact. Patients, doctors, and the pharmaceutical business always gain from new drug designs in this field. There are a number of dosage forms available on the market, but more that work both locally and systematically are needed.

Formulation of lozenges:

The lozenges are intended to offer a consistent dosage form. and offer a more viable way to administer a range of medications.

Table 1: Ingredients Used [3,4,24,25]

Sr. No	Ingredients	Example
1	a) Sugar b) Sugar-free vehicle c) Fillers	Maltose, lactose, sucrose, dextrose Polyethylene glycol (PEG) 600 and 800, sorbitol, mannitol. Calcium carbonate, calcium sulfate, lactose, di calcium phosphate, microcrystalline cellulose.
2	Lubricants	Calcium stearate, stearic acid and peg, vegetable oils, and fats, magnesium stearate.
3	Binders	Corn syrup, sugar syrup, gelatin, polyvinyl pyrrolidone, tragacanth, methylcellulose and acacia.
4	Colouring agents	fd & c colors, orange color paste, red color cubes, water-soluble and lakolene dyes, etc.
5	Flavouring agent	Spearmint, cherry flavor, menthol, eucalyptus oil,etc.
6	Whipping agent	Xanthan gum, starch, pectin, algin, carrageenan, milk protein, egg albumin, gelatin.
7	Humectants	Sorbitol, propylene glycol, glycerin.

Sugar:

A derivative of sugarcane or beets is sucrose, glucose, and fructose disaccharide. Geographical considerations and availability determine whether to use cane or beet sugar. Because of their usefulness as neutral sweeteners, their quick solubility, and their ability to act as a "drier" to reduce the confection's load through crystallization, sucrose and its derivatives are used in medicinal lozenges.

Lubricants:

They contain stearate of calcium, stearate of magnesium, stearic acid, and PEG and are applied to enhance the flow of the finished troche mixture and keep the candy from adhering to the teeth.

Binders:

Acacia, corn syrup, sugar syrup, gelatin, polyvinylpyrrolidone, methylcellulose, and tragacanth are among the materials that are frequently utilized in compressed tablets that are employed as distinct granules to maintain particles of mass.

Colorants:

Colorants are added to pharmaceutical lozenges to improve appearance, product recognition, and conceal physical deterioration. Before being used, dyes and other organic colorants should have their compatibility with medications, excipients, and process conditions examined because they can degrade when exposed to heat or light through oxidation, hydrolysis, photo-oxidation, and other processes.

Flavouring agents:

Medicated lozenges need to have flavors that are compatible with the medication and excipients, and that can withstand the harsh conditions of production. Flavors are composed 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 a flavor–drug interaction is when a primary amine drug (benzocaine, phenylpropanolamine) with aldehyde-containing flavor components like cherry, banana, etc., which results in the formation of a Schiff base, the breakdown of the drug, and a loss of efficacy. A change in the lozenge's pH base to enhance certain flavors (like citrus) may also cause incompatibility with some medications (like benzocaine).

Preservatives:

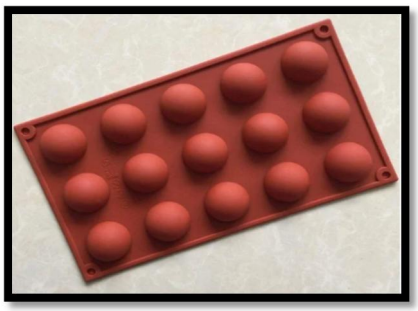
Preservatives are usually not required because these dose forms are solid. However, because lozenges of hard candy are hygroscopic, improper packing may result in larger particles and the development of germs. The extremely concentrated sucrose solution that results from some sucrose being dissolved by the current water will be bacteriostatic and will not promote the growth of bacteria. [15,17,26]

Different types of moulds:

1. Circle mould

2. Square shape mould

3. Octagonal shape mould



4. Dome shaped mould

Evaluation test for lozenges:

The lozenges were tested for drug content uniformity, hardness, thickness, diameter, weight variation, friability, in vitro dissolution test, drug content, moisture content analysis, and stability.

1. Thickness and diameter:[27]

To calculate the deviation from ±5% of the standard value, the thickness and diameter of lozenges were measured using vernier callipers, and the average values were computed.

2. Hardness:[3,27,28,29]

The lozenges were determined using the Monsanto Hardness tester, noting the force needed to break them. The unit of measurement for hardness was kg/cm2.The hardness of their resistance to lozenges is determined to breakage or shipment during storage, transit, and handling circumstances prior to use.

3. Weight variation:[28,29,30]

An electronic balance was used to weigh each of the twenty randomly chosen lozenges. [Either the original weight is compared with the computed average weight, or the average weight and standard deviation of 20 tablets were determined.]

$$weight\ variation = \frac{Average\ weight\ - Initial\ weight}{Average\ weight} \times 100$$

4. Friability:[24]

To determine if lozenges are friable, a friabilator is utilized. For four minutes, the apparatus rotates at 25 rpm. [Lozenges are put in the friabilator once their initial weights are determined. The lozenges were reweighed and de-dusted following the revolution. The value that was observed was not greater than 1%. The formula below is used to calculate friability. Friability as a percentage = (1- Wt. / W) × 100 where W is the lozenges' initial weight. Wt. = Lozenges' weight after revolution

5. Moisture content analysis:[31]

[After the material was weighed and crushed in a mortar, the moisture balance apparatus was used to determine the material's moisture content.] The Helium moisture balancing device is used to determine the moisture content in the finished candy.

6. Mouth dissolving time test: [3,28,29]

To find out how long it took for the candy to completely dissolve, the USP Disintegration device was utilized. The apparatus's tubes were filled with hard-boiled candy lozenges, and the phosphate buffer pH 6.8 at 37°C was used to measure how long it took for the lozenges to dissolve entirely.

7. In-vitro drug dissolution studies:[32]

The efficacy of the lozenge tablet may be correlated with the rate of dissolving. Using the USP II paddle technique at 150 rpm, a dissolution investigation was conducted in 800 milliliters of phosphate buffer with a pH of 6.8. [Samples were taken out every five minutes, replaced right away with a comparable quantity of new buffer, and examined using a UV spectrophotometer.]

8. Drug content:[33]

The drug concentration is determined by crushing and dissolving lozenges in a solvent, then measuring the absorbance using spectrophotometry.

9. Disintegration test:[34]

Using a USP disintegration device, the disintegration time of the lozenges was measured at 37ºC in a pH 6.8 phosphate buffer containing 2% SLS.

10. Microbiological test for lozenges:

The formulation of lozenges is examined for the presence of bacteria, mold, or spores in raw materials, final goods, equipment, cooling tunnels, storage drums, and environmental conditions, among other things. Salmonella, E. Coli, Staphylococcus species, yeast and mold, total plate counts, and total coliform are examples of laboratory microbiological assays.

11. Stability studies: [3,28,29]

A seven-week accelerated stability investigation was carried out at 45°C and 75% ratio in accordance with ICH criteria (zone IV). An adequate quantity of improved formulations were stored in screw-capped bottles with amber hues and kept in an incubator that was kept at 37°C. To estimate the drug content and assess the organoleptic qualities, samples were collected every 15 days.

12. Storage:[30]

It is important to keep these preparations out of children's reach and away from heat sources. It is important to shield them from excessive moisture. It is typically recommended to store the medicine and base at room temperature or in a refrigerator, depending on their respective storage needs.

13. Packaging: [35]

Hard candies are prone to absorbing moisture from the air because they are hygroscopic. Because the candy base is hygroscopic, the lozenges' storage circumstances, how long they are kept in storage, and the possibility of drug interactions must all be taken into account. To avoid drying out, these goods should be kept in tightly sealed containers. This is especially valid for chewable lozenges, which can become challenging to chew if they dry out excessively. It is preferable to place this unit within a clearly marked, airtight plastic bag if a disposable mold with a cardboard sleeve is being used. Proper and appealing packaging is essential.

Conclusion:

Pediatric patients and patients with dysphagia accept lozenges as an organoleptic formulation. Lozenges are becoming more and more popular as medicated confections for both local and systemic drug delivery. As novel dosage forms for powerful medications that appear to be the perfect dose form, they are anticipated to have greater demand in the pharmaceutical industry. Lozenges offer fast start of action, a lower dosage schedule, cost-effectiveness, ease of administration, patient convenience, high patient compliance, and successful treatment of low drug dosage. Patients, doctors, and the pharmaceutical industry all gain from new drug design in this field. This will provide a more inventive and superior dose form. Lozenges holds a significant role in the pharmacy industry and will do so in the future.

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