

COMPREHENSIVE REVIEW ON LOZENGES

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ABSTRACT

Lozenges are solid dosage form, sweetened or flavoured medicaments from which has drawn and retain in oral cavity to cure mouth infection. A Lozenges have intrinsic as well as local action. Type of lozenges are chewable lozenges ,constrict tablet lozenges ,mushy lozenges and stiff lozenges . Lozenges prepare with utilizing several elements like caramel base ,binding agent ,lubed agent ,seasoning agent ,colorants and humectants. Formulation is assisted by hardness, friability, diameter, thickness ,weight variation, moisture content and drug content and drug content .Lozenges give easy administration , convenient for geriatric and Paediatrics patient and improved drug effect.

Key words: Heating and congealing method, Lozenges, Seasoning agent

INTRODUCTION

Then term "Lozenges" are Procure by designation "Lozenge" that indicates the pearl like structure with four sides. Lozenges are solid dosage form, Sweetened or flavoured medicament form which is proposed to be drew and detain in oral cavity to cure the infection mouth or pharynx .Lozenges are alone famous and best creative not only dosage form but also oral confectionary product. The

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reasons for the widely accepted by the geriatric and pediatric patient are easy of administration , improved the drug efficacy ,By pass first pass metabolism ,Not required water intake and enhanced bioavailability by reducing the dose recurrence with less side effects . In the formulation of lozenges the diluents and binders plays vital role. (1) (2)

The word “Troches” and “Lozenges” are used inter changeable, the term troches may be used for compressed lozenges. Lozenges are very helpful for those patients who has problem of swallowing (Dysphagia) of solid dosage form in addition to gradual and constant release of the drug. Lozenges are allocated due to their ability to retain or hold on to the nasopharyngeal mucosa moist and improve the swallowing reflex and keep the drug in contact with mucosal layer for prolong period of time. Lozenges are apply for local effect as well as integral effect when the API go through the systemic circulation and shows its pharmacological effect. Overall, lozenges offer a convenient and effective means of medication administration, especially for patients with swallowing difficulties, while also providing localized and systemic therapeutic benefits. The combination of their unique shape, pleasant taste, and medicinal properties makes lozenges a widely accepted and valuable pharmaceutical and confectionary product. In addition to their pearl-like shape, lozenges are available in various other shapes, catering to different preferences and needs. These shapes can range from round and oval to square and rectangular, depending on the manufacturer and specific product. The composition of lozenges typically includes a medicinal agent, which is the active ingredient responsible for the therapeutic effect. This can be a wide range of substances, such as analgesics, antiseptics, cough suppressants, or throat soothing agents, among others. To enhance palatability and make them more enjoyable to consume, lozenges are formulated with sweeteners and flavouring agents. These ingredients not only mask the taste of the medicinal agent but also add a pleasant flavour to the lozenge. Common sweeteners used in lozenges include sugar, artificial sweeteners, or natural sweeteners like honey or stevia. The choice of flavourings can vary widely, encompassing fruity, minty, herbal, or other appealing tastes. The primary mode of administration for lozenges is through slow dissolution in the buccal cavity (mouth). This allows for both localized

effects, such as soothing a sore throat or reducing oral discomfort, as well as systemic effects when the active ingredients are absorbed through the oral mucosa and enter the bloodstream. Overall, the availability of different shapes, the inclusion of medicinal agents, sweeteners, and flavourings and the potential for both localized and systemic effects make lozenges a versatile and widely used product for oral medication delivery and confectionary enjoyment.(3)

Definition: Lozenges are available in different shapes, they are mainly contains a medicinal agent, sweetener and flavorings agents, proposed to be dissolved gently in a buccal cavity for not only have a localized effect but also systemic effect. Are also known as pills ,troches, Lozenges and pastilles.

Authentic titles for lozenges:

Authentic titles for lozenges may vary depending on regional or regulatory considerations. However, some commonly used authentic titles for lozenges include: It's important to note that the specific title or label used for lozenges may vary depending on regulatory guidelines, marketing strategies, and regional preferences. The authentic title for lozenges may be subject to specific labelling requirements to ensure accurate representation of the product's intended use and ingredients.

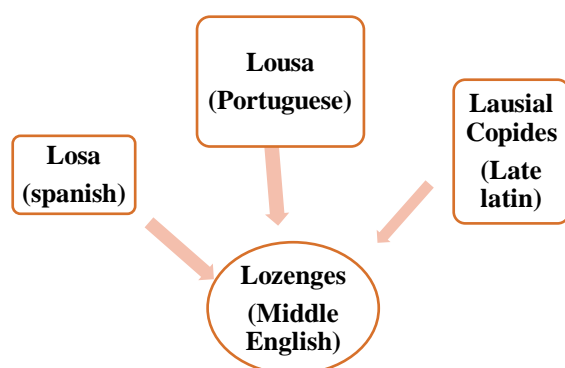


Figure. 1. Authentic titles for lozenges

Merits(3)

- It should be stated for those one who have dysphagia.
- Geriatric and pediatric patients can easily administer lozenges.
- It expands the time of API in the mouth to give desired effects.
- Least equipment's and time required .
- No need of water for administration.
- Intrinsic absorption of drug attainable through oral cavity.
- The sweeteners and flavors used in the formulation for taste masking.
- It may enhance bio accessibility
- Regularity of dose get minimal.
- It may bring down gastric irritation.
- It may bypass pre-systemic metabolism .
- Enhanced pre-systemic metabolism.

Demerits(3)

- Children less than 6 years age can not use lozenges safely.
- Feasible depletion of drug from mouth to stomach along with saliva.
- These dosage form might be falsely taken as candy by children .
- High temperature required for preparation.
- Stiff candy lozenges become gritty.

Lozenges categorization(4)

Lozenges may be Categorized depending on different methods as follows.

A)Based on the active site

- a) Narrow or limited action: Ex Bactericide, Inhalers .
- b) Integral Action: Ex. Vitamin, Nicotine Supplements.

B) Based on appearance and constitution

- a) Chewable and sugar base treated lozenges
- b) Constrict tablet Lozenges
- c) Mushy Lozenges
- d) Stiff Candy Lozenges



Figure 3. Mushy Lozenges



Figure 2 . Stiff Lozenges



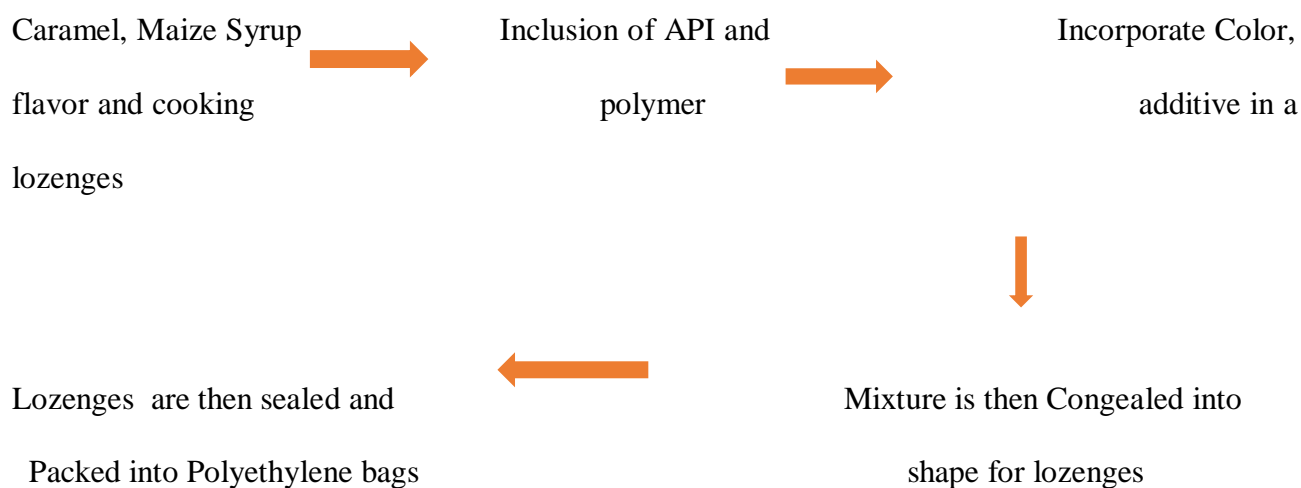
Figure 4. Chewable Lozenges

Table 1. Additives Used In Lozenges Formulation(5)

Additives Name	Examples
Candy Base: Sugar Unsweetened Vehicle	Dextrose, Sucrose, Maltose, Lactose. Sorbitol, Mannitol, Polyethylene Glycol
Diluent	Monohydrate, Xylitol, Lactaid, Calcite, Gypsum, Avicel.

Binder	Maize Syrup, Glucose syrup, Collagen , wattles, Astragal, Avicel.
Lubricants	Octadecanoic acid, Calcium Salt, Miralax, Triglycerides, Fats.
Whipping Agents	Para Casein, Albumen, Collagen, Xanthan gum, Amylum, Pectic polysaccharides, Alginate
Humectant	Honey, Glycerol, Hydroxyacetic Acid, Propylene Glycol, Sorbitol and lactic acid.
Seasoning Agent	Lemon, Orange, Menthol, Basil, Spearmint, Mint .
colorants	Water Soluble dyes, Food and drug cosmetic colours, Titanium oxide, Orange Colour.

Pathway elaborated in the manufacturing of lozenges(3)



Class of lozenges and their manufacturing(6):

- 1)Chewable and Sugar base treated Lozenges
- 2)Constrict Tablet Lozenges
- 3)Mushy Lozenges
- 4)Stiff Lozenges

1) Chewable and sugar base treated lozenges

Kids more favored with chewable lozenges. As long as “Gummy Type” Lozenges. Lozenges contains drug which is integrated in a sugar based which is chewed other than that it will get dissolved in oral cavity. The other excipients which are incorporate in lozenges are Sugar base, Flogging agent, Humidifiers, Emollients, Seasoning agent and Active Pharmaceutical Ingredients.

Ingredients:**Caramel Base**

The blend of caramel and maize syrup of 50:50 to 75:25 caramel to maize ratio.

Humectant's

The role of humectant is to enhance the munch or mouth pleasure effects for examples glycerol , macrogol and D-glucitol.

Whipping Agent

The whipping agent are applicable for aerate the toffe contain sweetness to get required type of fudge while munching . Ex Casein, Albumen, collagen, amylum and Beta-D galactopyranuronic acid .

lubricants

Lubricants Like fats and vegetable oil are used to prevent the sticking of lozenges while chewing.

medicament

Lozenges contains about 30 to 40 % of medicated.

flavors

Mint, Spearmints, Clove, Tulsi, zinger.

Manufacturing processes:

The confectionery is heated at 95 to 125 °C then shifted in a sigma blade mixer



Then a mass is cool Up to 120 °C



Then add whipping agent below 105 °C



The addition of medicament between 95to 105 °C

Color is incorporated in humectants less than 85 °C and then addition of lubricant above 85°C



Chewable and sugar based medicated lozenges are formed of

Desired thickness and then cut into suitable shape and size and packed .

2) Constrict tablet lozenges:

Constrict tablets are produced with the aid of direct compression and wet granulation method. It is helpful for thermolabile drug to form suitable formulation of compressed lozenges. Then Are vary from ordinary tablets in case of palatability, with absence of disintegration and gradual depletion. A heavy compression equipment are used to manufacture a lozenges. They have generally flat faced with size range of 5/8 to 3/4 inch , total weight of lozenges between 1.5 to 4kg, Hardness of 30 to 50 inch square and erosion time 5 to 10 min.(6)

Constituents:

Sugar: Maltose, Lactose, Sucrose ,Dextrose

Unsweetened solvents: D-glucitol, Osmitrol, macrogol 6000 and 8000.

Filler: Lactose, Starch, Di-Basic calcium phosphate, Dextrin, Calcium Carbonate, Microcrystalline Cellulose.

Binder: Wattles, Caramel syrup, collagen, povidone, locoweed and Ethyl Cellulose.

Hydraulic Acid : Talc, Magnesium Stearate, Sodium stearate ,Calcium Stearate, Steric Acid ,Sodium lauryl sulphate and Boric Acid .

Colours: Water Soluble dyes

Flavouring Agent: Mint ,Eucalyptus, Tulsi and Ginger.

Process:

In this compression process entire constituents are rigorously blended and then compressed into lozenges wet Granulation Method :

These methods requires crushing sugar by mechanical agitation and then move through sieve no 40-80 mesh size. Then drug is put in sugar mass then blend consistently. For granulation adequate quantity of sugar and corn syrup is incorporate to form uniform mixing of a dump mass. Then this granules are massed through sieve no 2-8 to get moist Particles .Moist granules are desiccated in forced air circulating oven and then this dried granules are moved through sieve no 10-30 . At last flavour and Lubricant are incorporate to prior to compression to the desire size of lozenges(6)

3) Mushy Lozenges:

Soft texture to the lozenges is obtained due the use of polyethylene Glycol, truffle, caramel and Gum acacia base .Silica has role of suspending agent to prevent the sticking of materials at base of mould cavity while cooling . Soft lozenges are produce by the application of handed rolled method to get required size and shape or a warm mass is congealed into plastic mould .The temperature requires for heating of formulation up to 50°C.So this method is mostly applicable for thermolabile substances (3)

Constituents:

Base: Macrogol 1000, Chocolate Sugar and Gelidium vagum Base.

Hydrophilic colloids: Xanthan gum, Silica Gel and Cellulose ether

4) Stiff Lozenges(8)(9)

These are made up sucrose and other sugar in glassy or Fine powder form. Lozenges are prepared from aqueous syrup, water get evaporated as syrup get heated during manufacturing process for the removal of excess of moisture . It should be between 0.5 to 1.5 % . weight of lozenges lies between 1.5 to 4.5 gm .Lozenges shows sedate and constant cessation of 5 to 10 min .Hence only suitable for heat resistant substances.

Constitution:

Base :Sugar base and corn base.

Sweeteners: Dextrose, Lactose , Sucrose and Maltose.

Acidulants: Vinegar acid, Hydroxybutanedioic acid, Hexanedioic acid, Calcium Acetate and Citric acid .

Colorants: Green, Yellow, Red, Orange and Pink .

Flavouring agent: Mint, Eucalyptus, Tulsi ,Ginger and Mint.

drug: About 2 to 4% of drug is added in stiff Lozenges.

5) Core Pervade Stiff Lozenges

Various kinds of core fill up lozenges such as contains juice of fruits, Caramel syrup, Mannitol and solution which fills weight about of 10 to 20 % of lozenges.

Medicament and flavour are added in center of the lozenges. Drug is get dissolved and suspended in hydrogenated fats. In market core filled lozenges ,Fruit juice core filled, Jellies and Jams are easily accessible. Base is made up of corn and sugar syrup and distilled water and this mixture is get heated to withdraw water to get cooked based having moisture content of about 0.02 to 5.0%. Then colour, flavour and polymer are incorporated in above mixture .Poured this mixture into mould of required size and shape . And then Sealed and packed .

Kinds Of Lozenges Mould :



Figure 5. Rectangular shape mould

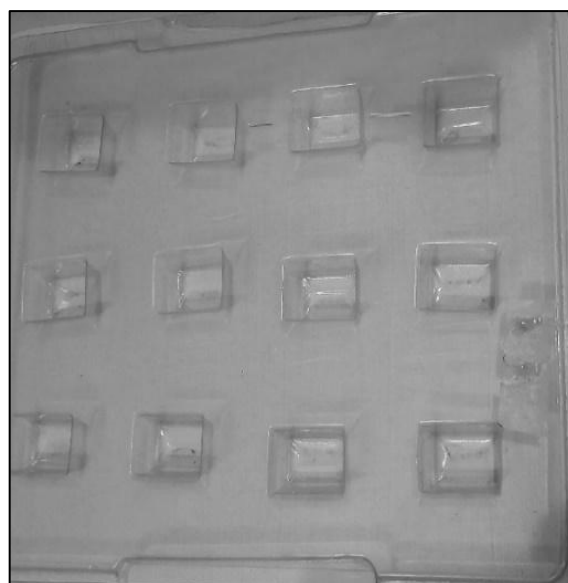


Figure 6. Square shape Mould



ASSESSMENT OF FORMULATED LOZENGES

Hardness(10)

Pfizer or Monsanto hardness tester are measure the hardness of medicated Lozenges. The pressure on lozenges while shipping or breakage in situation of transport, Warehouse and dealing previous use depends on hardness .

Thickness and diameter(11)

The instrument vernier calliper is used to measured diameter and thickness of formulated lozenges. It is measured in mm.

Friability(12)

The apparatus Roche Friabilator is utilise for the establishment of friability of formulated lozenges. Friabilator is revolve at 25 RMP for about 4 min. 20 Lozenges are initial weight and put in a

Friabilator. Then lozenges are removed after 4 min and then lozenges are dedusted and reweighed.

The obtained weight underneath 1 %.

% Brittleness is figure out by blueprint

$$\text{Percentage Brittleness} = \frac{\text{Primary Weight} - \text{Terminal Weight}}{\text{Primary Weight}} \times 100$$

Drug Content(14)

Lozenges in allocated number is squeeze and then dissolved allocated solvent and then the absorbance of that solution is determined by UV visible spectrophotometry.

Moisture Content Test (13)

Moisture content is determine by the method of Gravimetric analysis. Where 1 gm of the crushed lozenges sample is taken and record the primary weight. Then it is site in vacuum oven at the temperature of 60 to 70 °C for the 12 to 16 hrs .After that reweight a specimen and enumerate a moisture meter with blueprint

$$\% \text{ Moisture content} = \frac{\text{Preliminary Weight} - \text{Final Weight}}{\text{Preliminary weight}}$$

Preliminary weight

Mouth Dissolving Time Test (15)

In this test, USP disintegration Apparatus is applied to measure the disintegration time of lozenges .The point time is acclamed in pH 6.8 Gomori Buffer at 37°C.

In Vitro Dissolution test(16)(17)

This study brought off adopting paddle Type Apparatus. Dissolution study is performed in dissolution media 900 ml of gomori buffer pH 6.4 at 37°C. Sample is withdraw at 5 min time interval and add another fresh 5ml of phosphate buffer. Then sample is absorbance is measured at UV -Visible spectrophotometric.

Stability Studies(18)

The stability studies were conducted to assess the drug's physical and chemical cohesion as well as the potential edibility of lozenges. Over the course of seven weeks, expedite stability investigations were carried out in accordance with ICH guidelines (zone IV) at 45°C and 75% relative humidity. A sufficient quantity of the optimised formulation was placed in amber-coloured screw-top bottles and housed in an incubator with a 37 °C temperature control. For the purpose of determining the drug concentration and assessing the organoleptic qualities, samples were collected at intervals of 15 days.

Stability testing of lozenges before packaging:

Lozenges are carried out for stability testing under following conditions

1-2 months at 60 °C

3-6 months at 45°C

9-12 months at 37°C

36-60 months at 25°C and 4°C

Stability testing of lozenges after packaging:

Lozenges after final packing is carried for stability testing under following conditions;

25°C at 80 % RH 6-12 Month

37°C at 80%

Storage(14)

Lozenges can be put away from heat and kids. They should be protect from supreme of dampness.

According to the storage demand of drug and base., instead of room temperature or refrigerator.

Packaging(14)

Stiff lozenges are absorptive and mainly subject to immersion of atmospheric dampness.

Deliberation required Hygroscopic nature of base, depot conditions of the lozenges, duration of lozenges been stored, and the potential drug interaction .These products should stored in tight container to prevent dryness. These is especially true of the chewable lozenges that may dry out

excessively and become difficult to chew .If disposable mould with a cardboard sleeve is used, it is best to slip this unit into a properly labelled, sealable plastic bags.



Figure 9. Blister Packaging Of Lozenges



Figure 10. Lozenges Packed In Plastic Tube

Table 2. Lozenges Available In Markets And Its Applications(14)

Brand name	Contains	Application
Robitussin	Amylmetacresol 2,4Dichlorobenzyl alcohol	To treat cough
Equate	Zinc Gluconate Glycine	Sore Throat
Sucrets	Dyclonine Menthol Pectin	Sore throat Cough and Dry mouth
Covonia	Chlorhexidine Dihydrochloride Lidocaine HCL	Fight Infection Numbs Pain
Strepsils	2,4Dichlorobenzyl alcohol Amylmetacresol	Throat Infection
Dequadin	Dequalinum Chloride Chlorure de dequinium	Sore Throat
Cold -EEZE	Zinc Gluconate Glycine	Common Cold
Throat Disc	Eight Blended Herbs and Botanicals	Dryness Hoarseness
Andolex -C	Lemon and honey	Sore Throat
Cepacol	Benzocaine and menthol	Relieves sore throat pain
Chloraseptic	Menthol and benzocaine	Fast acting numbs the throat in seconds

Tejasya	Honey and lemon	Cold and cough
Prasol	2,4-Dichlorobenzyl , Alcohol and Amylmetacresol	Cough lozenges
Kevox	2,4-Dichlorobenzyl , Alcohol and Amylmetacresol lozenges	Cough and sore throat lozenges
Tyrozets	Benzocaine and tyrothricin	Anaesthetic and antibiotic
Codral	Benzyl alcohol and cetyl pyridinium chloride	Antibacterial

CONCLUSION :

Lozenges are medicated confection that have been developed about 20 th century ago and are still under commercial production. Most of the preparations are available over the counter products and very economic dosage forms. They are designated for local as well as systemic therapy. A wide range of activities can be incorporated within their structure .Lozenges enjoys an important position in pharmacy and will continue to remain so in future. Lozenges are the formulation which is easy and time saving process, and also it is the formulation which is ore ever accepted and preferable for elder and children.

Medicated lozenges such as used for treatment of throat infection, sore throat etc, are ideal dosage form for children's and additional advantages of this include patient compliance ,comfortable and effective treatment including fast onset of action, it requires low dose ,dose regimen is also reduced, and very important role in pharmacy and also acquired a great position in the field and will remain it its position at the same in future.

ACKNOWLEDGMENTS: None

CONFLICTS OF INTEREST: None

FINANCIAL SUPPORT : None

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