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AN OVERVIEW ON MEDICATED CHEWABLE LOZENGES

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ABSTRACT

Oral solid dosage forms is the most widely use dosage forms for their easy mode of administration and many other advantages when compared to other conventional dosage forms. Under oral dosage forms, lozenges play a vital role in delivery of drugs to the patients. Lozenges are flavoured solid dosage form with one or more medicament, in a sweetened base and are intended to dissolve or disintegrate slowly in the mouth. They are medicated candies which are to be dissolved slowly in the mouth to sooth and lubricate the irritated tissues of throat. They are intended to produce local as well as systemic effect. Although they have many advantages, they have disadvantages too. Lozenges are of different types and are manufactured by different methods. Various types of synthetic as well as herbal lozenges are available in the market. The formulation and quality control tests of lozenges have been discussed in this review. Not only in children, in adults too, the acceptance ratio for lozenges as a dosage form is high.

KEYWORDS

Lozenges, Caramel based medicated lozenges, Hard candy lozenges and Soft lozenges.

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INTRODUCTION

Lozenges are prepared as single solid dose medication, producing a local effect in the oral cavity and the throat, which is intended to be sucked in mouth. The active substances mixed with a flavored and sweetened base dissolve or disintegrate slowly inside the mouth¹. Lozenges give smoothening effect to the throat and they release the medicament slowly in a constant rate remaining in the mouth. For the patients who find difficulty in swallowing of solid oral dosage form, lozenges remain as a best dosage form. A throat lozenge

includes troche, cachou or cough sweet, cough drop, 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 caused due to common cold and influenza.

Chewable lozenges are intended to treat local irritation or infection of mouth or pharynx and may also be used for systemic drug absorption. They are commonly used by children and old age patients². Lozenges produce local effect by soothing and purging the throat. Systemic effect is produced by lozenges by the absorption of drug through the buccal linings or when it is swallowed. Lozenges are taken in oral cavity. Because of their size, sublingual lozenges are impractical. Buccal lozenges are formulated and extensively used by placing 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. Subsequent production of saliva and sucking also leads to increased dilution of the drug and accidental swallowing of lozenges³. Lozenges are prepared by molding method or fusion method and by compression method. Molded or fused lozenges are also known as pastilles, whereas compressed lozenges are also known as troches. They are used for patients to bath the throat tissues in a solution of the drug. Since long time lozenges are used for the relief of minor sore throat pain and irritation. They are also used to deliver topical anesthetics and antibacterial agents. Now a days the use of lozenges has spread wide for drugs like anesthetics, antimicrobials, analgesics, antiseptics, antitussives, astringents, corticosteroids, aromatics, decongestants, and demulcents and other classes and combinations⁴.

MERITS^{5,6}

- Lozenges are easily administered to patients who have difficulty in swallowing.
- They can reduce dosing frequency by producing long term release of medicament.

- They can be easily administered to children and old age people.
- The contact time of lozenges in the oral cavity is more to produce the specific effect.
- Sweeteners and flavors can be used to mask the bitter taste of the drug used in formulation.
- It can increase bioavailability.
- Since drugs are systemically absorbed in buccal cavity, it reduces absorption time.
- There is no need for disintegration of lozenges.

DEMERITS⁷

- Drugs drain from oral cavity to stomach along with saliva without producing required action.
- The hard candy lozenges require high temperature for their preparation.
- Aldehyde candy bases are not suitable for certain drugs e.g. Benzocaine.
- The non- uniformity drug distribution within saliva affects the local therapy.
- Accidental intake of the lozenges dosage form by children as candy can lead to serious effects.

FORMULATION OF LOZENGES⁸⁻¹⁰

The formulation of lozenges normally includes Candy base, lubricant, binder, colouring agent, flavouring agent, whipping agent and humectants.

Candy base

Candy base consists of sugar, sugar free vehicle and fillers. Dextrose, sucrose, maltose and lactose are commonly used sugars. Sugar free vehicles includes mannitol, sorbitol, polyethylene glycol (PEG) 600 and 800. Di calcium phosphate, calcium sulphate, calcium Carbonate, lactose and microcrystalline cellulose are common fillers.

Lubricants

Magnesium stearate, calcium stearate, stearic acid, PEG, vegetable oil and fats.

Binders

Binders are added to obtain uniform shape and flexibility to the preparation. Binders such as Acacia, corn syrup, sugar syrup, gelatine, polyvinyl pyrrolidone, tragacanth, methyl-cellulose, etc are used.

Colouring agent

Colouring agents give colour to the preparation which makes it more attractive to the paediatric patients. Water soluble and lake dyes, FDC colour, orange colour paste, red colour cubes etc, are used as colouring agents.

Flavouring agent

Flavouring agents are selected based on the colouring agent used. Some of the flavouring agents used are menthol, eucalyptus oil, spearmint and cherry flavour.

Whipping agent

Milk protein, egg albumin, gelatine, xanthan gum, starch, pectin, algin and carrageenan.

Humectants

Glycerine, propylene glycol and sorbitol.

TYPES OF LOZENGES

Lozenges are classified according to site of action, texture and composition.

According to site of action

According to the site of action lozenges are classified as local effect and systemic effect lozenges. Examples of local effect lozenges are antiseptic, decongestion, etc. Example of systemic effect lozenges are vitamins, nicotine, etc¹¹.

According to Texture and Composition

According to texture and composition lozenges are classified into caramel based medicated lozenges, compressed tablet lozenges, soft lozenges and hard candy lozenges.

CARAMEL BASED MEDICATED LOZENGES

These are also known as chewy lozenges. In this type the medicament is incorporated into a caramel base which is chewed instead of being dissolved in mouth. These lozenges are especially used for paediatric patients and are a very effective means of administering medications for gastrointestinal

absorption and systemic use. "The gummy-type" candy lozenge is commonly used for children. These are gelatin based pastilles were prepared by pouring the melt into molds or out onto a sheet of uniform thickness¹².

COMPRESSED TABLET LOZENGES

This method is used for preparation of lozenges with heat sensitive active ingredient. The granulation method used for preparation of these types of lozenges is similar to that used for other compressed tablets. These tablets differ from conventional tablets in terms of organoleptic property, non disintegrating characteristics and slower dissolution profiles. The compressed tablet lozenge is made using heavy compression equipment to give a harder tablet than usual, since it is required for the troche to dissolve slowly in oral cavity. The preparation of lozenges by tablet compression method is very less common¹³.

SOFT LOZENGES

Soft lozenges are used to prepare a wide variety of drugs. So they are commonly used lozenges. 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, glycerol-gelatin or acacia: sucrose base. Pastilles are easy to use, easy to store at room temperature, convenient to carry and are pleasant in taste. If exposed to high temperatures, polyethylene glycol-based lozenges have the tendency to be hygroscopic and may soften¹⁴.

HARD CANDY LOZENGES

Hard candy lozenges are solid syrups of sugars. These are mixtures of sugar and other carbohydrates in an amorphous or glassy state. 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 not disintegrate and should undergo a slow and uniform dissolution over 5-10min. Since hard candy lozenges require high temperature for

their preparation heat labile materials cannot be incorporated in them. These pastilles were prepared by heating and congealing method¹⁵.

PREPARATION METHODS OF LOZENGES **CARAMEL BASED MEDICATED LOZENGES**

After cooking the candy base at 95-125°C, it is transferred to planetary or sigma blade mixer. The mixed mass is allowed to cool to the temperature of 120°C. Then the whipping agent is added below 105°C. The medicaments are incorporated between 95- 105°C. Above 90°C color is dispersed in humectant and added to the above mass. Flavor and seeding crystals and are then added below 85°C. Candies are formed by rope forming following addition of lubricant above 80°C¹⁶.

Compressed Tablet Lozenges

Direct compression and wet granulation method is used in the preparation of compressed tablet lozenges. In direct compression, all the ingredients are thoroughly mixed together and then compressed. In wet granulation method, the sugar content is milled by mechanical pulverisation to a fine powder using 40-80 mesh size. The active medicament is then added and thoroughly mixed. The blended mass is granulated with sugar or corn syrup and size separated through 2-8 mesh screens. Then it is dried and milled using 10-30 size mesh. Before compression the flavouring agent and lubricant are added¹⁷.

Soft Lozenges

Soft lozenges are prepared using fusion method, in which the warm mass is poured into in a plastic mould. Mould 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. They are also prepared by hand rolling method, where, they are hand rolled and then cut into pieces¹⁸.

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°C. Corn syrup is added and cooked till the temperature reaches 145-156°C. 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 length¹⁹.

Evaluation Test for Lozenges

Quality Control is performed for candy base and lozenges.

For the candy base the evaluation is performed for corn syrup and sugar delivery gears, steam pressure, temperature, cooking speed, temperature and vacuum of candy base cooker²⁰.

Moisture Analysis²¹

Moisture analysis of lozenges is performed by gravimetric method: In this method 1g of sample is weighed and placed in vacuum oven at 60-70°C for 12-16 hrs. After specific time interval, the sample is weighed and moisture content is calculated using the following formula.

Moisture content = initial weight - final weight

Azeotropic Distillation Method

10-12g of powdered lozenges is used for this method. 150-200ml toluene was added to the powder placed in 500ml flask. The flask was fitted to a reflux condenser and refluxed for 1-2 hours. The collected water gives the amount of water present in sample. Karl fisher titration is carried out – A sample of prepared lozenge is calculated to obtain 10-250mg of water which is then titrated with Karl Fisher reagent.

PHYSICAL AND CHEMICAL TESTING²²

Hardness

The hardness of lozenges is determined by Monsanto or Pfizer hardness tester.

Diameter and thickness

The diameter and thickness of the lozenges is determined by using Vernier calipers.

Drug excipient interaction studies

Drug excipient interaction studies are carried out to check whether any interactions take place between the drug and the excipients. It is determined by using Fourier-transform infrared spectroscopy.

Friability

Friability is determined by Roche Friabilator operated at 25rpm for 4min.

Weight variation

The variation in weight of the lozenges is determined by weighing 20 lozenges and determining the average weight. Individual weight of the lozenges is compared with the average weight.

In-vitro drug release

In-vitro drug release studies is carried out using 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 Lozenges²³

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°C
- 3-6months at 45°C
- 9-12months at 37°C
- 36-60months at 25 and 40°C

Stability testing of packaged products

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

- 25°C at 80% RH for 6-12months
- 37°C at 80% RH for 3 months
- 25°C at 70% RH for 6-12 months

Packaging

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

Storage²⁴

The storage of lozenges should be done carefully. They should be stored away from heat. They should be kept out of reach of children. They should be protected from extreme humidity, since they are hygroscopic. Depending upon the storage requirements of both, the drug and the base, either room temperature or refrigerator temperature is usually preferred for storage of medicated chewable lozenges.

Applications

Many drugs have been tried and were successfully incorporated in lozenges. Generally they belong to one of the following categories: Antiseptics, local anesthetics, antibiotics, antihistaminics, antitussives, analgesics, decongestants and demulcents.

Table No.1: Classification of lozenges

According to site of action	According to texture and composition
1. Local effect. Ex. Antiseptic, Decongestants 2. Systemic effect. Ex. Vitamins, Nicotine	1. Caramel based medicated lozenges 2. Compressed tablet lozenges 3. Soft lozenges 4. Hard candy lozenges



Figure No.1: Lozenges

CONCLUSION

Lozenges are medicated sweetened candies that have been used for delivery of drugs for centuries. The commercial production of lozenges holds a great place in the field of pharmaceutical industry. Lozenges are organoleptically accepted formulation by the pediatric and geriatric patients. They are one of the easiest routes of drug administration. They are easy to prepare and store. Lozenges produce both local and systemic effects during administration. They are used to incorporate a wide range of active ingredients. Sweetened and flavored lozenges hold a prime place in the pharmaceutical market. They are expected to acquire more demand in pharmaceutical production as innovative dosage forms for potent drugs which seem to be an ideal dosage form. Most of the medicated chewable lozenges are available as OTC products and are very cheap when compared to other dosage forms. Lozenges enjoy an important position in pharmacy and will continue to remain so in the future.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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