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A COMPREHENSIVE REVIEW ON MOUTH ULCER LOZENGES

¹Bhushan Dilip Mali , ²Yashpal M. More ,

¹Student, ²Assistant Professor,

¹ Department of Pharmaceutics,

¹Loknete Dr.J.D.Pawar College of Pharmacy, Manur, Kalwan Dist- Nashik

Abstract : Lozenges are popular solid dosage forms with both local and systemic therapeutic effects that dissolve gradually in the oral cavity. Because they are easy to administer and patient-friendly, lozenges, which have been used since the 20th century, continue to be a significant and profitable medication delivery method. The formulation, assessment, and uses of lozenges are highlighted in this review, with a focus on their adaptability in combining a variety of active pharmaceuticals. The preparation techniques for a variety of lozenges, such as crushed tablet lozenges, soft lozenges, and hard candy lozenges, are covered. To guarantee palatability and stability, the choice of excipients, such as flavourings, sweeteners, and preservatives, is carefully examined. Important evaluation criteria, quality control tests, packaging considerations, storage conditions, and dispensing procedures are also thoroughly discussed. Lozenges' benefits—such as enhanced patient compliance, extended medication action, and targeted delivery—as well as its drawbacks are presented. In order to offer useful insights, marketed formulation examples are also provided. All things considered, lozenges show great promise as a novel and efficient drug delivery method, with bright futures for both local and comprehensive treatments.

KEYWORDS- Bupivacaine HCl, Lozenges, Mouth Ulcers, Sustained Release, Local Anaesthetic, Oral Drug Delivery

INTRODUCTION

Mouth Ulcer: Mouth ulcers are small, painful lesions that appear on the entrance's self-lubricating surface. They are still occasionally referred to as canker sores or aphthous sores. Consumption, eating, and talking are all uncomfortable due to these ulcers, which can significantly affect daily life. Among the things that could lead to their creation are stress, trauma, or underlying medical conditions. Effective therapies are required to manage symptoms and encourage healing [1].

They can be made by moulding or by making hard candy lozenges with a base of cooked sugar. While hard candy lozenges are distinguished by their rigid, glassy structure created by boiling sugars to high degrees, moulded lozenges are sometimes referred to as pastilles.^[9]

They are used for patients who have trouble swallowing solid oral dose forms, as well as for drugs that are meant to be given gradually in order to keep the drug level in the mouth steady or to soak the tissues in the throat with a medicated solution. In the past, lozenges have been used extensively to provide topical anaesthetics and to reduce minor sore throat pain and irritation.

NEED OF THE STUDY.

Mouth ulcers are a common oral health problem that affects people of all age groups and can cause significant pain, irritation, difficulty in eating, speaking, and swallowing. Conventional treatment options such as gels, ointments, and mouthwashes often have limitations including short contact time with the oral mucosa, unpleasant taste, and poor patient compliance. Recent evidence shows that localized oral dosage forms such as mucoadhesive tablets and lozenges may improve pain relief and ulcer healing by maintaining longer contact with the lesion site.

Lozenges offer several advantages because they dissolve slowly in the mouth, provide prolonged drug release, enhance local therapeutic action, and improve patient convenience. Despite increasing interest in this dosage form, information regarding the formulation strategies, therapeutic agents, mechanism of action, and clinical effectiveness of mouth ulcer lozenges remains scattered in the literature. Existing reviews on recurrent aphthous stomatitis mainly focus on disease management in general rather than lozenge-based delivery systems specifically.

Therefore, this study is needed to compile and critically evaluate the available scientific literature on mouth ulcer lozenges, highlight their formulation approaches, therapeutic benefits, and limitations, and identify future research opportunities for developing more effective and patient-friendly treatments for oral ulcer management.

TYPES OF MOUTH ULCER :

Minor Aphthous Ulcers: usually less than 1 cm in diameter, are minor aphthous ulcers. oval or round in form. usually heal without leaving scars in one to two weeks.

Major Aphthous Ulcers: Usually larger than minor ulcers, with a diameter of more than 1 cm. It may be shaped erratically. Healing could take longer, and scarring might occur.

Herpetiform Ulcers: Each ulcer typically has a diameter of one to three millimeters. Small, oval or circular in form. They typically recover on their own in one to two weeks.^[4]

BASIC TYPES OF LOZENGES:

Hard lozenges: Similar to how hard candy confections are formed, hard lozenges are typically made using sucrose or other sugars that result in a hardened, amorphous, glassy substance. Polymers like PEGs and HPMC can be added to delay the rate of dissolution. Compressed powders could be used to make another kind of hard lozenge. Clotrimazole troches (lozenges), which are huge, compressed tablets that dissolve gradually in the tongue, are one example of this. Dextrose, MCC, and povidone make up the tablet base material.

Soft lozenges: PEGs with a high enough molecular weight to dissolve slowly in saliva are frequently used to make soft lozenges. Hydrocolloids, like acacia, can also be used as an adhesive. This method of creating soft clotrimazole troches involves mixing the medication and acacia with melted PEG 1450 base, then pouring the mixture into troche-shaped cavities.

Chewable lozenges: Glycerinated gelatine, a mixture of glycerine, gelatine, and water, is the usual base for chewable lozenges. Drug, acacia, and suitable flavour and sweetening ingredients can be mixed with this base.^[5]

ADVANTAGES: ^[6]

Easy Administration: Patients who have trouble swallowing tablets or capsules can use lozenges since they are easy to use.

Local Action: They act directly and locally in the mouth and throat (e.g., for oral infections, coughs, and sore throats).

Palatability: They are frequently sweetened and flavoured, which makes them more enjoyable to consume, particularly for kids.

Extended Contact: By dissolving gradually, the medication can remain in contact with mucosal membranes for extended periods of time, increasing its therapeutic efficacy.

Convenience: Water-free, lightweight, and portable.

DISADVANTAGES: ^[6]

Restricted Drug Types: Only medications that are stable in the mouth and throat are appropriate; medications that taste bad or irritate the oral mucosa are not.

Risk of Choking: Young children are particularly vulnerable to choking hazards.

Slow Onset: Compared to certain alternative dose forms (such as liquids or injections), medication release is slower.

Restricted Dose Size: The amount of active medication that can be added is limited.

Sugar Content: A lot of lozenges have sugar, which can cause tooth rot or cause issues for diabetics.

HARD CANDY LOZENGES :

Hard candy lozenges are amorphous (no crystalline) or glassy combinations of sugar and other carbohydrates. These can be thought of as solid sugar syrups, and lozenges have long been used to administer topical anesthetics and antibiotics as well as to relieve minor sore throat pain and irritation. Lozenges are solid dosage forms with a variety of shapes that are meant to dissolve gradually in the oral cavity for either localized or systemic effects.

They often contain a medical drug and a flavouring element. Hard lozenges typically have a moisture level of 0.5 to 1.5%. They should dissolve or erode slowly and uniformly over a period of 5 to 10 minutes, not disintegrate, have a smooth surface texture, and have a pleasant flavour that masks the taste of the medicine.

The high temperature needed to prepare hard candy lozenges is one of their main drawbacks. The typical weight range for hard candy lozenges is 1.5 to 4.5 grams. Sorbitol and sugar are examples of excipients with demulcent actions that ease the discomfort of abraded tissue caused by irritation from coughing and sore throats. In fact, some of the active drug product may be absorbed through the buccal mucosa, avoiding the first-pass metabolism that happens when a medication is ingested and absorbed through the GI tract. ^[7-8]

Preparation of Method (Hard Candy Method) :

Syrup Base Preparation: Dissolve sugar in a little amount of water, then heat the mixture to a clear, thick syrup (around 110°C).

Addition of Glucose and Heating: To achieve the hard crack stage, which results in sugar inversion, add liquid glucose and continue heating the mixture to a high temperature (141–156°C or 300°F).

Cooling and Ingredient Addition: Take off the heat, let it cool slightly (to between 90 and 135°C), and then add the active medication, flavours, colours, and plasticizers (such as glycerine).

Moulding: Transfer the material onto butter paper or into oiled moulds, then let it cool and solidify.

Finishing: Take out of the moulds and wrap after letting it cool and solidify.

Physicochemical Evaluation :

To guarantee quality and consistency, the manufactured lozenges will be assessed for physicochemical criteria such as weight fluctuation, thickness, diameter, hardness, friability, drug content uniformity, and moisture content.

CONCLUSION :

To guarantee safety and effectiveness, the formulation process entails meticulous ingredient selection, proportion optimization, and compliance with legal requirements.

The formulation can be improved to maximize flavour, texture, and medicinal advantages through research in science.

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