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Comprehensive Review on Drotaverine Hydrochloride Lozenges.

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Abstract
Drotaverine hydrochloride is a well-known antispasmodic agent widely used for the management of smooth muscle spasms. The development of lozenge dosage forms offers several advantages, including ease of administration, improved patient compliance, and controlled drug release in the oral cavity. This review article focuses on the design and development of drotaverine hydrochloride lozenges, covering formulation strategies, excipient selection, manufacturing methods, evaluation parameters, and recent advancements. The aim is to provide a comprehensive understanding of lozenge formulation for effective drug delivery. dditionally, this review highlights the potential of lozenge formulations to enhance local therapeutic action and reduce systemic side effects.

Keywords
Drotaverine hydrochloride, Lozenges, Antispasmodic, Direct compression, Oral drug delivery, Formulation

I. Introduction

Oral drug delivery remains the most widely accepted route for therapeutic administration due to its convenience, cost-effectiveness, and high patient compliance. Within this category, alternative solid dosage forms such as lozenges have gained significant attention, particularly for patients who experience difficulty swallowing conventional tablets and capsules. Lozenges are designed to dissolve slowly in the oral cavity, allowing the drug to be released gradually, which may provide both local and systemic effects depending on the drug properties.

Oral dosage forms are available in different types and provide many advantages over other methods of drug delivery. They are affordable, safe, and easy for patients to use. This route is the most simple and natural way of taking medicine, as it does not need the help of healthcare professionals—patients can take it by themselves. Another benefit is that the drug acts more slowly in the body, so if any toxic effects occur, they appear later and can be managed more easily. Oral dosage forms are also suitable for people of all age groups, making them a widely preferred option.

Lozenges are solid oral dosage forms that are meant to dissolve slowly in the mouth or throat. They contain one or more active drugs mixed with a sweetened and flavored base, making them easy and pleasant to take while delivering the medicine either locally in the throat or throughout the body. Lozenges can also produce a systemic effect when the drug is absorbed through the buccal mucosa or after it is swallowed. They are usually placed in the mouth, between the cheek and gums, as placing them under the tongue (sublingual route) is not suitable due to their larger size.

II. Advantages of Oral Drug Delivery System

- **Convenience and patient compliance**
- **Ease of administration**
  It does not require trained personnel, unlike parenteral routes, making it suitable for self-medication.
- **Cost-effective**
  Manufacturing, packaging, and distribution are economical compared to sterile dosage forms.
- **Flexible formulation design**
  Various dosage forms such as tablets, capsules, lozenges, and syrups can be easily developed.
- **Controlled and sustained release possibilities**
- **Wide range of drug candidates**

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- **Better stability of dosage forms**
  Oral dosage forms generally have **greater chemical and physical stability** than liquid or injectable forms.
- **Accurate dosing**
- **Reduced risk of overdose (compared to injections)**
  Oral drugs are absorbed gradually, reducing the risk of sudden toxicity.
- **Possibility of taste masking**
  Techniques like coating and flavoring improve palatability.

3. Limitations of Oral Drug Delivery System

- **First-pass metabolism**
  Drugs may undergo extensive metabolism in the liver, reducing bioavailability
- **Variable absorption**
  Drug absorption may vary due to factors like pH, gastric emptying time, and presence of food.
- **Not suitable for all drugs**
  Drug that are unstable in gastric pH or degraded by enzymes cannot be administered orally.
- **Delayed onset of action**
  Compared to parenteral routes, oral drugs show slower onset.
- **Gastrointestinal irritation**
  Some drugs may irritate the gastric mucosa causing discomfort or ulceration
- **Difficulty in swallowing**
  Pediatric and geriatric patients may face problems in swallowing tablets or capsules.
- **Influence of food and drug interactions**
  Food can enhance or reduce drug absorption, leading to variability.

4. Introduction of Drotaverine hydrochloride [5-9]

Drotaverine hydrochloride is a synthetic isoquinoline derivative that has been extensively utilized as a potent antispasmodic agent. Unlike classical anticholinergic drugs, Drotaverine acts directly on smooth muscle without interfering with the autonomic nervous system. This unique mechanism minimizes typical anticholinergic side effects such as dry mouth, blurred vision, and tachycardia, making it a safer option for long-term use in various spasm-related conditions. Drotaverine is a strong antispasmodic medicine that works by directly relaxing the smooth muscles of the intestine. Because of this action, it helps in relieving abdominal pain effectively. An important advantage of drotaverine is that it does not produce the common side effects associated with anticholinergic drugs.

Many studies have shown that Drotaverine is useful in managing spasmodic pain in patients with Irritable Bowel Syndrome (IBS), and it has been found to be generally safe. In one study, patients with IBS who were given 80 mg of drotaverine three times a day for two weeks experienced a noticeable decrease in their average weekly abdominal pain scores. The overall effectiveness of the treatment was reported to be around 78%, and no serious side effects were observed.

Pharmacologically, Drotaverine hydrochloride functions primarily through selective inhibition of phosphodiesterase-IV (PDE-IV), an enzyme responsible for the degradation of cyclic adenosine monophosphate (cAMP). Inhibition of this enzyme leads to elevated intracellular cAMP levels, which in turn promotes smooth muscle relaxation. Additionally, drotaverine exhibits mild calcium channel blocking activity, further contributing to its spasmolytic effect. Due to this dual mechanism, the drug is effective in relieving spasms of the gastrointestinal, biliary, urinary, and uterine smooth muscles.

Clinically, Drotaverine hydrochloride is widely prescribed for conditions such as irritable bowel syndrome, dysmenorrhea, renal colic, and biliary colic. However, its conventional oral dosage forms (tablets and injections) may present limitations including delayed onset of action, variable bioavailability, and reduced patient adherence in specific populations.

5. INTRODUCTION OF LOZENGES [10-12]

Definition

Lozenges are solid oral dosage forms that contain flavouring and sweetening agents, designed to dissolve or disintegrate slowly in the mouth or oral cavity. They are primarily used to provide a localized effect within the oral cavity but may also produce a systemic effect if the active ingredient is effectively absorbed through the buccal mucosa or pharyngeal lining.

Lozenges are flavoured medicated dosage forms that are meant to be sucked and kept in the mouth or throat, where they slowly dissolve and release their active ingredients. They usually contain one or more drugs mixed in a sweet base, making them pleasant to use. These are mainly used to relieve problems of the mouth and throat, especially those caused by local infections. In some cases, lozenges can also produce a systemic effect if the drug is absorbed through the buccal lining or swallowed.

Lozenges are widely used to reduce throat pain and irritation and are especially useful for

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delivering drugs with local anaesthetic or antibacterial action. Their formulation allows the drug to be released slowly in the mouth, providing prolonged local effect and, in some cases, better absorption.

TYPES OF LOZENGES

a) Medicated lozenges

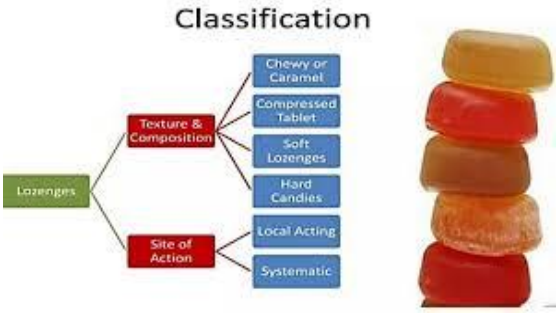
These lozenges are prepared for therapeutic use and contain one or more active medicinal ingredients. They are commonly used to treat throat infections, cough, and oral discomfort.

Example: Strepsils lozenges

b) Non-medicated lozenges

These lozenges do not contain any active drug. They are mainly used to relieve dryness or irritation in the throat by increasing saliva production and keeping the throat moist.

Example: Flavored candies



- **Chewy or Caramel-Based Medicated Lozenges**
  Chewy lozenges are a type of oral dosage form in which the active drug is mixed into a soft, caramel-like base. Unlike traditional lozenges that slowly dissolve in the mouth, these are meant to be chewed. This type of formulation is especially useful for children, as they may find it easier and more comfortable to take compared to regular lozenges
- **Compressed Tablet Lozenges**
  When the drug is sensitive to heat, lozenges can be prepared by using compression methods instead of heating. In this process, the ingredients are first converted into granules and then compressed into lozenge form, similar to the method used for making regular tablets.
- **Soft Lozenges**
  Soft lozenges are made to be either chewed or to slowly release the drug in the mouth. They have a softer and more flexible texture than hard lozenges, making them easier to use. The preparation of soft lozenges typically involves heating the base to approximately 50°C, making this method suitable only for heat-stable ingredients.
- **Hard Candy Lozenges**
  Hard candy lozenges are made from sugar and other carbohydrates that form a non-crystalline (glassy) structure, similar to a solid syrup. These lozenges are designed to dissolve slowly and evenly in the mouth over about 5 to 10 minutes, without breaking apart.

Challenges in Formulation

- Bitter taste of drug
- Maintaining mechanical strength
- Achieving controlled release
- Moisture sensitivity

Recent Advances

- Use of natural polymers for binding
- Sugar-free lozenges for diabetic patients
- Use of effervescent agents
- Improved taste masking techniques such as microencapsulation

6. FORMULATION CONSIDERATION OF LOZENGES [13-14]

The raw materials used in lozenges contain sugar, corn syrup, acidulant, colorant, flavor, and the medicament.

Sugar

Sucrose is a type of sugar made up of glucose and fructose. It is obtained from sources like sugarcane or sugar beet, and the choice between them usually depends on availability and location. In medicated lozenges, sucrose and its derivatives are widely used because they provide sweetness without affecting the drug's action.

Sugar Bases

Common sugar bases used in lozenge tablets include sucrose or compressible sugar, dextrose, mannitol, and sorbitol. These ingredients are available in specialized tableting grades from various excipient manufacturers. While primarily designed for direct compaction, they can also be used in wet granulation formulations with appropriate binders.

Binders

Binder are materials used in compressed tablets to hold the powder particles together, forming strong and uniform granules. They help maintain the shape and strength of the tablet. Common examples of binders include acacia, corn syrup, sugar syrup, gelatin, polyvinylpyrrolidone (PVP), tragacanth, and methylcellulose.

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Lubricants

Lubricants are added to prevent the candy from sticking to the teeth and to improve the flow of the final troche mixture during manufacturing. Common lubricants used include magnesium stearate, calcium stearate, stearic acid, and polyethylene glycol (PEG).

Colorants

Colorant are added to medicated lozenges to improve their appearance, help in easy identification, and hide any visible changes due to degradation. However, dyes and other colorants can break down when exposed to heat or light through processes like oxidation, hydrolysis, and photo-oxidation. Therefore, it is important to carefully check their compatibility with the drug, other ingredients, and manufacturing conditions before using them.

Acidulants

Acidulants are commonly added to medicated lozenges to enhance and strengthen their flavor profile. Organic acids such as citric, malic, fumaric, and tartaric acids are most frequently used, with citric acid—either alone or combined with tartaric acid—being the most common. Additionally, acidulants help adjust the pH of the lozenge formulation to maintain the stability and integrity of the active drug.

Flavors

Flavors used in medicated lozenges must be compatible with the drug and excipients and be able to withstand the stresses of the manufacturing process. Since flavors are composed of numerous chemicals, they may potentially interact with excipients or active ingredients, which makes careful selection and compatibility testing essential to ensure the final product's stability and taste quality.

7. METHODS OF PREPARATION LOZENGES [15-16]

1. **Melting and Mold Technique:** In this approach, polyethylene glycol (PEG) is melted using a water bath and blended with the other ingredients to form a homogeneous mixture. The molten blend is then poured into stainless steel molds of the desired shape and size to form lozenges.
2. **Heating and Congealing Technique:** A syrupy base is prepared by heating sugar and water to 105–110°C until thick. After 30 minutes, the drug and excipients (excluding plasticizer) are added and mixed. The mixture is heated for another 45 minutes, then the plasticizer is added. The hot mass is poured into pre-cooled, lubricated moulds, left to set for 10–15 minutes, then demoulded and air-dried.
3. **Direct Compression Technique:** The ingredients are thoroughly mixed and then directly compressed into tablets without further processing.
4. **Wet Granulation Technique:** Sucrose is mechanically pulverized into a fine powder. The medicaments (active ingredients) are uniformly mixed with the powdered sugar. A binder solution is then added to form a cohesive mass, which is passed through a #16 sieve to produce granules. These granules are dried, and afterwards, lubricants and flavoring agents are added before the final compression into tablets lozenges.

8. EVALUATION OF LOZENGES [17-19]

Physical and chemical testing

General Appearance

The overall appearance of the lozenges will be carefully assessed to ensure that they are visually appealing and acceptable to patients. Evaluation parameters will include:

- Size and shape
- Color and surface smoothness
- Odor and taste
- Presence of visible defects such as cracks or chips
- Clarity and legibility of any imprinted markings

Hardness

The hardness of lozenges is typically measured using instruments such as the Pfizer or Monsanto hardness tester. This parameter is crucial as it determines the lozenge's resistance to mechanical stress during storage, transportation, and handling.

Diameter and Thickness

The diameter and thickness of lozenges are measured using a vernier caliper, a precise instrument that ensures uniformity in size. Consistent dimensions are important for dose uniformity, packaging compatibility, and aesthetic appearance of the final product.

Friability

The friability is assesses by using a Roche friabilator. **Friability** refers to the tendency of a dosage form (like a tablet or lozenge) to crumble or break under stress. It is assessed by rotating the dosage forms in a friabilator, measuring their weight before and after the test, and calculating the percentage of material lost. The acceptable friability limit is not more than 1%, Calculate friability by using the following formula:

$$\% \text{ Friability} = (1 - \text{Wt.} / \text{W}) \times 100$$

Where, W= Initial weight of lozenges, Wt.= Weight of lozenges after revolution.

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Weight Variation

Weight variation is a critical quality control test performed on solid dosage forms like tablets or lozenges to ensure uniformity in weight among individual units in a batch. It involves weighing a specific number of randomly selected units (usually 20), calculating the average weight, and comparing each unit's weight to this average.

Disintegration Test

The USP disintegration apparatus is use to evaluate the disintegration time of dosage forms. The test is performe using pH 6.8 phosphate buffer or artificial saliva maintaine at a temperature of 37 ± 0.5°C, which simulates physiological conditions in the oral cavity. Disintegration test is used to ensure that a dosage form disintegrates within a specified time, allowing the drug to be released and absorbed effectively in the body.

In-vitro Drug Dissolution Study

Drug absorption from lozenges depends on the dissolution rate, affecting bio-availability and efficacy. The study uses USP Type II apparatus with 900 mL of pH 6.4 buffer or artificial saliva at 37 ± 2°C and 100 rpm paddle speed. Samples are taken every 5 minutes, replace with fresh medium, and analyze Spectrophotometric for drug concentration.

Drug Content

Drug content, also known as assay of active pharmaceutical ingredient (API), is a quantitative test used to determine the amount of active drug present in a dosage form (e.g., tablet, capsule, lozenge). To determine the drug content, an appropriate number of lozenges are crush into a fine powder and dissolve in a suitable solvent. The resulting solution is then analyze spectrophotometrically by measuring its absorbance, which is use to calculate the amount of drug present.

Stability Studies

Stability studies are conducted to determine how well a pharmaceutical product maintains its quality, safety, and efficacy over time under various environmental conditions such as temperature, humidity, and light. To ensure that the lozenge maintains its physical appearance, drug potency, and performance throughout its shelf life.

9. Conclusion

Drotaverine hydrochloride lozenges offer a convenient and patient-friendly alternative to conventional dosage forms, with improved compliance and ease of administration. Proper formulation, including suitable excipient selection and taste masking, is essential to achieve optimal drug release and stability. The potential for enhanced bioavailability and controlled drug delivery makes this dosage form promising. Further research and optimization can help in developing more effective and widely acceptable drotaverine lozenge formulations.

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