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### Formulation of Sugarless Medicated Lozenges for Diabetic Patients

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#### ABSTRACT

*Diabetes Mellitus is a chronic disease caused by high blood sugar, necessitating stringent dietary management to prevent hyperglycaemia and its associated complications. One of the challenges diabetic patients faces is the limited availability of sugar-free alternatives for common confectionery items, including lozenges. Lozenges are often used for throat relief, cough suppression, and delivering active pharmaceutical ingredients. Traditional lozenges, however, are typically made with sucrose or other sugars, making them unsuitable for diabetic patients. This study focuses on the formulation and evaluation of sugarless lozenges specifically designed for diabetic individuals. The primary aim of this research is to create a sugarless lozenge that not only caters to the dietary restrictions of diabetic patients but also maintains the efficacy and sensory qualities of conventional lozenges. The formulation replaces sucrose with non-glycaemic sweeteners such as stevia, xylitol, and erythritol, which do not elevate blood sugar levels. These sugar alcohols and natural sweeteners are selected for their low caloric content and minimal impact on blood glucose. Additionally, their properties contribute to the desired texture and mouthfeel of the lozenge. The formulation process involves several key steps: selecting appropriate sweeteners and active ingredients, determining the optimal ratios, and conducting trials to achieve the desired balance of sweetness, efficacy, and stability.*

**Keywords:** *Diabetes, sugar-free lozenges, formulation, non-glycemic sweeteners, stevia, throat relief, cough suppression, diabetic-friendly confectionery, glycemic control, herbal extracts, menthol.*

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## INTRODUCTION

Diabetes Mellitus is a metabolic disease characterized by elevated blood sugar levels due to impairment of insulin secretion, insulin action, or both.<sup>[1]</sup> According to the World Health Organization (WHO), the prevalence of diabetes has been steadily increasing worldwide, reaching epidemic proportions. Management of diabetes involves various strategies including lifestyle modifications, pharmacotherapy, and regular monitoring of blood glucose levels. One common challenge faced by diabetic patients is the administration of oral medications, particularly in forms that contain sugar, as they can exacerbate glycemic control.<sup>[2]</sup>

Conventional medicated lozenges often contain sugars or artificial sweeteners to improve taste and palatability. However, for diabetic individuals, the consumption of such lozenges can lead to undesirable fluctuations in blood glucose levels. Therefore, there is a growing need for the development of sugarless medicated lozenges tailored specifically for diabetic patients.

The formulation of sugarless medicated lozenges presents a unique opportunity to address the therapeutic needs of diabetic individuals while ensuring compliance and convenience in medication administration.<sup>[3]</sup> By eliminating sugars and incorporating diabetic-friendly ingredients, these lozenges offer a safe and effective alternative for delivering medications orally.

The development of sugarless medicated lozenges involves careful consideration of several key factors, including the selection of suitable excipients, active pharmaceutical ingredients (APIs), and flavoring agents.<sup>[4]</sup> Excipients play a crucial role in the formulation by providing structural integrity, controlled release, and enhanced drug solubility. Common excipients used in sugarless lozenges include polyols (e.g., xylitol, sorbitol), cellulose derivatives, and natural gums.<sup>[5]</sup>

Millions of people worldwide suffer from diabetes mellitus, a chronic metabolic disorder marked by consistently elevated blood sugar levels. Diabetes is becoming more common as a result of factors like poor nutrition, sedentary lifestyles, and rising obesity rates.<sup>[6]</sup> Management of diabetes involves a multifaceted approach including medication, lifestyle modification, and strict dietary control to prevent complications like cardiovascular diseases, neuropathy, nephropathy, and retinopathy. Among dietary modifications, the restriction of sugar intake is crucial as it directly impacts blood glucose levels.<sup>[7]</sup> This presents a challenge in finding suitable alternatives for common sugar-containing products, including therapeutic lozenges used for throat relief and cough suppression.

### Benefits of Sugarless Lozenges

#### 1. Glycemic Control:

**Minimal Impact on Blood Sugar:** Sugarless lozenges do not contribute to blood glucose spikes, making them safe for diabetic patients.

**Use of Safe Sweeteners:** Alternative sweeteners such as xylitol, sorbitol, and stevia are used, which have a low glycemic index and do not significantly affect blood sugar levels.<sup>[8]</sup>

#### 2. Dental Health:

**Reduced Risk of Dental Caries:** Sugarless lozenges help in reducing the risk of tooth decay and cavities, which is a common problem associated with sugar-containing lozenges.<sup>[9]</sup>

**Use of Xylitol:** Xylitol, a common sweetener in sugarless lozenges, is known for its dental benefits, including reducing plaque formation and promoting remineralization of enamel.

### 3. Patient Compliance and Acceptance:

**Palatability:** Sugarless lozenges can be formulated to have a pleasant taste, encouraging patient adherence to the medication regimen.

**Convenience:** Lozenges are easy to carry and consume, enhancing patient compliance, especially among those with busy lifestyles or those who have difficulty swallowing pills.

### 4. Fewer Calories:

**Weight Management:** For diabetic patients, managing weight is crucial.<sup>[10]</sup> Sugarless lozenges offer fewer calories compared to their sugar-containing counterparts, aiding in weight management.

#### Advantages:

**Effective Relief from Cold and Cough:** The powerful combination of turmeric, pomegranate, and ginger eases the symptoms of a cold or cough.

**Natural Ingredients:** The lozenges contain a lot of "Phyto-actives," which are naturally occurring plant substances that are well-known for their health benefits.<sup>[11]</sup>

**Strengthens Immune System:** It is commonly recognized that the immune-stimulating properties of ginger, pomegranate, and turmeric contribute to the body's natural defences.

**Calming Effect:** The lozenges soothe the throat, lessening irritation and discomfort associated with coughing and colds.

**Sugar-free Formula:** Perfect for diabetics managing their blood sugar levels or cutting back on sugar.

**Clinically Tested:** Phyto relief-CC's effectiveness has been demonstrated by scientific trials.

#### Different shapes of moulds:

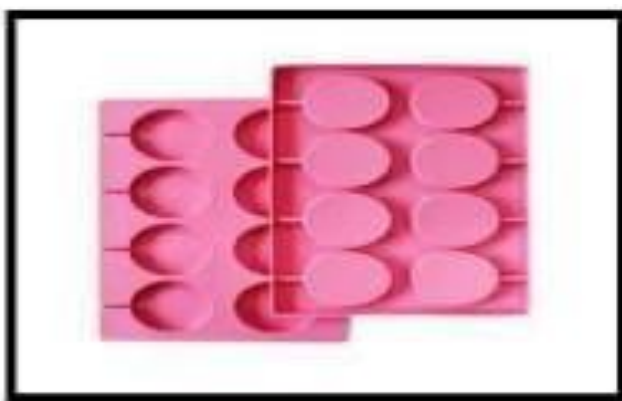


Figure No.1: Oval Shape

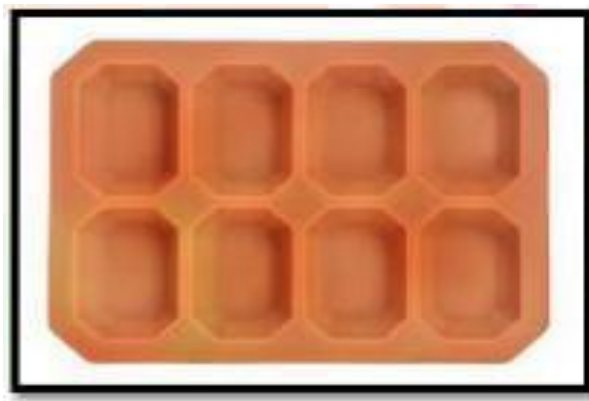


Figure No.2: Octagon Shape



Figure No.3: Square Shape



Figure No.4: Round Shape

**Formulation Profile:****1)Ginger:**

**Figure No. 5: Ginger**

Ginger, a widely used spice and medicinal plant, plays a significant role in various traditional and modern therapeutic practices.<sup>[12]</sup> Below is the scientific classification of ginger:

**Ginger Kingdom's classification according to science:**

**Class Plantae:** Angiosperms

**Group:** Monocots

**Family:** Zingiberaceae;

**Order:** Zingiberales Zingiber genus

**The Zingiber officinale species**

**Objective of Lozenges:**

**Inhibitory Effects:** Soothes Sore Throats: Because of its anti-inflammatory qualities, ginger helps relax and lessen throat irritation, making it a useful ingredient in lozenges that are meant to relieve sore throats.

**Antimicrobial Effects:** Fights Infections: Ginger has antimicrobial properties that can help combat bacterial and viral infections in the throat and respiratory tract.<sup>[13]</sup> This makes it a valuable component in lozenges aimed at treating colds and other respiratory infections.

**Antiemetic Effects:** Ginger has a well-known reputation for helping people feel less sick and nauseous. For people suffering from nausea from a variety of sources, such as chemotherapy or motion sickness, this characteristic is very helpful in lozenges.

**Pain Relief:** Alleviates Discomfort: Ginger can provide pain relief, helping to alleviate discomfort associated with sore throats and minor throat irritations.

**Improves Taste:** Enhances Palatability: The spicy and pleasant flavor of ginger can enhance the overall taste of the lozenges, making them more palatable, especially for patients who might be sensitive to the taste of other active ingredients.

**Digestive Aid:** Supports Digestion: Ginger aids digestion and can help manage digestive discomfort, which can be an added benefit for patients who might experience gastrointestinal issues.

**Anti-Oxidant Properties:** Protects Cells: The antioxidant properties of Ginger enhance overall health by shielding cells from harm from free radical's benefits.

## 2) Acacia Gum:



**Figure No. 6: Acacia gum**

Gum Arabic, another name for acacia gum, is a naturally occurring gum made from the hardened sap of several Acacia tree species.<sup>[15]</sup> The Acacia tree, which is often used to make acacia gum, is categorized scientifically as follows:

Classification of Acacia gum

**Kingdom according to science:** Plantae

**Angiosperm:** Clade

**Group:** Eudicots

**Group:** Rosids

**Place:** Fabales

**Fabaceae** family

**Class:** Acacia

Acacia senegal is one of the main species utilized.

**Purpose in Lozenges:**

**1. Binder:** Structural Integrity: Acacia gum acts as a binder, ensuring that the lozenge maintains its shape and structural integrity throughout its shelf life.<sup>[16]</sup> This is essential for maintaining the consistency and efficacy of the medication.

**2. Stabilizer:** Prevents Separation: In the lozenge formulation, acacia gum helps to stabilize the mixture, preventing the separation of ingredients. This ensures uniform distribution of the active pharmaceutical ingredients (APIs), such as ginger extract, and sweeteners.

**3. Emulsifier:** Enhances Texture and Mouthfeel: Acacia gum acts as an emulsifier, improving the texture and mouthfeel of the lozenges.<sup>[17]</sup> This enhances the palatability of the lozenges, making them more acceptable to patients, especially those who might be sensitive to the taste of certain APIs.

**4. Film-Forming Agent:** Controlled Release: Acacia gum forms a protective film around the APIs, which can help in the controlled release of the active ingredients. This ensures a sustained therapeutic effect, providing longer-lasting relief from symptoms.<sup>[18]</sup>

**5. Soluble Dietary Fiber:** Health Benefits: As a source of soluble dietary fiber, acacia gum contributes to the overall health benefits of the lozenges. It can improve gut health and aid digestion, which is particularly beneficial for diabetic patients who need to manage their dietary fiber intake.

### 6. Non-Glycemic:

Safe for Diabetics: Acacia gum does not contribute to blood sugar elevation, making it an ideal ingredient for sugarless lozenges.<sup>[20]</sup> Its inclusion helps ensure that the lozenges are safe for consumption by diabetic patients.

for consumption by diabetic patients.

### 3) Guar Gum:



**Figure No. 7: Guar gum**

Guar gum is derived from the seeds of the guar plant. Below is the scientific classification of the guar plant:

#### Scientific Classification of Guar Gum

**Kingdom:** Plantae

**Clade:** Angiosperms

**Clade:** Eudicots

**Order:** Fabales

**Family:** Fabaceae

**Genus:** Cyamopsis

**Species:** Cyamopsis tetragonoloba

#### Purpose in Lozenges:

**1. Thickening Agent:** Enhances Texture: Guar gum acts as a thickening agent, improving the texture and consistency of the lozenges.<sup>[21]</sup> This ensures that the lozenges dissolve slowly and evenly in the mouth, providing sustained release of the active ingredients.

**2. Stabilizer:** Prevents Ingredient Separation: Guar gum helps stabilize the formulation by preventing the separation of ingredients. This ensures uniform distribution of the APIs and sweeteners throughout the lozenge, maintaining its efficacy and consistency.

#### 3. Emulsifier:

**Improves Mouthfeel:** As an emulsifier, guar gum contributes to a smooth and pleasant mouthfeel, making the lozenges more palatable. This is particularly important for ensuring patient compliance, especially among those sensitive to the taste of certain APIs.

#### 4. Soluble Dietary Fiber

**Benefits to Health:** Guar gum contains soluble dietary fiber, which helps balance digestion and enhance gut health.<sup>[22]</sup>



For diabetic patients, who frequently need to carefully limit their fiber intake to maintain a healthy digestive system and glycemic management, this is an additional benefit.

### 5. non-Glycemic

Safe for Diabetics: Guar gum does not contribute to blood sugar spikes, making it a safe ingredient for diabetic patients.<sup>[23]</sup> Its inclusion in the lozenge formulation ensures that the product remains diabetic-friendly.

### Methodology/Experimental Work:

Making hard candies without added sugar lozenges to make hard lozenges without sugar, open fire frying was also used. The following substances were used to manufacture the samples in accordance with the mixture design: First, heat causes guar gum and Acacia to dissolve in water. Xylitol, gymnemic acid, cinnamon oil, giloy extract, and menthol are combined in a separate beaker. Once the temperature of the dissolved in water reached 170 °C, the mixture was cooled and glycerol and preservative were added. The bulk was mixed with menthol, giloy extract, cinnamon oil, and gymnemic acid at a temperature of 112-155 °C. The finished liquid was then transferred into silicone molds and allowed to cool for five minutes at 20 °C. After being taken out of the molds, the solid lozenges were placed in aluminum bags and kept cold.

### Formulation Table:

Sr. No.	Ingredients	Quantity
1	Ginger	5 gm
2	Cinnamon Oil	3-4 drops
3	Glloy Extract	0.5 gm
4	Menthol	3-4 drops
5	Acacia	2 gm
6	Guar Gum	2 gm
7	Glycerol	70 ml
8	Paraben Methyl	0.4 gm
9	Paraben Propyl	0.2 gm
10	Water	Q. S

**Table No.1: Formulation**

### Evaluation Tests:

#### Physical Evaluation:

**Appearance:** Assess the appearance of the lozenges for color, shape, and surface smoothness.

**Texture:** Evaluate the texture of the lozenges for hardness, friability, and mouthfeel.

**Hardness:** The hardness of the lozenges is determined using a Pfizer or Monsanto hardness tester. [Lozenges' resistance to breaking or shipping under storage, transit, and handling conditions before usage is determined by their hardness]



**Figure No. 8: Hardness**

**Weight Uniformity Test:**

**Objective:** Ensure uniformity in the weight of individual lozenges.

**Procedure:** Weigh a specified number of randomly selected lozenges and calculate the average weight. Compare individual weights to the average and determine if they fall within acceptable limits.

**Drug Content Uniformity:**

**Objective:** Verify consistency in the content of active pharmaceutical ingredients (APIs) within individual lozenges.

**Procedure:** Analyze the content of APIs in a sample of lozenges using validated analytical methods such as high-performance liquid chromatography (HPLC) or spectrophotometry. Compare the results to specified acceptance criteria.

**Disintegration Test:**

**Objective:** Determine the time taken for the lozenges to disintegrate in simulated saliva.

**Procedure:** Place a lozenge in a disintegration apparatus filled with simulated saliva at 37°C. Record the time taken for complete disintegration of the lozenge.

**Dissolution Test:**

**Objective:** Assess the release profile of APIs from the lozenges over time.

**Procedure:** Conduct dissolution studies using a suitable dissolution apparatus and media. Analyze samples at specified time intervals to quantify the amount of APIs released.





**Figure No. 9: Dissolution Test**

### **Taste Evaluation:**

**Objective:** Evaluate the taste and palatability of the lozenges.

**Procedure:** Administer the lozenges to a panel of volunteers and collect feedback on taste, flavor, and overall acceptability using a structured questionnaire or hedonic scale.

### **Stability Testing:**

**Objective:** Determine the stability of the lozenges under various storage conditions.

**Procedure:** Samples of the lozenges should be kept in an environment that promotes both long-term and rapid stability. Stability should be evaluated over time by periodically analyzing physical characteristics, medication content, and performance metrics.

## **RESULT**

Formulating sugarless medicated lozenges for diabetic patients involves using alternative sweeteners like xylitol, sorbitol, or stevia to maintain sweetness without affecting blood sugar levels. The active pharmaceutical ingredient (API) is incorporated into a base mixture of these sweeteners, along with binders, flavoring agents, and stabilizers.

## **DISCUSSION**

Diabetes Mellitus is a chronic disease caused by high blood sugar, necessitating stringent dietary management to prevent hyperglycemia and its associated complications. One of the challenges diabetic patients faces is the limited availability of sugar-free alternatives for common confectionery items, including lozenges. Lozenges are often used for throat relief, cough suppression, and delivering active pharmaceutical ingredients. Traditional lozenges, however, are typically made with sucrose or other sugars, making them unsuitable for diabetic patients. This study focuses on the formulation and evaluation of sugarless lozenges specifically designed for diabetic individuals.

The primary aim of this research is to create a sugarless lozenge that not only caters to the dietary restrictions of diabetic patients but also maintains the efficacy and sensory qualities of conventional lozenges. The formulation replaces sucrose with non-glycemic sweeteners such as stevia, xylitol, and erythritol, which do not elevate blood sugar levels. These sugar alcohols and natural sweeteners are selected for their low caloric content and minimal impact on blood glucose. Additionally, their properties contribute to the desired texture and mouthfeel of the lozenge. The formulation process involves several key steps: selecting appropriate sweeteners and active ingredients, determining the optimal ratios, and conducting trials to achieve the desired balance of sweetness, efficacy, and stability.

## CONCLUSION

The formulation of sugarless lozenges for diabetic patients is a promising development in diabetic-friendly products. By addressing the need for low-glycemic, low-calorie alternatives to traditional lozenges, this study provides a viable solution that aligns with the dietary requirements and health goals of diabetic individuals. The successful integration of non-glycemic sweeteners and therapeutic ingredients ensures that these lozenges are not only safe and effective but also enjoyable for diabetic patients. This breakthrough marks a substantial advancement in the variety of diabetic-friendly confectionery goods accessible, ultimately improving the quality of life and health outcomes for those with diabetes.

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