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FORMULATION AND PRELIMINARY EVALUATION OF CAFFEINE LOZENGES PREPARED USING A SILICON MOLD

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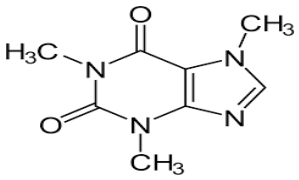
ABSTRACT

Caffeine is a widely consumed beverage containing caffeine, which is known for its stimulating effects. The present work aimed to formulate Caffeine lozenges for oral delivery. The formulation was prepared using Caffeine along with suitable excipients such as sweetening agents, binders, and flavoring agents. The ingredients were mixed and processed to obtain lozenges of uniform shape by using silicon mold with pre greased and appearance. The prepared lozenges provide a convenient dosage form for Caffeine consumption. The study demonstrates the successful formulation of Caffeine lozenges and their potential use as an oral dosage form.



1. INTRODUCTION

Caffeine is one of the most widely consumed psychoactive substances in the world and is naturally present in coffee beans, tea, cocoa, and various energy beverages. It acts as a central nervous system stimulant and is commonly used to improve alertness, concentration, and mental performance while reducing fatigue and drowsiness.

Lozenges are solid oral dosage forms designed to dissolve slowly in the mouth, allowing the active ingredient to be released gradually. They are convenient, portable, easy to administer, and do not require water for consumption. Due to these advantages, lozenges have gained considerable attention as an alternative oral delivery system for various active ingredients.

The formulation of caffeine into a lozenge dosage form offers a novel and convenient method of caffeine administration. Such a dosage form may provide ease of use and improved patient acceptability compared to conventional caffeine-containing products. The present work focuses on the formulation of caffeine lozenges using suitable excipients to develop an effective oral dosage form.

- Overview of lozenges as oral dosage forms intended to dissolve slowly in the mouth for local or systemic delivery.
- Advantages of lozenges, including improved palatability, convenience, prolonged residence time in the oral cavity, and potential to bypass some first-pass effects.
- Importance of formulation variables such as sweeteners, binders, flavoring agents, and manufacturing methods in determining performance.
- Justification for using coffee or coffee extract as a functional ingredient, including caffeine content, sensory appeal, and possible consumer acceptance.
- Statement of the research problem: limited formulation-focused work specifically on Caffeine lozenges for oral administration.
- Study aim and objectives.
- Research hypothesis or expected outcome.

2. Biological Activity

Caffeine exhibits several biological activities primarily due to its action as a central nervous system stimulant. It acts by blocking adenosine receptors, thereby increasing alertness, reducing fatigue, and enhancing mental concentration. Caffeine also stimulates cardiac muscle activity, increases metabolic rate, and promotes mild bronchodilation. Additionally, it possesses diuretic properties and can enhance physical performance by increasing energy availability and reducing perceived exertion. Owing to these pharmacological effects, caffeine is widely utilized in beverages, pharmaceutical formulations, and nutraceutical products.

3. Literature Review

- Classification and types of lozenges: compressed, molded, and hard candy lozenges.
- Common excipients used in lozenge formulation, including diluents, binders, sweeteners, lubricants, and flavors.
- Manufacturing methods and their implications for stability, texture, and dissolution behavior.
- Quality control parameters for lozenges: hardness, friability, weight variation, content uniformity, dissolution, and stability.
- Pharmacological and sensory properties of caffeine are relevant to oral dosage formulation.
- Previous research on lozenges and related oral solid dosage forms.
- Knowledge gap addressed by the present study.

4. MATERIALS AND METHODS

- Materials

❖ Anhydrous caffeine, sucrose, citric acid, liquid glucose as binder and water

- Pre-formulation studies.
- Organoleptic properties of caffeine material
- Compatibility assessment between caffeine material and excipients
- Formulation design.
  - Selection of lozenge base
  - Development of multiple trial formulations with varying binder, sweetener, and flavor concentrations
  - Choice of manufacturing method is molding using silicon moulding.

5. Formulation for 10 lozenges

Ingredient	Function	Quantity
Caffeine Anhydrous	Active ingredient	500mg
Sucrose	Base/Sweetener	15g
Liquid Glucose	Binding agent and texture modifier	3g
Citric Acid	Taste enhancer	200mg

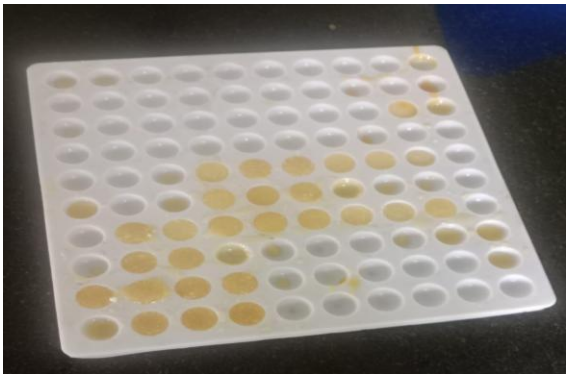
6. Procedure

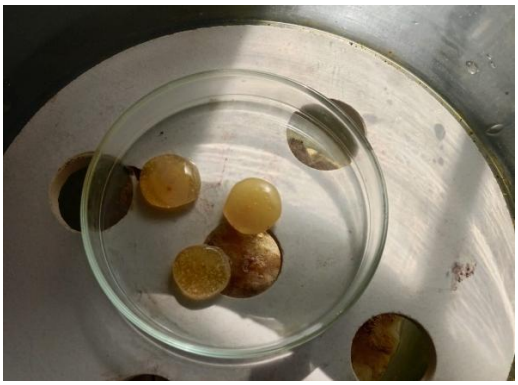
Preparation of Caffeine Lozenges

1. All ingredients were accurately weighed according to the required formulation.
2. Sucrose and purified water were heated (140 degree) with continuous stirring until a clear syrup was obtained. Add drop of a clear mixture solution into beaker fill with water to

check the hard crack of the solution sugar mixture. This checking is called hard crack stage check.

3. Liquid glucose was added to the syrup and mixed thoroughly to obtain a uniform base.
4. The syrup was allowed to cool slightly from 140 degree to 110 degree to prevent degradation of the active ingredient (anhydrous caffeine)
5. Caffeine was added gradually to the syrup with continuous stirring to ensure uniform distribution throughout the formulation.
6. Citric acid, flavoring agents, and excipients were incorporated into the mixture and mixed thoroughly.
7. The prepared mass was poured into pre-lubricated lozenge silicon molds of suitable size and shape.
8. The molds were allowed to cool at room temperature until complete solidification of the lozenges occurred.
9. Then place it in desiccator for airtight condition wait for solidification





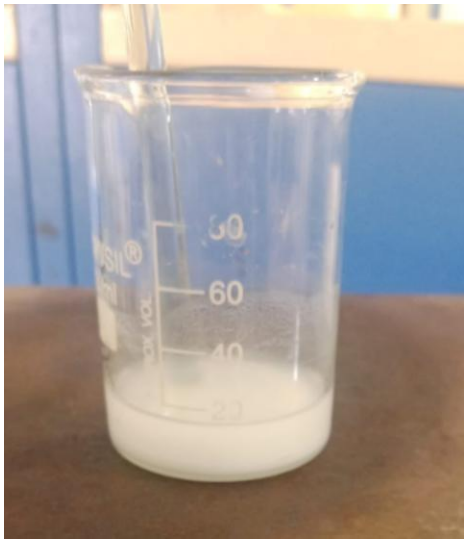
7. Liquid Glucose Preparation.

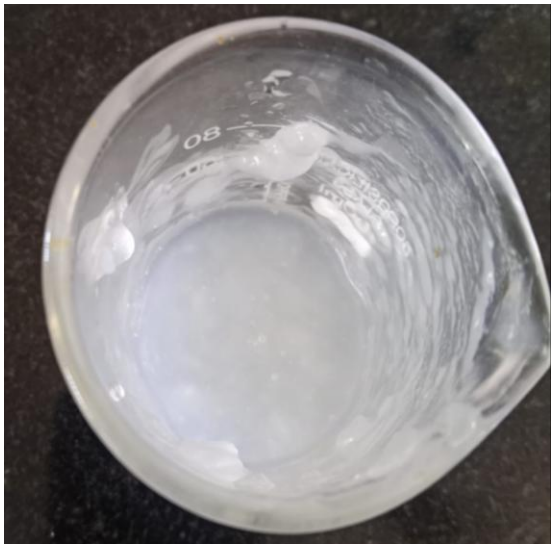
Preparation of Liquid Glucose

1. Corn starch was dispersed in purified water to form a uniform slurry.
2. The slurry was heated with continuous stirring to achieve complete gelatinization of the starch.
3. A suitable quantity of diluted acid was added to hydrolyze the starch into glucose syrup.
4. The mixture was heated for the required period until hydrolysis was completed.
5. The hydrolyzed solution was cooled and neutralized carefully.
6. The solution was filtered to remove any insoluble impurities.
7. The filtrate was concentrated by gentle heating until a viscous syrup consistency was

obtained.

8. The prepared liquid glucose was allowed to cool and stored in a well-closed container until further use in the formulation of caffeine lozenges.





8. Evaluation Test

➢ Organoleptic Test

Organoleptic Evaluation of Caffeine Lozenges

The prepared caffeine lozenges were evaluated for their organoleptic characteristics by visual inspection and sensory observation.

Parameter	**Observation**
Color	Light brown to brown
Appearance	Smooth and uniform
Shape	Round
Odor	Characteristic coffee aroma
Taste	Sweet with slight bitterness of caffeine
Texture	Hard and smooth
Mouthfeel	Pleasant and slowly dissolving

- **RESULT**

The formulated caffeine lozenges exhibited acceptable organoleptic properties with a uniform appearance, characteristic aroma, pleasant taste, and satisfactory texture, indicating suitability as an oral dosage form.

➢ Weight variation

Weight Variation Test

- **Procedure**

Ten caffeine lozenges were selected randomly and individually weighed using a calibrated digital balance. The average weight of the lozenges was calculated. The weight of each lozenge was then compared with the average weight to determine any variation.

- **Observation Table**

Lozenges No	Weight of lozenges
1	1.52
2	1.55
3	1.50
4	1.54
5	1.50
6	1.53
7	1.52
8	1.53
9	1.53
10	1.51

TOTAL WEIGHT: 15.30g AVERAGE WEIGHT: **15.30%10=1.53g** ACCEPTANCE CRITERIA.

SINCE LOZENGES WEIGH MORE THAN **324mg**

LIMIT±

UPPER LIMIT ±

1.53+ (1.53X5/100) =1.61g LOWER LIMIT±

1.53- (1.53X5/100) =1.45g

ALL LOZENGES SHOULD FALL BETWEEN:

1.45-1.61g

- **Result**

The average weight of caffeine lozenges was found to be 1.53g. All the lozenges were within the pharmacopeial limit of ±5%. Therefore, the formulation passed the weight variation test.

➢ **Stability Test**

The prepared caffeine lozenges were stored in an airtight container at room temperature for a period of one week. The formulation was evaluated periodically for changes in appearance, color, odor, texture and physical integrity. No significant changes were observed during the storage period. The lozenges remained hard, non-sticky and retained their original appearance. Hence, the formulation was found to be physically stable for one week under airtight storage conditions.

- **Result**

The prepared caffeine lozenges showed satisfactory physical stability for one week under airtight storage conditions.

➢ Theoretically absorbed amount of bioavailability:

❖ Since caffeine has high oral bioavailability from 90 to 100 rate percentage

❖ 95% is a commonly cited approximate value

- **Formula**

Absorbed amount= dose x bioavailability/100 Example: dose is 50mg per lozenge 50x95/100=47.5mg

- **Result**

SO ABOUT 47.5mg IS EXPECTED TO BE ABSORBED.

9. DISCUSSION

- Interpretation of how excipient composition affected the quality of lozenges.
- Influence of manufacturing methods on texture, hardness, and release characteristics.
- Role of Caffeine material in taste, color, stability, and content uniformity.
- Comparison with previous lozenge formulation studies.

- Practical implications for oral administration and product acceptability.
- Study limitations and recommendations for further optimization.

10. CONCLUSION

- Summary of whether caffeine lozenges were successfully formulated for oral administration.
- Statement on the optimized formulation and its key properties
- Implications for future product development and research

11. Back Matter

- Keywords: Caffeine lozenges, oral administration, formulation, evaluation, caffeine, excipients, dissolution.

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- **Conflict of interest statement**

The authors declare no conflict of interest.

- **Funding statement**

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This formulation studies showing that lozenges can be prepared by molding and are commonly evaluated using hardness, friability, weight variation, dissolution, stability, and sensory testing. Recent examples also indicate that coffee beans-derived materials can be incorporated into mold lozenges, supporting the feasibility of a caffeine lozenges formulation study for oral administration and its bio availability.