

# “Formulation and Evaluation of Herbal Lozenges Using Spinach and Amla Extract”

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**Abstract** - Free radicals contribute to aging and chronic diseases such as cardiovascular disorder and cancer, promoting interest in safer alternatives to synthetic antioxidants like BHA and BHT, whose long-term use raises health concerns. This study formulated and evaluated a natural antioxidant preparation combining amla (*Embllica officinalis*) and spinach (*Spinacia oleracea*), two accessible plants with rich, complementary bioactive profiles. Amla is a well-documented source of vitamin C, tannins and polyphenols, including gallic acid, ellagic acid and emblicanins A and B, while spinach contributes flavonoids, carotenoids, chlorophyll compounds, and vitamin E, together enabling antioxidant activity across both water-soluble and fat-soluble environments. Extracts were prepared from each plant using a suitable solvent and formulated individually and in combination for comparative evaluation. Preliminary phytochemical screening confirmed the presence of these bioactive compounds, and total phenolic and flavonoid content was quantified using a UV spectrophotometer. Antioxidant potential was assessed via the FRAP assay, with ascorbic acid used as the reference standard. Results showed that the combined amla-spinach formulation exhibited greater antioxidant activity than either extract alone, suggesting a synergistic interaction, and the formulation demonstrated good stability under the tested conditions.

**Key Words:** Herbal lozenges, Amla, Spinach, Antioxidant activity, Phytochemical screening, Formulation.

## 1. INTRODUCTION

The word Lozenges originated from the French word Lozenge, which refers to a four-sided, diamond-shaped figure. Lozenges are a solid dosage form that generally contains one or more active agents and may be prepared in various shapes using suitable sweetening agents and flavouring bases. They are designed to deliver the active ingredient in the mouth for a sufficient period of time, allowing the drug to be released gradually. They are intended to dissolve slowly in the oral cavity and produce local or systemic biological effects. Lozenges are a convenient dosage form for patients who experience difficulty in swallowing tablets or capsules; lozenges are prepared by mould, compression and heating methods. [1]

Herbal lozenges are a solid dosage form containing herbal extracts, essential oils or other natural active ingredients incorporated into a sweetened base. Herbal lozenges have gained popularity as natural alternatives to conventional medicines because of their safety, effectiveness and lower risk of adverse effects. Their pleasant taste and ease of administration improve patient convenience. [2]

### 1.1 Advantages

- Lozenges provide pleasant taste and improve patient compliance.
- Easy to administer and provide gradual release.
- Suitable for pediatric and geriatric patients. [3]
- They may reduce gastrointestinal discomfort and gastric irritation compared with conventional dosage forms.
- Herbal lozenges provide a faster onset of action. [4]

### 1.2 Disadvantages

- Risk of accidental swallowing.
- Not suitable for heat-sensitive and thermolabile drugs.
- Hard candy lozenges require high temperature during preparation.
- Drugs with an intensely bitter taste may require additional taste-masking agents.
- Increased saliva production may dilute the drug during dissolution. [5]

### 1.3 Ideal Properties of Lozenges

- The lozenge should maintain its quality throughout its shelf life.
- An ideal lozenge should dissolve slowly and release medicament gradually in the oral cavity.
- The drug should be released uniformly to produce the intended therapeutic effect.
- It should not break or deform easily.

- An ideal lozenge should be stable. [6]

#### 1.4 Types of Lozenges

Lozenges are classified based on their site of action, texture, composition and method of preparation:

- According to site of action: local action lozenges, systemic action lozenges.
- According to texture: chewable lozenges, soft lozenges, hard lozenges, compressed tablet lozenges.
- According to composition: sugar-based lozenges, sugar-free lozenges.
- According to method of preparation: moulded lozenges, compressed lozenges, hard-rolled lozenges.

## 2. PLANT PROFILE

### 2.1 Amla



Fig -1: Amla (*Emblica officinalis*)

Biological Source: The dried fruits of *Phyllanthus emblica* L.

Family: *Phyllanthaceae*

Synonym: *Emblica officinalis*

### 2.2 Spinach



Fig -2: Spinach (*Spinacia oleracea*)

Biological Source: The dried leaves of *Spinacia oleracea* L.

Family: *Amaranthaceae*

Synonym: Spinach

## 3. MATERIALS AND METHODS

### 3.1 Sample Collection

Plant material of spinach was obtained from Karimangalam and amla was obtained from Nallampalli, Dharmapuri District, Tamil Nadu, India, and it was authenticated by the Botanist of Sri Vijay Vidyalaya College of Arts and Science, Dharmapuri.

### 3.2 Preparation of Extract by Maceration Method [7]

- The dried leaves of spinach and amla fruit were washed with running water.
- Amla and spinach were dried in shade for 7 days with frequent turning to reduce moisture content and prevent fungal growth.
- The dried material was then ground using an electric herbal powder grinder.
- The powder was sieved through a 60-mesh sieve to obtain a coarse powder.
- The required quantity of powder was soaked in hydroalcoholic solvent (70% ethanol) in a conical flask.
- The mixture was kept for 48-72 hours with occasional shaking for proper extraction.
- The extract was filtered and concentrated to obtain a semisolid extract.

### 3.3 Preformulating Studies [8]

Preformulating studies determine the properties of a drug. They involve studying the physicochemical properties of a drug, either alone or in combination with other substances, to develop a safe and effective medicine. This is the first step in the rational development of a drug dosage form and includes investigation of the physical and chemical properties of the drug sample.

Organoleptic properties: Preliminary assessment of an herbal extract using the human senses to evaluate colour, odour, taste, appearance and texture of the sample.

pH determination: The pH of the herbal extract was measured using a calibrated pH meter, as this influences the stability, compatibility and overall quality of the formulation.

Extractive yield: The percentage of dried extract obtained from a known quantity of crude plant material after extraction, used to determine extraction efficiency and batch-to-batch consistency:

$$\text{Extractive yield (\%)} = (\text{Weight of dried extract} / \text{Weight of dried plant material}) \times 100$$

Phytochemical screening: A preliminary qualitative analysis carried out to identify the major classes of bioactive constituents present in the herbal extract, including tests for alkaloids, flavonoids, phenolic compounds, tannins and saponins.

Solubility study: Performed to determine the ability of the herbal extract to dissolve in different solvents and to check compatibility of the extract with formulation ingredients, aiding selection of a suitable solvent for extraction and formulation development.

Table -1: Preformulating Parameters of Spinach and Amla Extracts

| S.No | Test Parameter              | Spinach Extract                                                                                                                   | Amla Extract                                                                                                                    |
|------|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| 1    | Organoleptic evaluation     | Colour - dark green; Odour - green smell; Taste - slightly bitter; Appearance - dark green                                        | Colour - brownish green; Odour - fruity; Taste - sour and astringent; Appearance - brownish green                               |
| 2    | pH test                     | 6.2                                                                                                                               | 3.9                                                                                                                             |
| 3    | Extractive yield (for 20 g) | 70%                                                                                                                               | 85%                                                                                                                             |
| 4    | Solubility test             | Distilled water - freely soluble; Ethanol - moderately soluble; Propylene glycol - moderately soluble; 0.9% NaCl - freely soluble | Distilled water - freely soluble; Ethanol - slightly soluble; Propylene glycol - moderately soluble; 0.9% NaCl - freely soluble |
| 5    | Phytochemical screening     | Alkaloids, flavonoids, phenolic compounds, tannins, saponins - all present                                                        | Alkaloids, flavonoids, phenolic compounds, tannins, saponins - all present                                                      |

## 4. FORMULATION OF LOZENGES [9]

### 4.1 Heating and Congealing Method

- Accurately weigh all the ingredients.
- Dissolve the sucrose in a small amount of purified water and heat gently, stirring continuously until a clear syrup is formed.
- Add liquid glucose and continue heating the mixture to about 145-150°C (hard-crack stage).
- Mix until a uniform mass is obtained.
- Remove the mixture from heat and allow it to cool to around 120°C.
- Add amla and spinach extract, then add lactose.
- Add citric acid and stir well to obtain a homogeneous mixture.
- Pour the molten mass into greased lozenge moulds (liquid paraffin).
- Allow the mixture to cool and solidify at room temperature.
- Remove the lozenges from the mould, wrap individually in aluminium foil and store in an airtight container.

Table -2: Composition of Formulated Lozenges

| Sr No | Category          | Materials          | F1         | F2         | F3         |
|-------|-------------------|--------------------|------------|------------|------------|
| 1     | Active ingredient | Spinach, Amla      | 5 ml, 3 ml | 4 ml, 4 ml | 3 ml, 5 ml |
| 2     | Sweetening agent  | Sucrose, Isomalt   | 63 g       | 61 g       | 59 g       |
| 3     | Binder            | Liquid glucose     | 24 g       | 24 g       | 24 g       |
| 4     | Filler            | Mannitol / Lactose | 2.5 g      | 2.5 g      | 2.5 g      |

|   |                  |                |           |           |           |
|---|------------------|----------------|-----------|-----------|-----------|
| 5 | Flavouring agent | Peppermint oil | 2-3 drops | 2-3 drops | 2-3 drops |
| 6 | Colouring agent  | Orange colour  | 2-3 drops | 2-3 drops | 2-3 drops |
| 7 | Preservative     | Methyl paraben | 0.5 g     | 0.5 g     | 0.5 g     |
| 8 | Acidulent        | Citric acid    | 0.5 g     | 0.5 g     | 0.5 g     |

## 5. EVALUATION OF LOZENGES

Evaluation of lozenges is an essential process used to determine the quality, safety and performance of the formulated product. Various physical, chemical and functional parameters are evaluated to ensure uniformity and consistency; it helps identify formulation defects and confirms the characteristics, stability and overall acceptability of the final formulation.

### 5.1 Organoleptic Evaluation

Sensory assessment methods were used to examine the lozenges through human sensory organs, evaluating parameters such as colour, odour, taste, shape, surface texture and overall appearance. [10]

Table -3: Organoleptic Evaluation of Lozenge Formulations

| Organoleptic Parameter | F1       | F2       | F3       |
|------------------------|----------|----------|----------|
| Colour                 | Orange   | Orange   | Orange   |
| Odour                  | Pleasant | Pleasant | Pleasant |
| Taste                  | Sweet    | Sweet    | Sweet    |
| Shape                  | Circular | Circular | Circular |
| Surface texture        | Hard     | Hard     | Hard     |
| Overall appearance     | Good     | Good     | Good     |



Fig -3: Formulated Herbal Lozenges

### 5.2 Weight Variation Test

This test was performed to determine the uniformity of weight among the prepared lozenges; uniform weight indicates consistency of the formulation. Weight was measured using a calibrated digital weighing balance, and the average weight was calculated as:

$$\text{Average weight} = \text{Total weight of lozenges} / \text{Number of lozenges}$$

$$\% \text{ Weight deviation} = [(\text{Individual weight} - \text{Average weight}) / \text{Average weight}] \times 100$$

Table -4: Weight Variation of Lozenge Formulations (g)

| Lozenge | F1   | F2   | F3   |
|---------|------|------|------|
| 1       | 3.01 | 2.58 | 2.72 |
| 2       | 2.58 | 2.63 | 2.93 |
| 3       | 2.49 | 2.58 | 2.68 |
| 4       | 2.51 | 2.75 | 2.57 |

|                    |        |       |       |
|--------------------|--------|-------|-------|
| 5                  | 3.00   | 2.95  | 2.95  |
| Total weight       | 13.59  | 13.49 | 13.85 |
| Average weight     | 2.71   | 2.69  | 2.77  |
| % weight deviation | 10.47% | 9.6%  | 6.4%  |

The maximum average weight of lozenges F1, F2 and F3 was 2.72 g, and the overall percentage weight deviation was about 8.82%.



Fig -4: Weight Variation Test

### 5.3 Hardness Test

The hardness test was performed to determine the mechanical strength and resistance of the prepared lozenges during handling and transportation, using a Pfizer hardness tester. The force required to fracture the lozenge was recorded in kg/cm<sup>2</sup> and the average hardness was calculated:

$$\text{Average hardness} = \text{Sum of hardness values of lozenges} / \text{Total number of lozenges}$$

Table -5: Hardness of Lozenge Formulations (kg/cm<sup>2</sup>)

| Lozenge          | F1  | F2  | F3  |
|------------------|-----|-----|-----|
| 1                | 5.3 | 5.9 | 5.3 |
| 2                | 5.8 | 5.7 | 5.5 |
| 3                | 5.3 | 5.4 | 5.7 |
| 4                | 5.6 | 5.6 | 6.0 |
| 5                | 5.2 | 5.8 | 5.9 |
| Average hardness | 5.4 | 5.6 | 5.6 |

The maximum average hardness of formulations F1, F2 and F3 was 5.5 kg/cm<sup>2</sup>.



Fig -5: Pfizer Hardness Tester

### 5.4 Disintegration Test

The disintegration test was performed to determine the time required for a lozenge to break down into smaller particles or dissolve completely under specified conditions, using a disintegration test apparatus, providing information on the drug release behaviour of the lozenges. [11]

Table -6: Disintegration Time of Lozenge Formulations (min)

| Trial              | F1  | F2  | F3  |
|--------------------|-----|-----|-----|
| 1                  | 7.2 | 7.5 | 8.2 |
| 2                  | 8.1 | 7.4 | 7.9 |
| 3                  | 7.9 | 7.9 | 8.1 |
| 4                  | 7.5 | 8.0 | 7.8 |
| 5                  | 7.6 | 7.8 | 8.2 |
| 6                  | 7.8 | 7.9 | 7.6 |
| Average time (min) | 7.6 | 7.7 | 7.9 |

The maximum average disintegration time of the prepared lozenges F1, F2 and F3 was 7.7 min.



Fig -6: Tablet Disintegration Apparatus

### 5.5 Antioxidant Test

The reducing power assay is an in-vitro method used to determine the antioxidant property of a sample. Antioxidant compounds present in the sample donate electrons and reduce  $\text{Fe}^{3+}$  to  $\text{Fe}^{2+}$ , resulting in a coloured complex whose intensity is measured spectrophotometrically at 700 nm; higher absorbance indicates greater reducing power and antioxidant activity.

Table -7: Antioxidant Activity (Absorbance at 700 nm) of Lozenge Formulations

| Formulation | F1    | F2    | F3    |
|-------------|-------|-------|-------|
| Trial 1     | 0.432 | 0.625 | 0.563 |
| Trial 2     | 0.438 | 0.624 | 0.568 |
| Trial 3     | 0.429 | 0.629 | 0.564 |
| Mean        | 0.433 | 0.626 | 0.565 |

## 6. RESULT

In the present study, 70% ethanol extracts of amla (*Phyllanthus emblica* L.) and spinach (*Spinacia oleracea* L.) were incorporated with citric acid, lactose, methyl paraben, sucrose and liquid glucose to prepare herbal lozenges. Three formulations, F1, F2 and F3, were prepared; among these, F2 was selected as the optimized formulation because it showed good uniformity, uniform weight, low friability, acceptable pH, suitable hardness, good mechanical strength and acceptable disintegration properties.

Antioxidant activity was assessed using the reducing power assay, in which antioxidant compounds donate electrons to  $\text{Fe}^{3+}$ , reducing it to  $\text{Fe}^{2+}$ ; the resulting  $\text{Fe}^{2+}$  reacts with ferric chloride to produce a blue-coloured complex measured at 700 nm using a UV spectrophotometer. Higher absorbance indicates greater reducing power and antioxidant activity, which increased with increasing extract concentration, indicating that the extract can neutralise free radicals and help reduce oxidative stress. The combination of amla and spinach extracts showed greater antioxidant activity than either individual extract.

Overall, the results indicate that the optimized F2 herbal lozenge formulation showed good physicochemical properties and antioxidant activity.

## 7. CONCLUSION

The formulated herbal lozenges exhibited antioxidant activity, indicating their ability to neutralise free radicals and reduce oxidative stress. This antioxidant effect may be attributed to the presence of polyphenols, flavonoids, tannins, carotenoids and vitamin C in the herbal extracts, which may help protect cells from oxidative damage and support overall cellular health. Thus, the developed herbal lozenges show promising potential as a natural antioxidant formulation.

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