

FORMULATION OF HERBAL EFFERVESCENT TABLET OF MOUTHWASH

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Abstract:

The development of herbal effervescent tablets as a mouthwash represents an innovative approach to oral hygiene by combining natural plant-based actives with convenient dosage form technology. In this study, herbal extracts possessing antimicrobial, anti-inflammatory, and deodorizing properties were selected and formulated into effervescent tablets intended for oral rinsing. The formulation primarily includes herbal ingredients such as neem, clove, peppermint, and tulsi, along with effervescent agents like citric acid and sodium bicarbonate to ensure rapid disintegration in water and release of active compounds. Sweeteners and flavoring agents are incorporated to improve palatability and patient compliance. The prepared tablets were evaluated for physicochemical parameters including hardness, friability, effervescence time, pH, and uniformity of weight. The results indicated that the formulation produces a stable, fast-dissolving solution with effective cleansing and refreshing properties. This herbal effervescent mouthwash tablet offers a convenient, eco-friendly, and alcohol-free alternative to conventional liquid mouthwashes, with potential benefits in reducing microbial load and improving overall oral health.

Keywords:

Herbal formulation, effervescent tablets, mouthwash, oral hygiene, neem, clove, peppermint, natural antimicrobial agents, tablet formulation, herbal dentistry.

Introduction:

Maintaining good oral hygiene is essential for preventing dental problems such as tooth decay, gum infections, bad breath, and other periodontal conditions. Many commercially available mouthwashes contain alcohol and synthetic chemicals, which may lead to side effects like oral dryness, irritation, and disturbance of the natural oral microbiota when used frequently. These limitations have encouraged the search for safer and more natural oral care products. Herbal-based formulations have gained significant attention due to their long history of use in traditional medicine and their proven antimicrobial, anti-inflammatory, and antioxidant activities. Medicinal plants such as neem, clove, tulsi, and peppermint are commonly used in oral care preparations because they help reduce bacterial growth, control plaque formation, and provide a refreshing effect in the oral cavity.[1]

Effervescent tablet technology offers a modern and convenient dosage form that rapidly dissolves in water with the release of carbon dioxide, producing a palatable solution for use as a mouthwash. This system enhances stability, ease of transport, and user compliance compared to conventional liquid formulations. The aim of formulating herbal effervescent mouthwash tablets is to combine the therapeutic potential of natural plant extracts with effervescent drug delivery technology. This approach provides an alcohol-free, user-friendly, and effective alternative for maintaining oral hygiene and supporting overall dental health.[2]

Rationale:

- Oral diseases such as dental caries, gingivitis, periodontitis, and halitosis are highly prevalent and require effective preventive care.
- Conventional mouthwashes often contain alcohol and synthetic chemicals that may cause side effects like irritation, dryness, and altered taste sensation.
- Long-term use of chemical mouthwashes can disturb the normal oral microbial balance.
- There is increasing demand for safe, natural, and alcohol-free oral care products.
- Herbal ingredients such as neem, clove, tulsi, and peppermint possess antimicrobial, anti-inflammatory, and antioxidant properties.
- Herbal extracts help reduce oral bacteria, prevent plaque formation, and improve gum health naturally.
- Liquid herbal formulations may suffer from instability, shorter shelf life, and inconsistent dosing.
- Effervescent tablet technology improves stability and ensures uniform release of active herbal constituents.[3]
- Effervescent tablets dissolve quickly in water, producing a ready-to-use mouthwash solution.
- This dosage form enhances convenience, portability, taste masking, and patient compliance.
- The formulation combines the benefits of herbal therapy with modern drug delivery systems.
- It provides an alcohol-free, effective, and user-friendly alternative for oral hygiene maintenance.

Ingredients:

1. Neem

- **Scientific name:** *Azadirachta indica*
- **Family:** Meliaceae
- **Kingdom:** Plantae
- **Genus:** *Azadirachta*
- **Species:** *A. indica*



Fig 1. Neem

Explanation:

Neem is a well-known medicinal tree used extensively in Ayurveda for oral care. It contains bioactive compounds such as nimbidin, nimbin, and azadirachtin, which exhibit strong antibacterial and antifungal activity. These compounds inhibit oral

pathogens like *Streptococcus mutans*, reducing dental caries and plaque formation. Neem also helps in healing inflamed gums and maintaining oral microbial balance. Traditionally, neem twigs have been used as natural toothbrushes due to their cleansing properties.[5]

2. Clove

- **Scientific name:** *Syzygium aromaticum*
- **Family:** Myrtaceae
- **Kingdom:** Plantae
- **Genus:** *Syzygium*
- **Species:** *S. aromaticum*



Fig 2. Clove

Explanation:

Clove is a dried flower bud known for its high content of eugenol, which provides analgesic, antiseptic, and anti-inflammatory effects. It is highly effective in relieving toothache by acting as a natural pain reliever. Clove also shows strong antimicrobial activity against oral bacteria and helps in reducing bad breath. Its aromatic nature contributes to oral freshness and hygiene maintenance.[7]

3. Tulsi (Holy Basil)

- **Scientific name:** *Ocimum sanctum* (also *Ocimum tenuiflorum*)
- **Family:** Lamiaceae
- **Kingdom:** Plantae
- **Genus:** *Ocimum*
- **Species:** *O. sanctum*

Explanation:

Tulsi is an important medicinal herb in traditional medicine systems. It contains essential oils such as eugenol, ursolic acid, and flavonoids, which provide antimicrobial and anti-inflammatory effects. Tulsi helps in controlling bacterial growth in the oral cavity, reducing gingival inflammation, and preventing plaque formation. It also acts as an antioxidant, protecting oral tissues from damage.[11]



Fig 3. Tulsi

4. Peppermint

- **Scientific name:** *Mentha piperita*
- **Family:** Lamiaceae
- **Kingdom:** Plantae
- **Genus:** *Mentha*
- **Species:** *M. piperita*

Explanation:

Peppermint is widely used in oral hygiene products due to its refreshing flavor and cooling sensation caused by menthol. It has mild antibacterial properties that help control odor-causing bacteria in the mouth. Peppermint also stimulates saliva secretion, which naturally cleans the oral cavity and reduces bacterial buildup. It is primarily used to improve taste and freshness in formulations.[13]



Fig 4. Papermint

5. Aloe vera (Optional)

- **Scientific name:** *Aloe barbadensis miller*
- **Family:** Asphodelaceae
- **Kingdom:** Plantae
- **Genus:** *Aloe*
- **Species:** *A. barbadensis*[17]

Explanation:

Aloe vera is a succulent plant known for its soothing and healing properties. It contains polysaccharides, vitamins, and enzymes that help reduce inflammation and promote tissue repair. In oral care, it is effective in treating gum irritation, mouth ulcers, and bleeding gums. Its moisturizing properties help maintain oral mucosal health.[19]



Fig 5. Aloe vera

6. Liquorice

- **Scientific name:** Glycyrrhiza glabra
- **Family:** Fabaceae
- **Kingdom:** Plantae
- **Genus:** Glycyrrhiza
- **Species:** G. glabra

Explanation:

Liquorice root contains glycyrrhizin, which provides anti-inflammatory, antimicrobial, and demulcent effects. It helps reduce plaque formation, gingival inflammation, and oral bacterial growth. Additionally, its natural sweetness improves the taste of oral formulations, making them more acceptable to users.[23]



Fig 6. Liquorice

7. Green Tea (Optional)

- **Scientific name:** *Camellia sinensis*
- **Family:** Theaceae
- **Kingdom:** Plantae
- **Genus:** *Camellia*
- **Species:** *C. sinensis*

Explanation:

Green tea is rich in catechins, especially epigallocatechin gallate (EGCG), which possess strong antioxidant and antibacterial properties. It helps inhibit growth of oral pathogens, reduces plaque formation, and improves gum health. Its antioxidant activity protects oral tissues from oxidative stress and inflammation.[29]



Fig 7. Green tea

Excipients and Their Roles

1. Citric acid

Citric acid is a key acid component in effervescent systems. When the tablet comes in contact with water, it reacts with sodium bicarbonate to release carbon dioxide gas. This reaction produces effervescence, which helps in rapid breakup and dissolution of the tablet. It also contributes to a slightly tangy taste, improving the overall palatability of the mouthwash solution. Additionally, citric acid helps maintain an acidic environment that can support antimicrobial activity in the final formulation.

2. Sodium bicarbonate

Sodium bicarbonate acts as the alkaline component in the effervescent reaction. It neutralizes citric acid in water, producing carbon dioxide bubbles that aid in fast disintegration of the tablet. This rapid effervescence ensures uniform dispersion of herbal ingredients in the solution. It may also provide a mild buffering effect, helping to maintain an optimal pH for oral use and enhancing cleansing action in the mouth.[30]

3. Mannitol / Sorbitol

Mannitol and sorbitol are commonly used as diluents in effervescent formulations. They provide bulk to the tablet, ensuring proper size and uniform compression. Both are sugar alcohols with a pleasant sweet taste and cooling sensation, which improves the mouthfeel of the mouthwash solution. They also help mask the bitterness of herbal extracts, increasing patient acceptability. Mannitol is particularly preferred due to its low hygroscopic nature, which is important for moisture-sensitive effervescent tablets.

4. Polyvinylpyrrolidone (PVP K30)

PVP K30 is a synthetic polymer used as a binder. It helps in holding the powder particles together during granulation and tablet compression. It improves the mechanical strength and hardness of the tablet, preventing breakage during handling and packaging. PVP also ensures uniform distribution of herbal extracts and excipients, leading to consistent drug release when dissolved in water.[28]

5. Magnesium stearate

Magnesium stearate acts as a lubricant in tablet formulation. It reduces friction between the powder blend and the surfaces of the tablet machine punches and dies. This prevents sticking and ensures smooth ejection of tablets after compression. It also improves the flow properties of granules, which is essential for uniform tablet weight and consistency.

6. Colloidal silicon dioxide

Colloidal silicon dioxide is used as a glidant. It improves the flowability of powder blends by reducing interparticle friction. This ensures uniform filling of the die cavity during tablet compression, which is critical for maintaining consistent tablet weight and dosage uniformity. It also helps in preventing clumping caused by moisture absorption.

7. Aspartame / Saccharin sodium

These are artificial sweeteners used to enhance the taste of the mouthwash solution. Herbal extracts often have a bitter or astringent taste, which can reduce patient compliance. Sweeteners mask these undesirable flavors and make the formulation more acceptable. They are used in very small quantities due to their high sweetness intensity and stability in effervescent systems.

8. Peppermint oil / Menthol

Peppermint oil and menthol are flavoring agents that provide a strong refreshing taste and cooling sensation in the mouth. Menthol activates cold receptors, giving a feeling of freshness and cleanliness. These agents also help mask the herbal odor and improve the overall sensory experience of the mouthwash. In addition, peppermint oil has mild antimicrobial properties that complement the herbal actives.[27]

9. Coloring agents (optional)

Coloring agents are added to improve the visual appearance of tablets and the resulting solution. They help in product identification and enhance consumer appeal. In herbal formulations, natural colors such as chlorophyll or plant-derived pigments are preferred to maintain a natural and safe profile. They do not contribute to therapeutic activity but improve aesthetics.

10. Ascorbic acid (optional)

Ascorbic acid acts as an antioxidant in the formulation. It protects sensitive herbal constituents from oxidation, thereby improving stability and shelf life. It also helps maintain the potency of bioactive compounds present in herbal extracts. Additionally, it may provide a mild acidic taste and contribute to overall oral health due to its vitamin C content.[27]

11. Anti-caking agents (e.g., calcium silicate)

Anti-caking agents prevent the absorption of moisture and formation of lumps in the powder blend. Effervescent formulations are highly sensitive to humidity, so these agents are essential to maintain free-flowing powder characteristics. They ensure proper mixing, uniform compression, and stability of the final tablets during storage.

Formulation

Step 1: Collection, Authentication, and Preparation of Herbal Materials

- Select medicinal plants: *Azadirachta indica* (Neem), *Syzygium aromaticum* (Clove), *Ocimum sanctum* (Tulsi), and *Mentha piperita* (Peppermint).
- Authenticate plant material using botanical identification to ensure correct species.
- Wash raw materials thoroughly with clean water to remove dirt, dust, and microbial contamination.
- Dry the plant parts under shade (not direct sunlight) to preserve heat-sensitive phytoconstituents like essential oils and flavonoids.
- Grind dried material into fine powder using a mechanical grinder.
- Sieve the powder (e.g., #60 mesh) to obtain uniform particle size for efficient extraction.

Step 2: Extraction of Active Constituents

- Weigh the required quantity of powdered herbal drugs.
- Choose suitable extraction method depending on polarity of actives:
 - **Maceration:** soaking in solvent for 24–48 hours with occasional stirring
 - **Soxhlet extraction:** continuous hot extraction for higher yield
- Use solvents such as distilled water or hydroalcoholic mixture (ethanol:water).
- Filter extract using muslin cloth followed by Whatman filter paper to remove insoluble matter.
- Concentrate filtrate using rotary evaporator or controlled heating below 50°C.[24]
- Dry concentrated extract (spray drying or freeze drying preferred) to obtain stable powdered extract.
- Store dried extract in airtight container protected from moisture and light.

Step 3: Pre-Processing of Effervescent Components

- Separately dry citric acid and sodium bicarbonate in a hot air oven at 40–50°C for a short duration.
- Purpose: removal of adsorbed moisture which can trigger premature effervescence.
- Store both ingredients in desiccators immediately after drying.
- Maintain low humidity environment (preferably <40% RH) throughout handling.

Step 4: Preparation of Herbal Base Blend

- Accurately weigh dried herbal extract.
- Mix herbal extract with diluents such as mannitol or sorbitol using geometric dilution method to ensure uniform distribution.

- Add sweeteners (aspartame or saccharin sodium) to mask bitterness of herbal components.
- Incorporate flavoring agents such as peppermint oil or menthol for taste enhancement and cooling effect.
- Mix using a double cone blender or mortar-pestle for uniform blending.[25]

Step 5: Incorporation of Effervescent System

- Citric acid and sodium bicarbonate are added **at the final blending stage** to avoid premature acid-base reaction.
- Mixing is done gently and quickly in a controlled low-humidity environment.
- Ensure uniform distribution of both components to achieve consistent effervescence.
- Avoid excess mechanical force to prevent initiation of reaction due to friction or heat.

Step 6: Granulation Process (Wet or Dry)

Wet Granulation (if used):

- Prepare binder solution using PVP K30 dissolved in ethanol or suitable non-aqueous solvent.
- Slowly add binder to powder mixture to form damp mass.
- Pass the wet mass through sieve (#10–#16 mesh) to form granules.
- Dry granules in tray dryer at 40–45°C until moisture content is optimal (<2%).

Dry Granulation (alternative):

- Compact powder blend using slugging or roller compaction.
- Break slugs into granules and sieve for uniform size distribution.

Step 7: Lubrication and Final Blending

- Add lubricants such as magnesium stearate to reduce friction during compression.
- Add glidants like colloidal silicon dioxide to improve flow properties of granules.
- Mix gently for 2–5 minutes only to ensure uniform coating without over-lubrication.
- Ensure blend remains dry and free-flowing before compression.[22]

Step 8: Compression into Tablets

- Compress final blend using rotary tablet press or single punch machine.
- Maintain strict humidity control (preferably below 30–40% RH).
- Adjust compression force to achieve:
 - Adequate hardness
 - Low friability
 - Rapid disintegration in water
- Ensure uniform weight, thickness, and appearance of tablets.

Step 9: Packaging of Tablets

- Immediately package tablets after compression to avoid moisture exposure.
- Use moisture-resistant packaging such as:
 - Aluminum-aluminum blister packs
 - High-density polyethylene (HDPE) containers with desiccant

- Seal packaging tightly to prevent atmospheric moisture ingress.[21]
- Label with storage instructions and usage directions.

Step 10: Storage Conditions

- Store in a cool, dry place away from heat and humidity.
- Maintain temperature below 25°C if possible.
- Avoid exposure to direct sunlight and moisture.
- Ensure container remains tightly closed after each use.

Evaluation:

1. Appearance and Organoleptic Evaluation

- Tablets are checked visually for uniform color, shape, and smooth surface.
- They should be free from cracks, spots, or surface defects.
- Any sign of stickiness or discoloration may indicate moisture absorption.
- Odour is evaluated to confirm a pleasant herbal/menthol fragrance without unpleasant smell.

2. Uniformity of Weight

- A sample of 20 tablets is selected randomly.
- Each tablet is weighed individually using an analytical balance.
- Mean weight is calculated and compared with individual values.
- Variation should remain within acceptable pharmacopeial limits.
- This ensures consistent drug distribution in each dosage unit.

3. Size Uniformity (Thickness and Diameter)

- Tablet dimensions are measured using Vernier calipers or micrometer.
- Consistent thickness and diameter reflect proper compression.
- Uniform size ensures accurate packaging and predictable dissolution behavior.
- Large variation indicates poor blending or uneven compression force.[20]

4. Hardness Test

- Conducted using a hardness tester (Monsanto or similar).
- Measures the force required to break the tablet.
- Effervescent tablets require moderate hardness for easy handling and quick dissolution.
- Excess hardness may delay disintegration, while low hardness may cause breakage.

5. Friability Test

- Performed using a friabilator by rotating tablets under mechanical stress.
- Tablets are weighed before and after the test.
- Percentage weight loss is calculated.
- Ideal friability is generally below 1%.

- This ensures tablets can withstand packaging and transportation without damage.

6. Effervescence Time

- Tablet is placed in a measured volume of water (around 200 mL).[18]
- Time is recorded until complete dissolution and gas release stops.
- CO₂ is produced due to reaction between acid and base components.
- Faster effervescence indicates better user convenience (usually 2–5 minutes).

7. pH of Prepared Solution

- After complete dissolution, pH is measured using a calibrated pH meter.
- The solution should remain near neutral or slightly mild (6.5–7.5).
- Extremely acidic or alkaline solutions may cause oral irritation.
- Proper pH ensures safety and comfort for oral rinsing.

8. Disintegration Behavior

- Tablet is placed in warm water (about 37°C).
- Time required for complete breakup into fine particles is noted.
- Effervescent tablets should disintegrate rapidly due to CO₂ release.
- Slow disintegration suggests formulation or compression issues.

9. Content Uniformity

- Individual tablets are analyzed for active herbal content.
- Instrumental methods like UV spectrophotometry or HPLC may be used.
- Each tablet should contain a consistent amount of active constituents.
- Acceptable range is typically 85%–115% of labeled content.

10. Moisture Content (LOD Test)

- Moisture is measured using oven drying or moisture analyzer.
- Effervescent tablets must have very low moisture levels.
- Excess moisture can trigger premature reaction between ingredients.
- Ideal moisture content is generally below 2–3%.[16]

11. Stability Testing

- Tablets are stored under normal and accelerated conditions.
- Observations include physical appearance, effervescence time, and potency changes.
- Tests ensure product remains stable during its shelf life.
- Helps determine expiry period and storage conditions.

12. Microbial Quality Test

- Ensures absence of harmful microorganisms.
- Tests include total microbial count, yeast, and mold evaluation.
- Herbal formulations must comply with safety standards.

- Confirms product is safe for oral application.

Advantages of Herbal Effervescent Mouthwash Tablets[15]

1. Natural and Safe Composition

- Prepared using herbal ingredients like neem, clove, tulsi, and peppermint.
- Free from alcohol and harsh synthetic chemicals.
- Reduces risk of oral irritation and dryness.
- Suitable for long-term daily use.

2. Antimicrobial and Therapeutic Effect

- Herbal actives help inhibit growth of oral bacteria.
- Reduces plaque formation and gingival inflammation.
- Helps in prevention of dental caries and gum diseases.
- Provides mild anti-inflammatory and healing effects.

3. Rapid and Convenient Preparation

- Effervescent tablets dissolve quickly in water.
- Ready-to-use mouthwash solution is formed within minutes.
- No need for measuring or mixing multiple ingredients.
- Highly convenient for daily oral care routine.

4. Improved Patient Compliance

- Pleasant taste due to flavoring agents like peppermint.
- Herbal bitterness is effectively masked.
- Cooling and refreshing sensation improves user acceptance.
- Easy to use for all age groups.

5. Better Stability Compared to Liquid Form

- Solid form protects herbal extracts from degradation.
- Less prone to microbial contamination than liquid mouthwash.[14]
- Longer shelf life when properly packed.
- No need for preservatives in high concentration.

6. Accurate and Uniform Dosing

- Each tablet contains a fixed amount of active ingredients.
- Eliminates errors in measuring liquid formulations.
- Ensures consistent therapeutic effect with each use.

7. Portability and Ease of Storage

- Lightweight and easy to carry.
- No risk of leakage or spillage.
- Requires minimal storage space.
- Ideal for travel and outdoor use.

8. Enhanced Absorption and Action

- Effervescence helps rapid dispersion of herbal actives in solution.
- Carbon dioxide release may improve penetration into oral tissues.
- Ensures quick antimicrobial and cleansing action.[12]

9. Eco-Friendly Formulation

- Utilizes natural plant-based ingredients.
- Reduces dependence on synthetic chemicals.
- Environmentally safer compared to conventional mouthwashes.

10. Cost-Effective Production

- Herbal raw materials are generally inexpensive and widely available.
- Simple manufacturing process reduces production cost.
- Economical for large-scale production and consumer use.

Limitations & Challenges of Herbal Effervescent Mouthwash Tablets

1. Moisture Sensitivity

- Effervescent formulations are highly hygroscopic in nature.
- Even small exposure to moisture can trigger premature acid–base reaction.
- Requires strict humidity control during manufacturing, packaging, and storage.
- Improper handling may lead to loss of product stability.

2. Stability Issues of Herbal Extracts

- Herbal constituents may degrade over time due to oxidation or heat.
- Volatile oils (e.g., peppermint, clove) may evaporate or lose potency.
- Variability in plant composition can affect batch-to-batch consistency.
- Standardization of herbal extracts is often challenging.[10]

3. Taste and Palatability Challenges

- Some herbal extracts have strong bitter or astringent taste.
- Even with flavoring agents, complete masking may not always be achieved.
- Patient acceptability may vary depending on taste sensitivity.

4. Complex Manufacturing Conditions

- Requires low humidity environment for processing.
- Special equipment and controlled conditions increase production complexity.
- Effervescent systems demand careful handling of acid and base components separately.

5. Shorter Shelf Life Compared to Conventional Tablets

- Due to moisture sensitivity and herbal degradation, shelf life may be limited.
- Requires moisture-proof and airtight packaging for stability.
- Improper storage conditions can reduce effectiveness over time.[9]

6. Cost of Packaging

- Needs specialized packaging like aluminum blisters or desiccant-containing containers.
- Moisture barrier materials increase overall production cost.
- Higher packaging cost compared to normal tablets or liquid mouthwash bottles.

7. Standardization of Herbal Ingredients

- Variability in active constituents depending on plant source, season, and geography.
- Difficult to maintain uniform pharmacological activity across batches.
- Requires advanced quality control methods for consistency.

8. Limited Scientific Data for Some Combinations

- Not all herbal combinations are fully clinically validated.
- Lack of large-scale clinical trials for some formulations.
- May reduce acceptance in regulated pharmaceutical markets.

9. Possible Interaction Between Ingredients

- Herbal compounds may interact with excipients or each other.
- Effervescent agents may affect stability of certain phytochemicals.
- Requires careful compatibility studies during formulation.

10. Storage and Handling Restrictions

- Must be stored in cool, dry conditions.
- Exposure to humidity can cause caking or loss of effervescence.
- Not suitable for environments with high moisture without proper packaging.[8]

Conclusion

The formulation of herbal effervescent mouthwash tablets represents an innovative approach to oral care by integrating traditional herbal medicine with modern effervescent drug delivery technology. The use of medicinal plants such as neem, clove, tulsi, and peppermint provides natural antimicrobial, anti-inflammatory, and breath-freshening effects, making the

formulation effective in maintaining oral hygiene and preventing dental disorders. Effervescent tablet technology enhances the convenience, stability, and patient acceptability of the herbal formulation by enabling rapid dissolution in water and providing a ready-to-use mouthwash solution. This dosage form also ensures accurate dosing, improved portability, and better compliance compared to conventional liquid mouthwashes. However, the formulation requires careful consideration of moisture sensitivity, herbal stability, and packaging requirements to maintain product quality and shelf life. Despite these challenges, proper formulation techniques and controlled manufacturing conditions can effectively overcome these limitations.

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