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Research Paper

Formulation & Evaluation of Polyherbal Anti-tussive Gummies

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ABSTRACT

Cough is a common symptom often associated with respiratory infections and allergies, and it can significantly disrupt daily activities. While conventional cough medications are generally effective, they may cause side effects such as drowsiness, digestive issues, or even dependency. As a result, there is a growing interest in natural remedies that are both safe and effective. This study explores the development and evaluation of herbal cough-relief gummies, with Bael (Aegle marmelos) as the primary ingredient. Bael is known for its natural abilities to soothe coughs, reduce inflammation, fight microbial infections, and strengthen the immune system. These qualities make it beneficial for relieving both dry and productive coughs. The formulation also includes other well-known medicinal herbs such as Tulsi (Holy Basil), Liquorice, Ginger extract, and Honey, which complement each other to enhance the overall therapeutic effect. Agar, a plant-based gelling agent, was used to form the gummies. The gummies were tested for various parameters such as taste, weight, pH level, texture, moisture content, and shelf stability. Laboratory analyses showed that the gummies gradually release their herbal components over time, ensuring sustained relief. The final product was found to be palatable, safe for consumption, and effective in easing cough symptoms. These herbal gummies present an innovative and convenient way to deliver cough relief, particularly for children and the elderly who may prefer a sweet, chewable alternative to traditional syrups. In summary, herbal gummies formulated with Aegle marmelos offer a promising natural substitute for chemical-based cough medications, blending traditional herbal wisdom with modern formulation techniques.

INTRODUCTION

Cough serves as a protective reflex, helping to expel mucus, irritants, or foreign particles from the respiratory tract. It is frequently associated with

conditions such as respiratory infections, allergic reactions, and other pulmonary disorders. Although over-the-counter (OTC) synthetic antitussives are commonly used, extended usage can lead to unwanted side effects including

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drowsiness, dizziness, and gastrointestinal discomfort. This has led to increased interest in herbal-based alternatives that are safer, more natural, and better tolerated by the body. Gummies are an appealing dosage form due to their ease of use, pleasant taste, and high compliance, particularly among children and older adults. Integrating herbal extracts into a gummy formulation enhances the therapeutic effect while maintaining user acceptability. This specific formulation includes a blend of herbal ingredients known for their antitussive, expectorant, and soothing properties, described as follows:

Bael (Aegle marmelos):

Pharmacological Properties: Antimicrobial, anti-inflammatory, expectorant

Function in Gummies: The fruit and leaves of Bael are known for their ability to reduce respiratory tract inflammation and combat microbial infections. They contribute to immune support and promote respiratory healing by easing irritation and promoting expectoration.

Tulsi (Ocimum sanctum):

Pharmacological Properties: Immunomodulatory, antitussive, adaptogenic

Function in Gummies: Widely revered in traditional medicine, Tulsi enhances the immune response, relieves coughing, and soothes the respiratory system. Its natural adaptogenic and mucolytic properties help reduce mucus buildup and relax respiratory pathways.

Liquorice (Glycyrrhiza glabra):

Pharmacological Properties: Demulcent, expectorant, anti-inflammatory

Function in Gummies: Liquorice helps calm irritated mucous membranes in the throat and bronchi. Its expectorant action aids mucus clearance, while its soothing effect alleviates symptoms of dry and persistent coughs.

Ginger Extract (Zingiber officinale):

Pharmacological Properties: Anti-inflammatory, antimicrobial, antioxidant

Function in Gummies: Ginger reduces inflammation and throat discomfort. It promotes saliva production, which helps soothe dry throat irritation. Its antimicrobial properties support the immune system in fighting respiratory infections.

Honey:

Pharmacological Properties: Antioxidant, antimicrobial, demulcent

Function in Gummies: Honey naturally suppresses cough and provides a coating effect over irritated mucosa, helping to calm the cough reflex. It also enhances the flavor and palatability of the formulation, making it more acceptable, especially to children.

This herbal gummy formulation offers a holistic, user-friendly approach to managing cough, combining traditional herbal knowledge with modern dosage design for better safety and compliance.

INGREDIENTS & PROCEDURE:

INGREDIENT TABLE:

Table 1. Ingredients

Ingredients	Quantity Use for (50 gm)	Uses
Aegle Marmelos Leaves powder	10 gm	Cough Suppressant
Honey	5 gm	Sweetener, Cough Relief
Agar- Agar Powder	10 gm	Jelly Texture
Lemon Juice	1 tsp	Preservative, Taste



Ginger powder	5 gm	Cough Relief
Liquorice	5 gm	Cough Suppressant
Tulsi	5 gm	Anti Tussive
Water	Q.S.	Vehicle

Preparation of *Aegle marmelos* (Bael) Gummies for Cough –

Extraction: Simple Extraction Procedure:

Step 1: Bael Extract Preparation

Fresh Bael (*Aegle marmelos*) leaves are first collected and dried in a shaded area for about one week to preserve their active compounds. Once fully dried, the leaves are finely ground into a powder using a blender or grinder. To prepare the extract, 10 grams of the Bael leaf powder is added to 250 mL of water and simmered gently on low heat for 20 to 30 minutes.^[1] After boiling, the mixture is allowed to cool to room temperature and is then filtered to obtain the Bael extract (juice).

Step 2: Preparing the Agar-Agar Solution

Measure 150 mL of warm water and dissolve agar-agar in it. Let the solution rest for 5 to 10 minutes to allow full hydration and gel formation.^[2]

Step 3: Mixing All Ingredients

To the cooled Bael extract, add the following: Honey, Lemon juice, Powders of ginger, liquorice (*Glycyrrhiza glabra*), and Tulsi (*Ocimum sanctum*) Once these are thoroughly mixed, gently stir in the prepared agar-agar solution. Heat the mixture on low flame for another 5 to 10 minutes, ensuring all ingredients blend uniformly



Fig 1. Mixture of Ingredients

Step 4: Molding the Gummies:

Carefully pour the warm herbal mixture into silicone or food-grade gummy molds. Place the filled molds in the refrigerator and allow them to set for 2 to 3 hours or until they become firm and hold their shape.^[3]

Step 5: Storage and Usage

Once fully set, remove the gummies from the molds. Store them in a clean, airtight container to maintain freshness and prevent moisture absorption. For cough relief, consume 1 to 2 gummies per day as needed.^[4]



Fig 2. Gummies

TRANSVERSE SECTION (T.S.) OF *AEGLE MARMELOS* :

Aim : To study the transverse section of Aegle marmelos (Bael) leaf microscopically.

Materials Required:

Fresh leaf of Aegle marmelos,
Razor blade or microtome Watch glass,
Safranin and Fast Green stains Glycerin,
Slide and coverslip,
Compound microscope,
Brush, needles, forceps^[5]



Fig 3. Leaves of Aegle Marmelos

Procedure :

1. Sample Preparation:

Select a fresh, healthy Aegle marmelos leaf. Rinse thoroughly with water to eliminate dust, dirt, or any surface contaminants.

2. Sectioning:

From the central vein (midrib) of the leaf, cut a representative portion. Using a sharp razor blade or microtome, carefully make thin transverse sections. Use a fine brush to transfer and select the thinnest, undamaged sections for further processing.

3. Staining:

Place the selected sections in a watch glass containing safranin solution for about 2–3 minutes to stain lignified tissues. Rinse gently with water to remove excess safranin. Counterstain by immersing the section in Fast Green solution for 30 seconds to 1 minute, which stains cellulose and cytoplasmic components. Rinse again gently to clear any remaining stain.^[6]

4. Mounting:

Transfer the stained section onto a clean glass slide. Add a drop of glycerin to keep the tissue moist and prevent drying. Using a fine needle, carefully place a coverslip over the section, avoiding the formation of air bubbles.

5. Microscopic Examination:

Begin observation under low magnification, then switch to high power for detailed analysis. Look for and identify key anatomical features, including:

Upper and lower epidermis, Palisade parenchyma, Spongy parenchyma, Collenchyma near the midrib, Vascular bundles with xylem and phloem, Occasional presence of calcium oxalate crystals or oil glands^[7]



Fig 4. T.S. of *Aegle Marmelos*



Fig 5. Gummies

EVALUATION:

To ensure the quality, consistency, safety, and effectiveness of gummies whether nutraceutical or pharmaceutical it is essential to assess them using various evaluation parameters. These parameters are generally categorised into the following groups:

- Organoleptic properties – Assessing appearance, colour, taste, texture, and odour to ensure consumer acceptability.
- Physicochemical characteristics – Includes measurements such as pH, moisture content, and uniformity of weight and content.
- Mechanical properties – Evaluates the firmness, elasticity, and chewability of the gummies to ensure proper texture.
- Microbiological testing – Ensures the absence of harmful microorganisms to guarantee safety for consumption.
- Stability testing – Determines the shelf life and checks how well the product maintains its quality over time under different storage conditions.

1. ORGANOLEPTIC PROPERTIES :

Color: Visual appearance consistency

Odor: Should be pleasant and product-appropriate

Taste: Should mask active ingredient bitterness or unpleasant flavors

Texture & Mouthfeel: Should be chewy, soft, and non-gritty ^[8]

2. PHYSICOCHEMICAL PROPERTIES :

WEIGHT VARIATION:

Standard Procedure:

To assess uniformity in gummy weight, a standard method is followed similar to that used for tablets and capsules in dietary supplements. This involves:

Individually weighing 20 gummies. Calculating the average weight using the formula:

$$\text{Average weight} = \frac{\text{weight of 20 gummies}}{20}$$

Comparing each gummy's weight to the calculated average.

Acceptance Criteria:

No more than two gummies should differ from the average weight by more than the acceptable percentage range. None should differ by more than twice that range.

Percentage Weight Variation is determined using:

$$\% \text{ weight variation} = \frac{\text{average weight} - \text{weight of each tablet}}{\text{Average weight}} \times 100$$

This test ensures consistent dosing and quality in each unit.^[9]



Fig 6. Weighing of Gummies

pH MEASUREMENT :

The pH level of the gummy formulation plays a crucial role in determining its stability, texture, and taste. It was measured at room temperature using a digital pH meter (Electroquip). For optimal results, the pH of the gummy solution before gelation should ideally fall between 3.0 and 6.0. Maintaining the pH within this range helps avoid issues such as:

Instability of the final product. Syneresis (liquid separation from the gel), which tends to occur more frequently when the pH drops below 3.0

Gummies demonstrate greater stability when the pH is closer to neutral (around 6.0). To regulate and maintain the desired pH range, buffering agents such as citric acid and sodium citrate were incorporated during formulation.^[10]



Fig 7. pH Determination

DISSOLUTION TEST

The dissolution test assesses whether the active compounds in oral solid dosage forms—such as tablets, capsules, or gummies are released at the appropriate rate and extent.

This test is generally performed using Apparatus 1 (Basket method) unless specified otherwise, following standards such as those in the British

Pharmacopoeia (BP). The test unit is defined as a single dosage form (e.g., one gummy).



Fig 8. Dissolution Test

All components of the apparatus in contact with the sample or dissolution medium must be chemically inert and should not adsorb or react with the ingredients. Metal parts must be constructed from Type 316 stainless steel or an equivalent material, or be coated appropriately to ensure no interaction with the gummy or dissolution medium. This test helps determine if the gummy formulation meets regulatory and therapeutic release standards.

3. MECHANICAL PROPERTIES:

Hardness / Firmness:

The firmness of the gummies was assessed using a texture analyser to ensure product uniformity. To evaluate crushing strength, three units from each formulation were tested using a MAC hardness tester, and the average value was calculated for comparison.^[11]

Elasticity / Springiness:

This parameter reflects how well the gummy returns to its original shape after being compressed. It is an indicator of the chewiness and mouthfeel, important for consumer acceptability.

Stickiness:

Stickiness was evaluated manually by gently rubbing a sample between two fingers. The tactile feel, including stickiness and grittiness, was observed to assess handling properties and consumer experience.^[9]

4. STABILITY STUDIES:

Shelf-Life Evaluation:

Stability testing was carried out under both accelerated and real-time conditions to simulate typical and extreme storage environments.

Accelerated Testing:

Gummies were stored at $40^{\circ}\text{C} \pm 5^{\circ}\text{C}$ with $75\% \pm 5\%$ relative humidity (RH) to mimic long-term degradation over a short period.

Real-Time Testing:

Samples were stored at $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$ and 60–75% RH, mimicking standard room temperature storage.

Storage condition sensitivity:

Over a period of three months, the gummies were examined every 30 days for changes in: Appearance, pH, Crystallization of sugars, Firmness, Viscosity.

These assessments help determine the shelf life and identify optimal storage conditions (e.g., protection from heat, light, and moisture).^[12]

Preservative Effectiveness:

Especially important for natural or sugar-free formulations, preservatives must be evaluated to ensure they effectively prevent microbial growth without compromising product quality.^[13]



Moisture Content:

Moisture content is a critical parameter that influences both the shelf life and textural quality of gummies. Excessive moisture can lead to microbial growth, reduced stability, and texture degradation, while insufficient moisture may result in hard or brittle gummies.^[14]

5. MICROBIAL ANALYSIS:

Herbal-based gummies, due to their organic content and moisture, are prone to microbial contamination. This could lead to spoilage or potential health hazards.

Common Contaminants:

Bacteria: *Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*

Fungi and Yeasts: Often present in moist and sugary environments

Spore-forming Bacteria: *Bacillus subtilis* and others, which are more resistant to conventional sanitization methods

Significance:

Contaminated products, such as some herbal cough syrups, have been reported to contain pathogens like *Candida albicans*. Inadequate preservative systems can result in up to 30% of samples being vulnerable to fungal growth, underscoring the importance of microbial quality control.^[9]



Fig 9. Microbial Growth on Gummies

RESULT:

Evaluation of Gummies:

1. Organoleptique Properties:

Color	Light Brown
Odor	Pungent
Taste	Sweet, Pleasant
Texture	Smooth

2. Physicochemical Parameters:

Weight Variation	4-5 gm/dose
pH	5 (Acidic)
Dissolution Time	20-25 min

3. Mechanical Properties :

Hardness	4-5 N
Elasticity	0.6-0.8
Stickiness	0.1-0.3 N

4. Stability Studies :

	Cool Temperature	Room Temperature
Shelf Life	2-3 weeks (4-0 °C)	3- 4 days (40 °C)
Storage Condition	Seal pack container At cool Place	
Moisture formation	2 weeks	2 days

5. Microbial Studies:

At Room Temperature	3-4 days
At Cool Temperature	4-5 weeks

CONCLUSION

This study successfully developed and assessed a polyherbal gummy formulation incorporating *Aegle marmelos* along with other supportive herbal ingredients. The finalized product demonstrated the following key attributes:

- Pleasant taste and easy-to-chew texture
- Free from synthetic preservatives
- Effective in managing both dry and productive cough

- Exhibited sustained release of active components for prolonged therapeutic effect
- Overall, the formulation offers a natural, safe, and non-drowsy alternative to conventional cough remedies. Its chewable form enhances ease of use and acceptability, especially among children and elderly individuals, promoting better adherence to treatment.

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