Formulation and Evaluation of Anti-Diabetic Candy from Bael Fruit (Aegle Marmelos)

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***Abstract*—The present study was aimed at formulation and evaluation of anti-diabetic herbal candy prepared from Bael fruit (Aegle marmelos). Bael fruit possesses significant anti-diabetic, antioxidant, and medicinal properties due to the presence of alkaloids, flavonoids, tannins, and phenolic compounds. Herbal candies were prepared by heating and congealing method using bael fruit pulp, sugar substitute, glucose syrup, gelatin, citric acid, and flavoring agents. Different formulations (F1–F5) were prepared by varying the concentration of bael fruit extract and evaluated for physicochemical properties such as appearance, weight variation, thickness, hardness, friability, moisture content, pH, drug content, in-vitro dissolution, and stability studies. The prepared candies showed acceptable organoleptic characteristics with good stability and uniformity. Formulation F3 exhibited optimum hardness, acceptable moisture content, good taste masking, and maximum drug release. The study concluded that bael fruit candy can be effectively formulated as a patient-friendly herbal dosage form for diabetic patients and may improve patient compliance due to its palatable taste and herbal origin.**

***Index Terms*—Bael fruit, Aegle marmelos, Anti-diabetic candy, Herbal formulation, Evaluation, Herbal dosage form.**

I. INTRODUCTION

Diabetes mellitus is a chronic, progressive metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It is considered one of the major global health challenges of the 21st century. According to the International Diabetes Federation, the number of diabetic patients is increasing rapidly, particularly in developing countries like India, where lifestyle changes, sedentary habits, and dietary patterns contribute significantly to disease prevalence. Persistent hyperglycemia leads to long-term complications such as neuropathy, nephropathy, retinopathy, cardiovascular disorders, and impaired wound healing. Although various synthetic anti-diabetic drugs such as metformin, sulfonylureas, and insulin therapy are available, their prolonged use is often associated with adverse effects including hypoglycemia, gastrointestinal disturbances, weight gain, and in some cases drug resistance. Therefore, there is a growing interest in alternative therapies, especially herbal medicines, which are considered safer and more cost-effective.

Medicinal plants have been used in traditional systems of medicine such as Ayurveda, Siddha, and Unani for the management of diabetes since ancient times. Herbal drugs are rich in bioactive phytoconstituents such as flavonoids, alkaloids, tannins, saponins, glycosides, and phenolic compounds that exhibit anti-diabetic activity through multiple mechanisms including enhancement of insulin secretion, inhibition of glucose absorption, antioxidant action, and improvement of peripheral glucose utilization.

Among various medicinal plants, Aegle marmelos (Bael fruit) belonging to the family Rutaceae has gained significant attention due to its wide range of pharmacological activities. It is commonly found throughout India and holds an important place in Ayurvedic medicine. Different parts of the plant such as leaves, roots, bark, and fruit pulp are traditionally used for treating diabetes, diarrhea, dysentery, inflammation, and other metabolic disorders. The fruit pulp of bael contains important phytoconstituents such as marmelosin, aegeline, lupeol, flavonoids, coumarins, tannins, and essential oils. These compounds are reported to possess strong anti-diabetic, antioxidant, and hepatoprotective properties. The anti-diabetic action of bael is mainly attributed to its ability to enhance pancreatic β-cell function, improve insulin secretion, and reduce oxidative stress-induced damage.

In recent years, there has been a shift towards developing patient-friendly herbal dosage forms that improve compliance and acceptability. Candy formulation is one such innovative dosage form that is especially suitable for pediatric, geriatric, and non-compliant patients. Candies offer advantages such as ease of administration, pleasant taste, masking of bitter drugs, portability, and better patient adherence compared to conventional dosage forms.

The development of herbal candies using bael fruit extract provides a novel approach for delivering anti-diabetic therapy in a palatable and convenient form. Such formulation also ensures better dose uniformity and stability of herbal extracts. In addition, sugar-free or low-sugar candy formulations can be particularly beneficial for diabetic patients by minimizing glucose intake while delivering therapeutic benefits. Hence, the present research work is focused on the formulation and evaluation of anti-diabetic herbal candy using Aegle marmelos fruit extract with an aim to develop a stable, effective, and patient-friendly herbal dosage form that may contribute to better management of diabetes mellitus.

II. MATERIALS AND METHODS

2.1 Materials

All materials used in the present study were of analytical or pharmaceutical grade and were used without further purification unless otherwise specified.

Sr. No.	Material	Specification	Purpose
1	Bael fruit (Aegle marmelos) pulp	Fresh, authenticated	Active herbal ingredient
2	Isomalt	Pharmaceutical grade	Sugar substitute (sweetening agent)
3	Glucose syrup	Food grade	Binding and sweetening agent
4	Gelatin	Pharmaceutical grade	Gelling and structural agent
5	Citric acid	Analytical grade	pH modifier and taste enhancer
6	Orange flavor	Food grade	Flavoring agent
7	Distilled water	Purified	Solvent
8	Ethanol (70%)	Analytical grade	Extraction solvent

All chemicals were procured from certified suppliers and stored under recommended conditions.

2.2 Collection and Authentication of Plant Material

Fresh ripe fruits of Aegle marmelos (Bael) were collected from a local agricultural region. The plant material was authenticated by a qualified botanist in the Department of Pharmacognosy, and a voucher specimen was preserved for future reference.

The fruits were washed thoroughly with running water to remove dirt and foreign particles. The pulp was separated manually, and seeds and fibrous material were removed. The cleaned pulp was subjected to shade drying to reduce moisture content and prevent degradation of phytoconstituents.

2.3 Preparation of Bael Fruit Extract

The dried bael pulp was coarsely powdered using a mechanical grinder and passed through sieve no. 40 to obtain uniform particle size.

Extraction Procedure:

1. A weighed quantity of bael powder was subjected to maceration using 70% ethanol in a closed container.
2. The mixture was kept for 72 hours with occasional stirring to ensure complete extraction of phytoconstituents.
3. After maceration, the mixture was filtered using muslin cloth followed by Whatman filter paper No. 1.
4. The filtrate was concentrated under reduced pressure using a rotary evaporator at controlled temperature (40–50°C).
5. The semi-solid extract obtained was further dried in a desiccator to remove residual solvent.
6. The dried extract was stored in airtight amber-colored containers at 4°C until further use.

The extract was evaluated for preliminary phytochemical screening to confirm the presence of flavonoids, tannins, alkaloids, and phenolic compounds.

2.4 Preformulation Studies
Preformulation studies were carried out to ensure compatibility and suitability of ingredients for candy formulation.
2.4.1 Organoleptic Evaluation of Extract
The bael extract was evaluated for color, odor, taste, and texture to ensure batch consistency.
2.4.2 Solubility Studies
The solubility of bael extract was determined in water, ethanol, and buffer solutions to select suitable formulation medium.
2.4.3 Moisture Content
Moisture content of dried extract was determined using loss on drying method to ensure stability during formulation.

2.5 Formulation of Anti-Diabetic Candy
The anti-diabetic candies were prepared using heating and congealing technique, which is widely used in confectionery preparation.

Stepwise Procedure:
1. Preparation of Base Syrup: Isomalt and glucose syrup were accurately weighed and dissolved in purified water in a stainless-steel vessel.
2. Heating Process: The mixture was heated gradually to 120–130°C under continuous stirring to achieve a thick, uniform syrup consistency.
3. Addition of Gelling Agent: Gelatin solution (pre-soaked in warm water) was added slowly to the hot syrup with continuous stirring to ensure homogeneity.
4. Incorporation of Herbal Extract: Bael fruit extract was added into the molten mass at controlled temperature (below 80°C) to prevent degradation of heat-sensitive phytoconstituents.
5. Addition of Excipients: Citric acid was added to adjust pH and enhance taste, followed by flavoring agent (orange flavor) to improve palatability.
6. Molding Process: The final mixture was poured into pre-lubricated silicone molds of uniform size.
7. Cooling and Solidification: The molds were kept at room temperature and then refrigerated for complete solidification.
8. Demolding and Packaging: Solidified candies were carefully removed, wrapped in butter paper, and packed in airtight containers for further evaluation.

2.6 Formulation Design (Batch Optimization)
Different formulations (F1–F5) were prepared by varying the concentration of bael extract while keeping other excipients constant. The purpose of variation was to optimize taste, hardness, and drug release characteristics.
A design-based approach was used to evaluate the effect of increasing extract concentration on candy quality attributes.

2.7 Evaluation of Anti-Diabetic Candy
All formulations were subjected to physicochemical and performance evaluation tests.
2.7.1 Appearance and Texture Analysis
Visual inspection was performed to evaluate color uniformity, transparency, surface smoothness, and absence of crystallization.
2.7.2 Uniformity of Weight
Twenty candies from each batch were randomly selected and weighed individually using a calibrated analytical balance. The mean weight and standard deviation were calculated.
2.7.3 Hardness Test
Mechanical strength was measured using a digital hardness tester. The force required to break the candy was recorded in kg/cm^2.
2.7.4 Thickness and Diameter
Digital vernier calipers were used to measure the dimensions of candies to ensure uniform size and shape consistency.
2.7.5 Friability Test
Friability was evaluated using Roche friabilator at 25 rpm for 4 minutes to assess resistance to mechanical stress.
2.7.6 Moisture Content Determination
Candies were dried in a hot air oven at 105°C until constant weight was achieved. Moisture content was calculated using weight loss method.
2.7.7 pH Analysis
A solution of candy was prepared in distilled water and pH was measured using a digital pH meter previously calibrated with standard buffer solutions.

2.7.8 Drug Content Analysis
A known quantity of candy was dissolved in suitable solvent, filtered, and analyzed using UV spectrophotometry at specific wavelength for bael extract estimation.
2.7.9 In-Vitro Dissolution Study
Dissolution study was conducted using USP Type II apparatus in phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C. Samples were withdrawn at regular intervals and analyzed spectrophotometrically.
2.7.10 Stability Studies
Formulations were stored under ICH recommended conditions:

- Accelerated condition: 40°C ± 2°C / 75% RH
- Room condition: 25°C ± 2°C / 60% RH

for 3 months. Samples were periodically analyzed for appearance, hardness, drug content, and dissolution behavior.

III. FORMULATION TABLE

Ingredients (mg)	F1	F2	F3	F4	F5
Bael extract	100	150	200	250	300
Isomalt	1200	1200	1200	1200	1200
Glucose syrup	400	400	400	400	400
Gelatin	100	100	100	100	100
Citric acid	20	20	20	20	20
Flavor	q.s	q.s	q.s	q.s	q.s
Water	q.s	q.s	q.s	q.s	q.s

IV. RESULTS AND DISCUSSION

4.1 Preparation and Physical Appearance
All formulated bael fruit anti-diabetic candies (F1–F5) were successfully prepared using the heating and congealing method. The prepared candies were uniform in size, non-sticky (except higher extract batches), and showed good moldability.
It was observed that increasing the concentration of Aegle marmelos extract slightly affected color intensity and texture. Lower concentration batches (F1–F2) were light brown, whereas higher concentrations (F4–F5) produced darker shades due to increased phytoconstituent loading.
Interpretation:
The color change is attributed to the presence of natural tannins and flavonoids, which intensify with increasing extract concentration. However, no phase separation or crystallization was observed, indicating good compatibility between excipients and herbal extract.

4.2 Organoleptic Evaluation
All formulations were evaluated for taste, odor, appearance, and mouthfeel.

- F1–F2: Mild sweetness with weak herbal taste
- F3: Balanced sweetness and acceptable taste masking
- F4–F5: Slight bitterness due to higher extract load

Interpretation:
Formulation F3 showed the best palatability, indicating optimum balance between sweetness and herbal extract concentration. Excess extract in F4 and F5 led to incomplete taste masking despite flavor addition.

4.3 Weight Variation and Uniformity
All batches complied with acceptable pharmacopoeial limits. No significant variation was observed among individual candies.
Interpretation:
Uniform weight indicates proper mixing of molten mass and consistent molding process. This confirms good manufacturing reproducibility.

4.4 Hardness Analysis

Formulation	Hardness (kg/cm²)
F1	3.2
F2	3.8
F3	4.5
F4	5.1
F5	5.5

Trend Observed: Hardness increased with increasing extract concentration.
Interpretation:
The increase in hardness is due to higher solid content of bael extract, which contributes to matrix rigidity. However, excessive hardness in F4–F5 may reduce chewability. F3 exhibited optimum mechanical strength suitable for oral administration.

4.5 Friability Test
All formulations showed friability below 1%, indicating acceptable mechanical strength.
Interpretation:
Lower friability values confirm that candies can withstand handling, packaging, and transportation without significant damage. Slightly lower friability

in higher batches is due to increased compactness of polymeric matrix.

4.6 Moisture Content
Moisture content decreased slightly with increasing extract concentration.
Interpretation:
Reduced moisture improves stability and reduces microbial growth risk. However, very low moisture in F4–F5 may contribute to increased hardness and brittleness.

4.7 Drug Content Uniformity

Formulation	Drug Content (%)
F1	94.1
F2	95.8
F3	98.4
F4	97.2
F5	96.5

Interpretation:
All formulations showed acceptable drug content (90–110%). F3 showed maximum uniformity, indicating better distribution of extract within candy matrix.

4.8 In-Vitro Dissolution Study (KEY DISCUSSION)

Dissolution Profile (Observation)

Time (min)	F1	F2	F3	F4	F5
15	22%	28%	31%	25%	20%
30	40%	48%	56%	44%	39%
45	58%	67%	78%	63%	55%
60	72%	81%	92%	79%	70%

Graph Interpretation (Dissolution Curve Trend)
- F3 showed the highest and most rapid release (~92% at 60 min)
- F1 and F5 showed slower release profiles
- Release rate followed: F3 > F2 > F4 > F1 > F5

Discussion
The improved dissolution in F3 is due to:
- Optimum polymer–extract ratio
- Balanced hardness allowing faster disintegration
- Uniform distribution of bael phytoconstituents
- Adequate hydrophilic matrix formed by gelatin and syrup base

In contrast, F5 showed slower release due to higher extract concentration, which increased matrix density and delayed diffusion of active compounds.

Conclusion from graph behavior:
F3 exhibited a controlled yet efficient release profile, making it the optimized formulation.

4.9 pH Evaluation
All formulations showed slightly acidic pH (5.2–6.0).
Interpretation:
Slight acidity is beneficial for stability of bael phytoconstituents and improves taste masking. No irritation potential is expected at this pH range.

4.10 Stability Study (3 Months)
No significant changes were observed in appearance, hardness, or drug content at both storage conditions.
Observations:
- Slight decrease in moisture content over time
- Minor increase in hardness under accelerated conditions
- Drug content remained within acceptable range (>95%)
- No microbial growth observed

Interpretation:
The formulation is physically and chemically stable. The combination of sugar substitute (isomalt) and gelatin matrix provided good stability against temperature and humidity variations.

4.11 Overall Comparative Evaluation of Formulations

Parameter	Best Performing Batch
Taste	F3
Hardness	F3
Friability	F3–F4
Drug Content	F3
Dissolution	F3
Stability	F3

Final Interpretation:
Formulation F3 is identified as the optimized batch due to balanced mechanical strength, good palatability, high drug content, and maximum dissolution efficiency.

V. CONCLUSION

The present research work successfully focused on the formulation and evaluation of anti-diabetic herbal candy using bael fruit (Aegle marmelos) extract. The study demonstrated that bael fruit, rich in bioactive phytoconstituents such as flavonoids, tannins, coumarins, and alkaloids, can be effectively incorporated into a palatable confectionery dosage form without significant loss of its therapeutic potential.

All prepared formulations (F1–F5) were evaluated for various physicochemical and performance parameters including appearance, weight variation, hardness, friability, moisture content, drug content uniformity, in-vitro dissolution, and stability studies. The results indicated that all formulations were within acceptable limits, confirming good formulation design and process reproducibility. Among all batches, formulation F3 was identified as the optimized formulation based on its superior characteristics such as balanced hardness, excellent taste masking, highest drug content uniformity, and maximum in-vitro drug release. The stability studies further confirmed that the formulation remained physically and chemically stable under both accelerated and room temperature conditions, indicating good shelf-life potential.

The study also highlighted that herbal candy formulation offers several advantages such as improved patient compliance, ease of administration, taste masking of bitter herbal extracts, and suitability for pediatric and geriatric populations. Additionally, the use of bael fruit provides natural anti-diabetic activity, making the formulation a promising alternative or supportive therapy for diabetes management. In conclusion, bael fruit-based anti-diabetic candy represents a novel, safe, and effective herbal dosage form with potential application in functional food and nutraceutical development. Further in-vivo studies and clinical evaluation are recommended to establish its therapeutic efficacy and commercial viability.

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