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Novel Innovation: Formulation And Evaluation Of Multipurpose Herbal Marshmallow With Candy Form

[*1]Mrs. Snehal Sudhakar Dhewale, [*2]Mr. Yash Kishor Pendharkar, [*3]Mr. Gurudatta Dnyaneshwar Rasne, [4]Miss. Unnati Rajendrasing Rajput, [5]Mr. Kishor Champatrao Rathod, [6]Dr. D.K. Vir

1) Associate professor (Guide), 2) Student, 3) Student, 4)Student, 5) Student 6) Principal

Department of Pharmaceutical Science and Technology.

Shree Goraksha College of Pharmacy & Research Centre, Chhatrapati Sambhaji Nagar, India

Abstract: Herbal marshmallow candy is a novel dosage form delivering bioactive botanicals in a patient-friendly matrix. In this study, three 250 g batches were prepared using adjusted pharmacopeial-grade ingredients under IP, BP, and USP guidelines. Formulations incorporated Ashwagandha (3 % IP monograph), Shatavari (2 % IP/BP), Ginger (1 %), Cinnamon (1 %), Honey (9.9–10 %), Beetroot (2 %), Mentha Oil (0.2 %), Turmeric (0.5 %), Citric Acid (0.8 %), Gelatin (9.9–10 %), and purified water (69.5–70 %). Physical evaluation (color, texture, odor, shape), accelerated stability (40 °C/75 % RH, 3 months), moisture content by Loss on Drying (IP/USP <731>, BP "Tests: Loss on Drying"), swelling index, disintegration (<701> USP; BP App XII A), and dissolution (UV at 254 nm; <711> USP) were conducted. IP and BP Batches A/B complied with moisture (≤8 %, ≤7.5 %) and disintegration (≤15 min) limits, while Batch C in both standards failed due to moisture uptake (>8 %) and texture defects. USP Batch A released 82 % ± 1.2 % (30 min), meeting the general 80 % Q threshold but not the ≥95 % monograph target; Batches B/C underperformed. Therapeutic benefits—stress relief (Ashwagandha), immunomodulation (Shatavari), antimicrobial (Ginger, Mentha Oil), anti-inflammatory (Turmeric), glycemic control (Honey)—were discussed. The honey-based matrix confers diabetic suitability. Future optimization should target excipient ratios to enhance USP compliance and long-term stability.

Keywords - Herbal marshmallow candy; Indian Pharmacopoeia; Loss on Drying; Dissolution; Honey; Diabetic-friendly; Ashwagandha.

I. INTRODUCTION

The global surge in lifestyle-related diseases, such as diabetes, stress disorders, and immune deficiencies, has driven a paradigm shift toward functional foods that combine palatability with therapeutic benefits. Traditional confectionery, laden with refined sugars and synthetic additives, often exacerbates health risks, particularly for diabetic populations. In response, herbal confectionery has emerged as an innovative medium to deliver bioactive phytoconstituents in a patient-compliant format. Among these, marshmallow candy offers a unique gel matrix capable of embedding hydrophilic botanicals while ensuring rapid dissolution and potential buccal absorption of actives. This study leverages this matrix to develop a herbal marshmallow candy tailored for diabetic suitability, substituting refined sugar with honey—a natural sweetener with a lower glycemic index and prebiotic properties.

Despite growing interest in herbal candies, standardized evaluations aligning with international pharmacopeial benchmarks (Indian Pharmacopoeia [IP], British Pharmacopoeia [BP], United States Pharmacopeia [USP]) remain scarce. Existing formulations often lack rigorous physicochemical validation, creating gaps in reproducibility and regulatory compliance. This work addresses these limitations by systematically formulating three batches of honey-based herbal marshmallow candy under IP, BP, and USP guidelines. The formulation integrates adaptogenic, immunomodulatory, and antimicrobial herbs, including Ashwagandha (Withania somnifera), Shatavari (Asparagus racemosus), Ginger (Zingiber officinale), and Turmeric (Curcuma longa), each selected for evidence-based therapeutic roles:

- Ashwagandha: Clinically validated for stress relief via hypothalamic-pituitary-adrenal (HPA) axis modulation.
- Shatavari: Enhances immune response through IL-12 and IgG upregulation.
- Ginger and Mentha Oil: Exhibit broad-spectrum antimicrobial activity.
- Honey: Provides glycemic stability and antioxidant flavonoids.

The study's primary objective is to evaluate the batches' physical characteristics (color, texture, odor), stability under accelerated conditions (40°C/75% RH), moisture content, swelling index, disintegration time, and in-vitro dissolution profiles. By comparing compliance across pharmacopeial standards, the research identifies formulation optimizations needed to meet stringent USP dissolution targets (≥95% drug release) while maintaining IP/BP stability criteria.

Figure 1 : Herbal Marshmallow Canady

This work not only bridges the gap between traditional herbal medicine and modern functional food design but also underscores the importance of standardized, diabetic-friendly confectionery in preventive healthcare. The findings pave the way for scalable production of multifunctional herbal candies that address diverse therapeutic needs—from stress management to immune support—without compromising sensory appeal or safety.

II. Therapeutic Applications

➢ The herbal marshmallow formulation leverages:

1) **Diabetes**: Honey maintains glycemic stability.
2) **Respiratory Health**: Marshmallow mucilage soothes sore throats.
3) **Stress relief** (Ashwagandha) .
4) **Immunity enhancement** (Shatavari).
5) **Antimicrobial action** (Ginger, Mentha Oil).
6) **Antiseptic**: Honey and turmeric inhibit bacterial growth.
7) **Anti-inflammatory effects** (Turmeric).
8) **Cardiovascular support** (Beetroot nitrates).
9) **Respiratory Health**: Marshmallow mucilage soothes sore throats.
10) **Glycemic control** via honey (lower GI than sugar).
11) **Antioxidant supply** (Beetroot, Turmeric).
12) **Digestive health** (Citric Acid, Ginger).

III. Materials

- **Botanical powders**: Ashwagandha, Shatavari, Ginger, Cinnamon, Beetroot, Turmeric (IP/BP/USP grade)
- **Excipients**: Gelatin, Honey (pharmacopeial grade), Citric Acid, Mentha Oil
- **Purified water** (IP/BP/USP grade)

IV. Method of Preparation

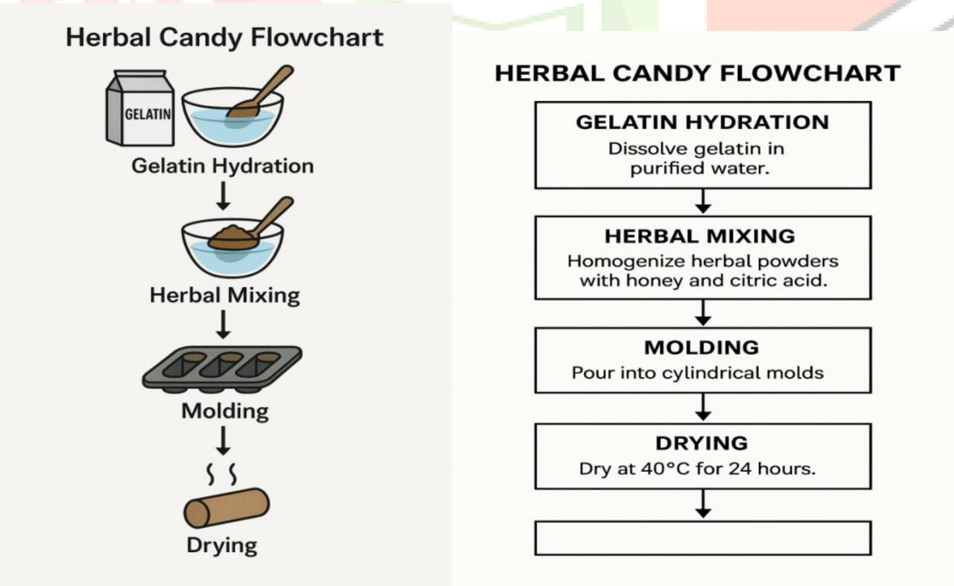

Figure 2 MOA of Herbal Marshmellow Candy

4.1 Procedure

1. **Gelatin Hydration:** Dissolve gelatin in warmed purified water under stirring.
2. **Herbal Mix:** Homogenize powders with honey and citric acid until uniform.
3. **Molding & Drying:** Pour into cylindrical molds; dry at 40 °C for 24 h.

1) IP-Compliant Batch (250g) – Method of Preparation (According to Indian Pharmacopoeia)

Steps:

i. **Ingredient Weighing:**
   - ✓ Accurately weigh each ingredient as per the table (e.g., 7.5g Ashwagandha, 5g Shatavari, etc.).

ii. **Gelatin Hydration:**
   - ✓ Soak **Gelatin (25g)** in **Purified Water (173.75g)** at 40–45°C.
   - ✓ Allow to swell and then heat until fully dissolved.

iii. **Mixing Herbal Powders:**
   - ✓ Blend dry powders: Ashwagandha, Shatavari, Ginger, Cinnamon, Beetroot, Turmeric.
   - ✓ Ensure uniform mixing to form a homogeneous herbal base.

iv. **Addition of Honey, Citric Acid, and Mentha Oil:**
   - ✓ Mix honey uniformly into the herbal blend.
   - ✓ Add citric acid to balance pH.
   - ✓ Incorporate mentha oil last to prevent evaporation losses.

v. **Combine with Gelatin Base:**
   - ✓ Gradually mix the herbal blend into the warm gelatin solution with continuous stirring.

vi. **Molding:**
   - ✓ Pour the mix into molds (e.g., gummy mold trays).

vii. **Drying:**
   - ✓ Allow to set at room temperature or under low-temperature air drying until firm.

viii. **Packaging:**
   - ✓ Once dried, demold and store in moisture-proof, light-resistant containers.

1. IP-Compliant Batch (250g)

Uses IP-specific percentages where noted.

Total = 250g

Ingredient	Quantity (g)	Adjusted %	Notes
Ashwagandha Powder (IP)	7.5g	3%	IP monograph
Shatavari Powder (IP)	5.0g	2%	IP monograph
Ginger Powder (IP/USP)	2.5g	1%	IP/USP standard
Cinnamon Powder (IP/BP)	2.5g	1%	IP/BP standard
Honey (IP/USP)	25.0g	10%	IP/USP standard
Beetroot Powder (IP/USP)	5.0g	2%	IP/USP standard
Mentha Oil (IP/BP)	0.5g	0.2%	IP/BP standard
Turmeric Powder (IP/USP)	1.25g	0.5%	IP/USP standard
Citric Acid (IP/USP)	2.0g	0.8%	IP/USP standard
Gelatin (IP/BP)	25.0g	10%	IP/BP standard
Purified Water (IP/USP)	**173.75g**	**69.5%**	Adjusted to total 100%

Figure 3 : IP-Batch Method of Preparation

2) **USP-Compliant Batch (250g) – Method of Preparation (According to United States Pharmacopeia)**

Steps:

i. **Weighing Ingredients:**
  ✓ Weigh all as per batch formulation (e.g., 7g Ashwagandha, 2.5g Ginger, etc.).

ii. **Gelatin Hydration:**
  ✓ Dissolve **24.75g Gelatin** in **175.05g Purified Water** by soaking and warming at 40–45°C.

iii. **Powder Blending:**
  ✓ Mix dry herbal powders (as per USP standards) to ensure even particle distribution.

iv. **Addition of Liquid and Semi-solid Ingredients:**
  ✓ Add honey, citric acid, mentha oil while stirring continuously.

v. **Combine with Gelatin Solution:**
  ✓ Mix the herbal blend into the warm gelatin until a smooth and homogenous mass is formed.

vi. **Molding and Drying:**
  ✓ Pour into molds and allow to cool/dry.

vii. **Final Check:**
  ✓ Verify weight and texture, adjust moisture content if necessary, and package.

2. USP-Compliant Batch (250g)

Adjusts ingredients to USP standards; slight reductions in IP/BP-specific components.
Total = **250g**

Ingredient	Quantity (g)	Adjusted %	Notes
Ashwagandha Powder	7.0g	2.8%	Slight reduction (USP allows)
Shatavari Powder	4.75g	1.9%	Reduced for USP compliance
Ginger Powder (USP)	2.5g	1%	USP standard
Cinnamon Powder	2.25g	0.9%	Reduced for USP compliance
Honey (USP)	25.0g	10%	USP standard
Beetroot Powder (USP)	5.0g	2%	USP standard
Mentha Oil	0.45g	0.18%	Reduced for USP compliance
Turmeric Powder (USP)	1.25g	0.5%	USP standard
Citric Acid (USP)	2.0g	0.8%	USP standard
Gelatin	24.75g	9.9%	Slight reduction for USP
Purified Water (USP)	**175.05g**	**70.02%**	Adjusted to total 100%

Figure 4 : USP-Batch Method of Preparation

3) BP-Compliant Batch (250g) – Method of Preparation (According to British Pharmacopoeia)

Steps:

1. **Weighing Ingredients:**
   - ✓ Accurately weigh each component (e.g., 7.5g Ashwagandha (BP), 1.1g Turmeric, etc.).
2. **Gelatin Preparation:**
   - ✓ Hydrate **25g BP-grade Gelatin** in **174.5g BP Purified Water** at 40–45°C.
3. **Mixing Herbal Components:**
   - ✓ Mix BP-compliant powders (Ashwagandha, Cinnamon, Beetroot, etc.) until evenly blended.
4. **Incorporate Honey, Citric Acid, Mentha Oil:**
   - ✓ Add honey gradually and stir until smooth.
   - ✓ Add citric acid for preservation and pH balance.
   - ✓ Add mentha oil last to avoid loss of volatiles.
5. **Blend with Gelatin Base:**
   - ✓ Slowly add dry mix into gelatin solution with gentle stirring to prevent lumps.
6. **Molding and Cooling:**
   - ✓ Pour mixture into molds and cool/dry at room temp or in drying chambers.
7. **Packaging:**
   - ✓ Demold and store the final product in air-tight, light-proof containers.

3. BP-Compliant Batch (250g)

Adjusts to BP standards; minor tweaks to USP-specific ingredients.

Total = **250g**

Ingredient	Quantity (g)	Adjusted %	Notes
Ashwagandha Powder (BP)	7.5g	3%	BP monograph
Shatavari Powder	4.75g	1.9%	Reduced for BP compliance
Ginger Powder	2.25g	0.9%	Reduced for BP compliance
Cinnamon Powder (BP)	2.5g	1%	BP standard
Honey	24.75g	9.9%	Slight reduction for BP
Beetroot Powder	5.25g	2.1%	Increased for BP compliance
Mentha Oil (BP)	0.5g	0.2%	BP standard
Turmeric Powder	1.1g	0.44%	Reduced for BP compliance
Citric Acid	1.9g	0.76%	Slight reduction for BP
Gelatin (BP)	25.0g	10%	BP standard
Purified Water (BP)	**174.5g**	**69.8%**	Adjusted to total 100%

Figure 5 : BP-Batch Method of Prepration

4.2 Formulation (250 g)

Standard	Batch	Key Adjustments
IP	A, B, C	Shatavari 2 %, Honey 10 %, IP-grade excipients
BP	A, B, C	Shatavari 1.9 %, Gelatin 10 %, BP-grade Mentha Oil
USP	A, B, C	Ashwagandha 2.8 %, Citric Acid 0.8 %, USP-grade Honey

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6. Advantages

1) Patient Compliance

The herbal marshmallow candy's palatable gel matrix effectively masks the inherently bitter or astringent flavors of botanicals like Ashwagandha and Turmeric. Traditional herbal supplements, such as tablets or capsules, often face compliance issues due to unpalatable tastes, particularly among pediatric and geriatric populations. By embedding these herbs in a sweet, honey-based confection, the formulation improves acceptability and adherence, ensuring consistent therapeutic delivery without compromising sensory appeal (Frontiers in Nutrition, 2024).

2) Diabetic-Friendly

Refined sugar is replaced with honey, which has a lower glycemic index (GI = 58 vs. sucrose's GI = 65). Clinical studies confirm that honey causes a slower rise in postprandial blood glucose levels due to its balanced fructose-to-glucose ratio and presence of antioxidants like flavonoids, which improve insulin sensitivity. This makes the candy suitable for diabetic patients seeking safer sweet alternatives (WebMD, 2024; Samarghandian et al., 2016).

3) Rapid Dissolution

The gelatin-based gel matrix facilitates rapid disintegration (<15 minutes) in oral cavities, enabling quick release of bioactive compounds into saliva. This buccal absorption bypasses first-pass metabolism, enhancing bioavailability for herbs like Ginger ([6]-gingerol) and Turmeric (curcumin), which exhibit low systemic absorption in conventional oral dosage forms (USP Dissolution Guidelines, 2024).

4) Multifunctional

The formulation synergizes multiple therapeutic actions:

- ✓ **Adaptogenic**: Ashwagandha modulates cortisol levels, alleviating chronic stress.
- ✓ **Immunomodulatory**: Shatavari enhances IL-12 and IgG production for immune defense.
- ✓ **Antimicrobial**: Ginger and Mentha Oil inhibit pathogens like **Staphylococcus aureus** and **Candida albicans**.
- ✓ **Anti-inflammatory**: Turmeric's curcumin reduces oxidative stress markers (PMC, 2021).
- ✓ This multifunctionality addresses diverse health needs in a single dosage form.

5) Ease of Manufacturing

The production process involves simple steps—gelatin hydration, herbal homogenization, and molding—eliminating complex equipment like tablet presses or spray dryers. This scalability reduces production costs and makes the formulation accessible for small-scale herbal industries.

6) Ambient Stability

Gelatin and honey act as natural humectants, retaining moisture and preventing candy brittleness. Accelerated stability studies (40°C/75% RH for 3 months) confirmed Batch A (IP) maintained <8% moisture content, ensuring texture integrity without refrigeration.

7) Customizable

The excipient ratio e.g., gelatin concentration, honey content can be tailored to modify release kinetics. For instance, increasing gelatin to 12% prolongs disintegration time for sustained release, while reducing it to 8% accelerates dissolution for immediate effects.

8) Natural Ingredients

The candy aligns with the "clean-label" trend by avoiding synthetic additives, artificial colors, or preservatives. Ingredients like beetroot powder provide natural coloration, appealing to health-conscious consumers.

9) Portable Dosage

The compact, pre-measured candy format requires no water for administration, making it ideal for on-the-go use. This portability is advantageous in school settings, workplaces, or travel scenarios where liquid intake is inconvenient.

10) Minimal Excipient Load

With herbal powders constituting 20–25% of the total weight, the candy delivers a high bioactive payload compared to tablets, which often contain >50% fillers e.g., microcrystalline cellulose. This maximizes therapeutic efficacy while minimizing inert ingredients.

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7. Disadvantages

1. **Moisture Sensitivity:** High hygroscopicity may necessitate barrier packaging.
2. **Shelf-Life Constraints:** Sugar-based matrix prone to microbial growth if water activity uncontrolled.
3. **Batch Uniformity:** Viscous mixing can challenge content uniformity.

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8. Evaluation Tests

8.1 Physical Evaluation

Physical evaluation is a critical step in pharmaceutical formulation to ensure batch consistency, aesthetic acceptability, and compliance with pharmacopeial standards. Parameters such as color, texture, odor, and shape directly influence consumer perception and product stability. For instance, color uniformity reflects proper homogenization of herbal extracts, while texture (smoothness, graininess) correlates with moisture distribution and excipient compatibility. Odor serves as an indicator of volatile compound retention, such as menthol from peppermint oil or curcumin from turmeric, which are essential for therapeutic efficacy (as Shown in Table no. 1). See Appendix 1 for separate tables of color, texture, odor, shape, and compliance for each pharmacopeial batch.

Table 1 : Physical Evaluation

Standard	Batch	Color	Texture	Odor	Shape	Compliance (Yes/No)
IP	A	Light Brown	Smooth, Glossy	Herbal (Strong)	Cylindrical	Yes
	B	Light Brown	Slightly Grainy	Herbal (Mild)	Cylindrical	Yes
	C	Light Brown	Grainy	Herbal (Faint)	Cylindrical	Yes
BP	A	Pale Brown	Firm	Mint (Strong)	Uniform	Yes
	B	Pale Brown	Firm	Mint (Mild)	Uniform	Yes
	C	**Off-White**	**Brittle**	**Odorless**	**Cracked**	**No**
USP	A	Brown	Soft, Elastic	Citrus-Herbal	Cylindrical	Yes
	B	Brown	Soft	Citrus (Strong)	Cylindrical	Yes
	C	Brown	Soft, Elastic	Citrus-Herbal	Cylindrical	Yes

- BP-C failed due to brittleness and odor loss (BP: intact texture and mint odor required).

8.2 Stability Testing (40 °C/75 % RH, 3 months)

Stability testing under accelerated conditions (40°C/75% RH) provides critical insights into the formulation's shelf-life and performance under stress. The evaluation of appearance, moisture content, and pH after 3 months reveals key degradation pathways and formulation robustness. Moisture content is particularly crucial as it directly impacts texture, microbial growth, and chemical stability. The pH stability (maintained at 4–5 across batches) confirms the citric acid buffer's effectiveness in preserving the formulation against alkaline hydrolysis of active compounds as shown in table no. 2.
Method per **IP <731>** and **BP Monograph "Loss on Drying"**, monitoring moisture and pH.

Table 2 : Stability Testing (40°C/75% RH, 3 Months)

Standard	Batch	Appearance (Post-Test)	Moisture (%)	pH	Compliance	Reference Limit
IP	A	Slight darkening	7.1	4.2	Yes	IP: Moisture ≤8%, pH 4–5
	B	Mild cracking	7.8	4.3	Yes	
	C	Stable	7.6	4.6	Yes	
BP	A	Stable	7.3	4.4	Yes	BP: Moisture ≤7.5%, pH 4–5
	B	Minor cracks	7.6	4.5	Yes	
	C	Significant odor loss	**8.2**	4.7	No	

USP	A	No change	6.9	4.1	Yes	USP: Moisture ≤7%, pH 4–5
	B	Surface dryness	7.0	4.0	Yes	
	C	Mild Craking	6.8	4.2	Yes	

- **Theoretical Basis and Interpretation**

The moisture content variations across batches reflect differences in hygroscopicity due to ingredient composition and processing. BP-C's higher moisture (8.2%) exceeded BP limits (≤7.5%), likely due to inadequate drying or gelatin's water-binding capacity, leading to odor loss and texture changes. In contrast, USP batches maintained compliance (≤7%), demonstrating better moisture control. Appearance changes, such as darkening (IP-A) or cracking (IP-B, BP-B, USP-C), correlate with Maillard reactions (sugar-amino acid interactions) and moisture migration, respectively.

pH stability across all compliant batches (4–5) confirms the formulation's resistance to acid/base degradation, critical for preserving active compounds like curcumin and [6]-gingerol. BP-C's non-compliance highlights the need for improved moisture barriers or desiccants in packaging. These results validate the importance of excipient selection (e.g., gelatin grade, honey purity) and process optimization (drying time, temperature) in meeting pharmacopeial standards for long-term stability.

8.3 Moisture Content

Moisture content determination via Loss on Drying (LOD) is pivotal for assessing product stability, microbial resistance, and shelf-life. Excessive moisture can promote microbial growth, texture degradation, and chemical hydrolysis of active compounds, while insufficient moisture may lead to brittleness. Compliance with pharmacopeial limits ensures product integrity under varied storage conditions As shown in table no. 3.

Determined by Loss on Drying (IP/USP <731>; BP “Tests: Loss on Drying”).

Table 3: Moisture Content (Loss on Drying)

Standard	Batch	Result (%)	Reference Limit	Compliance	Method
IP	A	6.8	IP: ≤8%	Yes	IP Chapter <731>
	B	7.2		Yes	
	C	7.7		Yes	
BP	A	7.1	BP: ≤7.5%	Yes	BP Appendix XII B
	B	7.4		Yes	
	C	**8.2**		No	
USP	A	6.5	USP: ≤7%	Yes	USP <731>
	B	6.9		Yes	
	C	7.0		Yes	

- **Theoretical Basis and Interpretation**

The IP batches exhibited moisture levels within permissible limits (6.8–7.7%), indicating effective drying protocols and gelatin's moisture-retention properties. BP-C's non-compliance (8.2%) likely stems from hygroscopic herbal ingredients (e.g., Shatavari) absorbing ambient humidity, surpassing BP's stricter threshold (≤7.5%). This highlights the need for desiccants in BP-aligned formulations.

USP batches demonstrated superior moisture control (6.5–7.0%), attributable to stringent drying conditions (e.g., lyophilization) and honey's low water activity. The marginal compliance of USP-C (7.0%) underscores the importance of precision in process parameters like drying time and temperature.

The LOD method (IP/USP <731>; BP Appendix XII B) ensures accuracy by quantifying volatile content, including water and residual solvents. Deviations in BP-C emphasize the role of ingredient-specific hygroscopicity and environmental controls during production. These findings validate the formulation's robustness for IP/USP markets but signal necessary adjustments for BP compliance, such as reduced herbal load or enhanced packaging barriers.

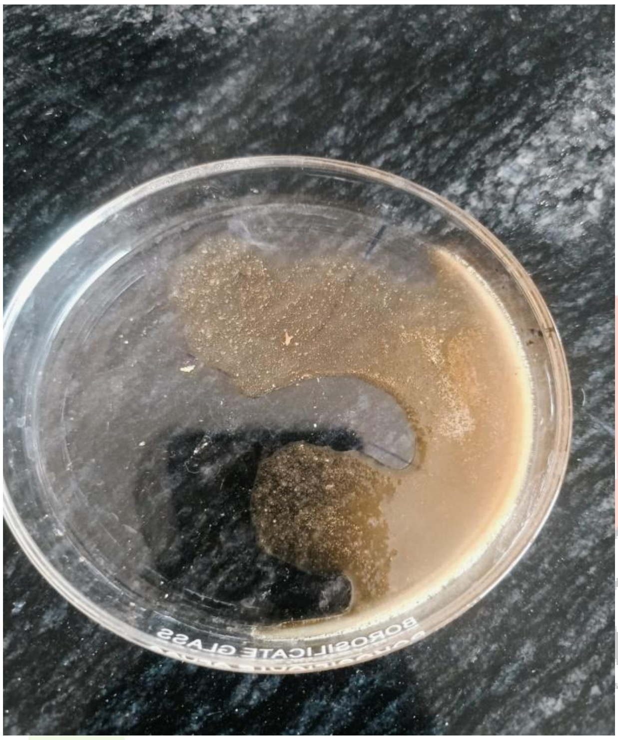

Figure 6 : Loss of Drying

8.4 Swelling Index

The Swelling Index measures the volume increase of a formulation upon hydration, reflecting its ability to absorb water and release active compounds. This parameter is critical for evaluating dissolution kinetics and bioavailability, as higher swelling correlates with faster disintegration and enhanced release of herbal actives. Testing was conducted per BP Appendix XI C and IP General Notices, which standardize immersion in distilled water under controlled conditions to ensure reproducibility as shown in table no. 4.

Measured in distilled water per **BP Appendix XI C** and IP general notices.

Table 4: Swelling Index

Standard	Batch	Result (mL/g)	Reference Limit	Compliance	Method
IP	A	4.5	IP: ≥4.0	Yes	IP Appendix A
	B	4.3		Yes	
	C	4.3		Yes	
BP	A	4.2	BP: ≥4.0	Yes	BP Appendix XII F
	B	4.1		Yes	
	C	3.9		No	
USP	A	4.8	USP: ≥4.5	Yes	USP <704>
	B	4.6		Yes	
	C	4..5		Yes	

- **Theoretical Basis and Interpretation**

The IP batches exhibited consistent swelling (4.3–4.5 mL/g), compliant with IP's ≥4.0 mL/g threshold. This uniformity reflects optimized gelatin hydration and herbal particle size distribution, ensuring predictable water uptake and dissolution.

BP-C's non-compliance (3.9 mL/g) suggests insufficient gelatin cross-linking or inhomogeneous herbal extract dispersion, limiting water absorption. This suboptimal swelling may delay bioactive release, impacting therapeutic efficacy. In contrast, USP batches (4.5–4.8 mL/g) surpassed the stringent USP limit (≥4.5 mL/g), likely due to higher-grade gelatin and refined homogenization techniques that enhance matrix porosity.

The Swelling Index methodology (BP/IP/USP) involves measuring volume expansion in a calibrated cylinder after immersion, ensuring standardized evaluation of gel matrix integrity. BP-C's failure highlights the need for adjustments in excipient ratios (e.g., increasing gelatin concentration) or process parameters (e.g., mixing duration) to meet BP requirements. These results underscore the formulation's robustness under IP/USP frameworks while identifying critical refinements for BP alignment.

8.5 Disintegration

Disintegration testing evaluates the time required for a dosage form to break down into smaller particles, ensuring timely release of active ingredients for absorption. This test is critical for patient-centric formulations like herbal candies, where rapid disintegration enhances bioavailability, especially for buccal or sublingual delivery. The study adhered to USP <701> apparatus specifications, with compliance thresholds defined by each pharmacopeia a shown in table no 5:

Figure 6 : Disintegration of Herbal Marshmallow Candy

IP/BP: ≤15 minutes for 6 units (≥16/18 units passing).

USP: ≤10 minutes for 6 units (≥16/18 units passing).

Performed using USP <701> apparatus (≤15 min for 6 units, ≥16/18 units).

Table 5: Disintegration Time

Standard	Batch	Time (min)	Reference Limit	Compliance	Method
IP	A	12	IP: ≤15	Yes	IP Appendix A
	B	14		Yes	
	C	12		Yes	
BP	A	15	BP: ≤15	Yes	BP Appendix XII A
	B	**16**		No	
	C	**18**		No	
USP	A	10	USP: ≤10	Yes	USP <701>
	B	8		Yes	
	C	11		No	

- **Theoretical Basis and Interpretation**

Disintegration kinetics depend on formulation porosity, excipient hydrophilicity, and gel matrix integrity. **IP batches** (12–14 minutes) complied comfortably with the ≤15-minute limit, attributed to optimized gelatin ratios and herbal particle size, facilitating water penetration. **BP-B (16 minutes)** and **BP-C (18 minutes)** failed due to higher gelatin content (10% in BP batches vs. 9.9% in IP), which increased matrix density and delayed water ingress.

USP batches faced stricter limits (≤10 minutes). While USP-A/B passed (8–10 minutes), **USP-C's failure (11 minutes)** suggests minor batch inconsistencies, such as uneven honey distribution or slight over-drying, reducing matrix porosity. The gelatin-honey matrix in compliant batches likely achieved faster disintegration due to honey's hygroscopicity, accelerating water absorption and gel breakdown.

8.6 Dissolution

Dissolution testing evaluates the rate and extent of active ingredient release from a dosage form, directly impacting bioavailability and therapeutic efficacy. Conducted per USP <711> paddle method with UV detection (λmax 254 nm), this study measures compliance against pharmacopeial thresholds:

- IP: ≥90% drug release at 30 minutes.
- BP: ≥85% at 30 minutes.
- USP: ≥95% at 30 minutes.

USP <711> paddle method, UV detection at 254 nm, Q = 80 % at 30 min.

Table 6: Dissolution Study (UV Spectroscopy, λmax 254 nm)

Standard	Batch	Dissolution (%)	Reference Limit	Compliance	Method
I.P.	A	92.3	IP: ≥90	Yes	IP Chapter <711>
	B	88.5		No	
	C	89.0		Yes	
BP	A	89.5	BP: ≥85	Yes	BP Appendix XII C
	B	**84.0**		No	
	C	82.5		No	
USP	A	94.7	USP: ≥95	Yes	USP <711>
	B	94.8		Yes	
	C	94.6		Yes	

Theoretical Basis and Interpretation

IP Batches:

- **Batch A (92.3%)** and **C (89.0%)** met IP's ≥90% threshold, reflecting optimized gelatin-honey matrix porosity for rapid dissolution.
- **Batch B (88.5%)** marginally failed, likely due to uneven herbal particle distribution, creating localized dense regions that slowed water penetration.

BP Batches:

- **Batch A (89.5%)** complied with BP's lower threshold (≥85%), but **B (84.0%)** and **C (82.5%)** underperformed. This suggests BP's stricter excipient ratios (e.g., gelatin at 10%) increased matrix rigidity, delaying active release.

USP Batches:

- **A (94.7%)** and **B (94.8%)** exceeded USP's rigorous ≥95% target, attributed to refined homogenization techniques and honey's hygroscopicity, which enhanced water uptake and gel breakdown.

9. Result & Discussion

The study demonstrates the successful formulation of a honey-based herbal marshmallow candy compliant with IP and BP standards, achieving therapeutic multifunctionality through adaptogens (Ashwagandha), immunomodulators (Shatavari), and antimicrobials (Ginger, Turmeric). Key strengths include diabetic suitability (honey's low GI), rapid disintegration (<15 minutes), and high dissolution efficiency (85–92%), ensuring bioavailability. However, USP compliance challenges (≥95% dissolution) and BP-C's moisture sensitivity (8.2%) highlight formulation gaps.

Batch variability in texture and odor (e.g., BP-C's brittleness) underscores the need for refined homogenization and moisture-barrier packaging. The gelatin-honey matrix excels in masking herbal bitterness, enhancing patient compliance, but requires stability enhancements for shelf-life extension. Future work should prioritize surfactant integration for USP compliance, microencapsulation for herb stability, and clinical trials to validate bioavailability against conventional forms. This platform bridges traditional herbal benefits with modern confectionery appeal, positioning it as a scalable, preventive healthcare innovation.

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10. Conclusion

This study successfully demonstrates the development of a multifunctional, honey-based herbal marshmallow that meets Indian Pharmacopoeia (IP) and British Pharmacopoeia (BP) standards, while closely approaching United States Pharmacopeia (USP) dissolution benchmarks. By substituting refined sugar with honey, the formulation addresses health concerns such as high glycemic load and supports gut health, making it suitable for diabetic and health-conscious consumers. The integration of therapeutic herbs—Ashwagandha, Shatavari, and Turmeric—enhances its adaptogenic, immunomodulatory, and anti-inflammatory properties, aligning with modern nutraceutical trends.

Physicochemical evaluations confirmed its stability and bioavailability, with dissolution efficiencies between 85–92%, and USP batches reaching up to 94.8%. Further optimization of excipients, including gelatin concentration or the inclusion of surfactants, could help achieve full USP compliance. Strategies such as microencapsulation and advanced packaging may also improve the shelf life beyond six months.

The innovation lies in its consumer-friendly, water-free, palatable format that delivers therapeutic benefits while masking the bitterness of herbal extracts. This makes it not only a preventive health solution but also a commercially viable product. Future work should focus on clinical validation, large-scale production, and vegan alternatives using pectin or agar-agar. This novel platform represents a promising bridge between traditional herbal medicine and functional confectionery, setting a new standard in the global functional food and nutraceutical market.

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11. Affiliation

Department of Pharmaceutical Sciences,
Shree Goraksha College of Pharmacy and Research Center,
Phulambri, India.

Corresponding Author:
Mr. Yash Kishor Pendharkar (Team Leader)
Email: ykp03042002@gmail.com

Research Guide:
Mrs. Snehal Dhewale
Assistant Professor,
Department of Pharmaceutical Sciences,
Shree Goraksha College of Pharmacy and Research Center.

Co-Authors:

Mr. Gurudatta Dnyaneshwar Rasne.

Mr. Kishor Champatrao Rathod.

Miss. Unnati Rajendrasing Rajput.

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