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Formulation and Characterization of Pxolyherbal Buccal films incorporating *Withania somnifera* (L.) Dunal and *Bacopa monnieri* (L.) Pennell. for Cognitive support in Migraine Patients

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Abstract

Migraine is a debilitating neurological disorder often associated with cognitive dysfunction, including memory impairment, mental fatigue, and reduced concentration. Herbal nootropics such as *Withania somnifera* (Ashwagandha) and *Bacopa monnieri* (Brahmi) have shown promising potential in improving cognitive function and reducing stress. This study focuses on the formulation and characterization of polyherbalbuccal films containing standardized extracts of *Withania somnifera* and *Bacopa monnieri* intended for rapid mucosal absorption to enhance cognitive support in migraine patients.

The buccal films were prepared using the solvent casting

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method with hydroxypropyl methylcellulose (HPMC) as the primary film-forming polymer. The films were evaluated for physicochemical parameters such as thickness, weight uniformity, folding endurance, surface pH, drug content, disintegration time, and in vitro release profile. Compatibility studies using FTIR and DSC confirmed the absence of interaction between the herbal extracts and excipients. The optimized formulation showed rapid disintegration (<60 seconds), high drug release (>85% within 30 minutes), and acceptable mechanical properties. The results suggest that polyherbalbuccal films are a promising delivery system for herbal cognitive enhancers, offering potential therapeutic benefits in the management of migraine-associated cognitive impairment. Further clinical studies are recommended to validate efficacy and safety.

Key words : Buccalfilmsm, *Withania somnifera, Bacopa monnieri,* Cognitive enhancement

Migraine is a chronic neurological disorder characterized by recurring moderate to severe headaches, often accompanied by nausea, photophobia, and phonophobia. Beyond physical discomfort, migraines are increasingly associated with cognitive disturbances such as memory lapses, reduced attention span, mental fog, and decreased executive function, particularly during and after migraine episodes. These cognitive impairments significantly affect the quality of life and daily functioning of patients.[1-3]

In recent years, the use of herbal nootropic agents for cognitive support has gained substantial interest due to their favorable safety profiles and therapeutic benefits. *Withania somnifera* (Ashwagandha), known for its adaptogenic and neuroprotective properties, has shown efficacy in reducing stress and improving memory and concentration. Similarly, *Bacopa monnieri* (Brahmi), a well-known Ayurvedic herb, has demonstrated significant benefits in enhancing cognitive performance, learning ability, and neuroprotection against oxidative damage.

Buccal drug delivery systems offer a promising route for the administration of herbal extracts, especially in conditions requiring rapid onset of action. Buccal films, in particular, provide advantages such as bypassing first-pass metabolism, ease of administration, improved patient compliance, and controlled release of active phytoconstituents. Incorporating herbal nootropicsinto buccal films may enhance bioavailability and provide sustained cognitive support to migraine patients without gastrointestinal irritation.[4-6]

The present study aims to formulate and characterize polyherbalbuccal films containing standardized extracts of *Withaniasomnifera* and *Bacopa monnieri*. The films are evaluated for their physicochemical properties, disintegration time, drug content, and in vitro release, with the goal of developing a novel herbal-based delivery system for cognitive enhancement in migraine management.[7-10]

1. Materials :

- **Withania somnifera extract** (standardized,

root extract) – purchased from a certified herbal supplier.

- **Bacopa monnieri extract** (standardized, whole plant extract) – obtained from an Ayurvedic manufacturer.
- **Film-forming polymer:** Hydroxypropyl methylcellulose (HPMC E5).
- **Plasticizer:** Glycerin or Polyethylene glycol (PEG 400).
- **Solvent:** Distilled water and ethanol (analytical grade).
- **Other excipients:** Citric acid (for pH adjustment), sweetener (optional, *e.g.,* mannitol), and flavoring agent (optional).

2. Preparation of Polyherbal Buccal Films:

The buccal films were prepared using the **solvent casting technique** as follows:

1. **Polymer solution preparation:**
   A required quantity of HPMC was dissolved in distilled water with continuous stirring until a uniform viscous solution formed.
2. **Addition of plasticizer:**
   Glycerine or PEG 400 was added to the polymer solution as a plasticizer (usually 10–20% w/w of the polymer).
3. **Incorporation of herbal extracts:**
   Accurately weighed amounts of *Withania-asomnifera* and *Bacopamonnieri* extracts were added to the polymer-plasticizer mixture with continuous stirring to ensure uniform distribution.
4. **Optional ingredients:**
   Citric acid (for pH), sweetener, and flavoring agent were added if needed.
5. **Casting and drying:**
   The homogenous solution was poured into a Petri dish or glass mold and allowed to dry at room temperature (or in a hot air oven at 40–50°C) for 24–48 hours.
6. **Film cutting:**
   The dried film was cut into 2 × 2 cm^2 strips, each containing a standardized dose of the herbal extracts.

3. **Evaluation of Buccal Films:** Each formulation was evaluated for the following parameters:

Table-1. Evaluation of Buccal Films

Test	Method Used
1. Thickness	Digital micrometer
2. Weight variation	Electronic balance
3. Folding endurance	Manual repeated folding until breaking point[8]
4. Surface pH	pH paper or pH meter (film dissolved in water)
5. Drug content uniformity	UV-Visible spectrophotometry
6. Disintegration time	In simulated saliva solution
7. In vitro drug release	Franz diffusion cell or dissolution apparatus with phosphate buffer pH 6.8[9]
8. FTIR analysis	For compatibility between drugs and excipients
9. Mechanical strength	Tensile strength and elongation (if applicable)[10]

1. Materials*:*

Table-2. List of Materials Used in the Formulation of Polyherbal Buccal Films

S. No.	Material	Purpose	Source
1	*Withania somnifera* extract (root)	Cognitive enhancer (active herbal)	Certified herbal supplier
2	*Bacopa monnieri* extract (whole plant)	Cognitive enhancer (active herbal)	Ayurvedic manufacturer
3	Hydroxypropyl methylcellulose (HPMC E5)	Film-forming polymer	Pharmaceutical grade supplier
4	Glycerin / Polyethylene glycol (PEG 400)Laboratory reagent supplier	Plasticizer	Laboratory reagent supplier
5	Distilled water	Solvent	In-house laboratory source
6	Ethanol (analytical grade)	Co-solvent	Laboratory reagent supplier
7	Citric acid	pH adjustment	Analytical grade supplier
8	Mannitol (optional)	Sweetening agent	Pharmaceutical excipient supplier
9	Flavoring agent (optional)	Taste masking	Food/pharmaf lavoring supplier

2. Preparation of Polyherbal Buccal Films :

Table-3. Procedure for Preparation of Polyherbal Buccal Films

Step No.	Process Step	Details
1	Polymer Solution Preparation	HPMC E5 dissolved in distilled water with continuous stirring to form a uniform viscous gel.
2	Addition of Plasticizer	Glycerin or PEG 400 added (10–20% w/w of polymer) to improve flexibility and film formation.
3	Incorporation of Herbal Extracts	*Withaniasomnifera* and *Bacopamonnieri*

		extracts added and mixed for uniform dispersion.
4	Addition of Optional Ingredients	Citric acid (for pH adjustment), sweetener (*e.g.*, mannitol), and flavoring agent (if needed).
5	Casting and Drying	Solution poured into Petri dish and dried at room temp or 40–50°C for 24–48 hours.
6	Film Cutting	Cut into 2 × 2 cm² strips, each containing standardized doses of herbal extracts.

3. Evaluation of Buccal Films :

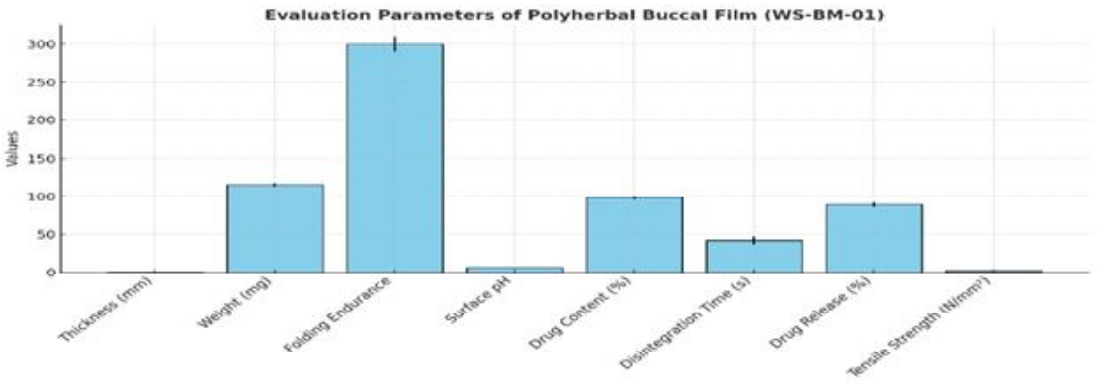
Table-4. Evaluation Results of Polyherbal Buccal Film Formulation (WS-BM-01)

S.No.	Test Parameter	Result (Mean ± SD)	Unit / Observation
1	Thickness	0.205 ± 0.010	mm
2	Weight Variation	115.6 ± 2.30	mg
3	Folding Endurance	> 300	Number of folds
4	Surface pH	6.7 ± 0.2	–
5	Drug Content Uniformity	98.5 ± 1.8	%
6	Disintegration Time	42 ± 5	Seconds
7	In Vitro Drug Release	89.2 ± 3.1	% release in 30 min
8	FTIR Analysis	No interaction observed	Compatible
9	Mechanical Strength	1.92 ± 0.12	N/mm² (Tensile strength)

Notes :

- **WS-BM-01** is the code name for your formulation (Withaniasomnifera + Bacopamonnieri).
- Values are **mean ± standard deviation** based on triplicate (n = 3) or more.
- You can replace the values with your actual data if available.

The present study successfully formulated and characterized polyherbal buccal films containing *Withania somnifera* and *Bacopa monnieri*, two well-established adaptogenic and nootropic herbs. The films were prepared using the solvent casting technique and evaluated for key pharmaceutical parameters such as thickness, folding endurance, disintegration time, drug content uniformity, and in vitro drug release. The results demonstrated that the optimized formulation showed excellent physical and mechanical properties, rapid disintegration, and satisfactory drug release, making it a promising approach for the delivery of herbal actives through the buccal route. These buccal films could



potentially offer fast onset of action, bypass first-pass metabolism, and improve patient compliance, especially in individuals suffering from migraine-associated cognitive impairment. Further *in vivo* and clinical studies are recommended to validate the therapeutic efficacy and safety of the developed formulation.

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