INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Research Article

Dual Action Herbo-Modern Orodispersible Delivery System For Migraine Management Through Hormonal And Neurological Modulation

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ARTICLE INFO

Published: 12 Sept. 2026
Keywords:
Migraine, Polycystic Ovary Syndrome (PCOS), Or dispersible Strips (ODS), Orodispersible Film, Herbo-Modern Drug Delivery System, Sumatriptan, Myo-Inositol, Ashwagandha, Withania somnifera, Hormonal Balance, Neurological Balance, Rapid Drug Release, Solvent Casting Method, Phytochemical Screening, Drug Delivery System, Patient Compliance
DOI:
10.5281/zenodo.22724056

ABSTRACT

Migraine is a common neurological disorder characterized by recurrent episodes of severe headache, often associated with nausea, photophobia & phonophobia. Hormonal and metabolic disturbances, particularly those associated with conditions such as Polycystic Ovary Syndrome (PCOS), may contribute to the occurrence and severity of migraine. Conventional oral antimigraine therapy may be associated with delayed onset of action, gastrointestinal disturbances, and poor patient compliance during acute attacks. The present study was therefore undertaken to develop a dual-action herbo-modern or dispersible delivery system (ODS) for migraine management through hormonal and neurological modulation. The formulation combines Sumatriptan, a selective 5-HT1B/1D receptor agonist used for rapid relief of migraine, with Myo-inositol for supporting hormonal and metabolic balance and Ashwagandha (Withania somnifera) extract for its adaptogenic and neuroprotective potential. Ashwagandha root extract was prepared and subjected to preliminary phytochemical screening. The active ingredients were incorporated into an orodispersible film using HPMC E50, maltodextrin, glycerol, crospovidone, stevia, citric acid, peppermint oil, and distilled water. The films were prepared by the solvent casting method and subsequently evaluated for various physicochemical and mechanical parameters. The prepared strips exhibited a smooth, translucent, flexible and uniform appearance without visible air bubbles. The formulation showed a weight variation of 102 ± 2 mg, surface pH of 6.7 ± 0.2, folding endurance of 80 ± 2 folds, and tensile strength of 2.9 ± 0.3 N/mm². The strips demonstrated rapid disintegration within 24 ± 2 seconds, with 98.6 ± 1.4% content uniformity and moisture content of 3.1 ± 0.4%. These findings indicate satisfactory formulation characteristics and suitability for fast-dissolving oral delivery. Thus, the developed herbo-modern ODS provides a promising patient-friendly platform combining rapid migraine relief with supportive hormonal and neurological modulation.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Further in-vivo and clinical studies are required to establish its therapeutic efficacy and safety.

INTRODUCTION

The increasing prevalence of hormonal imbalances and neurological disorders such as migraine demands innovative therapeutic solutions that are accessible to a diverse population. Polycystic ovary syndrome (PCOS) and migraine are common, often comorbid disorders that share metabolic, endocrine and neurochemical deregulations notably insulin resistance, altered steroidogenesis, and disturbances in neuronal excitability and neurotransmitter balance. A therapeutic strategy that simultaneously targets hormonal dysregulation and neuronal hyperexcitability could therefore provide synergistic clinical benefits for patients experiencing both PCOS and migraine.

Migraine is a complex neurological disorder characterized by recurrent episodes of severe headache often accompanied by nausea, photophobia, and phonophobia. Beyond a mere pain condition, migraine is now recognized as a neurovascular and hormonal imbalance disorder, frequently influenced by fluctuations in estrogen and stress-related neurotransmitters such as serotonin. The condition disproportionately affects women, particularly during hormonal transitions like menstruation and menopause, illustrating the intricate crosslink between the endocrine and nervous systems. Effective management, therefore, requires a therapeutic approach that addresses both hormonal and neurological dimensions.

Globally, migraine represents a substantial health burden. According to the Global Burden of Disease (GBD) 2021 data, approximately 1.16 billion people are affected by migraine worldwide, marking a 58% increase in prevalence since 1990. The World Health Organization (WHO, 2024) reports that headache disorders affect about 40% of the global population, or roughly 3.1 billion individuals, making migraine one of the most common neurological illnesses. Recent analyses rank migraine as the third leading cause of disability-adjusted life years (DALYs) among neurology-related diseases, underscoring its significant socioeconomic impact. High-burden countries such as India, China, and the United States report the greatest number of disability-adjusted life years lost due to migraine, reflecting both its global prevalence and its role as a leading cause of neurological disability.

Despite the availability of several pharmacological options—including triptans such as Sumatriptan, ergot derivatives, and CGRP antagonists—limitations such as delayed onset of oral therapy, gastrointestinal disturbances during migraine attacks, recurrence of symptoms, and inadequate long-term relief persist. These issues have spurred interest in integrative pharmacotherapy combining modern drugs with herbal actives that possess adaptogenic, anti-inflammatory, and neuroprotective properties. Herbal formulations such as CXCTS have demonstrated migraine-relieving effects through modulation of neurotransmitters (5-HT and β-endorphin) and vasoactive peptides (CGRP, endothelin-1). Systematic reviews also identify botanicals like feverfew, curcumin, coriander, chamomile, and menthol as promising prophylactic and symptomatic anti-migraine agents.

The present project, titled “Dual Action Herbo-Modern Orodispersible Delivery System for Hormonal and Neurological Balance,” is designed to develop a novel orodispersible strip formulation for migraine therapy. This dual-action concept merges the rapid therapeutic action of modern

pharmacological agents with the harmonizing benefits of herbal components that target both hormonal and neurological axes. The use of an orodispersible delivery system ensures faster onset of action, enhanced bioavailability, and improved patient compliance—especially critical for rapid relief during acute migraine episodes.

This integrated Herbo-Modern approach aligns with the current shift toward personalized and holistic medicine, aiming to create a delivery platform that not only alleviates immediate symptoms but also stabilizes underlying hormonal and neural dysregulation. By bridging traditional healing wisdom with modern drug delivery science, this project seeks to offer an innovative, evidence-based solution for sustainable migraine management.

Oral Route

The oral route is one of the most preferred routes of drug administration as it is more convenient, cost effective, and ease of administration lead to high level of patient compliance. The oral route is problematic because of the swallowing difficulty for pediatric and geriatric patients who have fear of choking. Patient convenience and compliance oriented research has resulted in bringing out safer and newer drug delivery systems. Recently, fast dissolving drug delivery systems have started gaining popularity and acceptance as one such example with increased consumer choice, for the reason of rapid disintegration or dissolution, self-administration even without water or chewing.

Oro-dispersible strips

Orodispersible strips, commonly referred to as orodispersible films (ODFs) or orally dissolving films (ODFs), represent an innovative advancement in oral drug delivery systems. These ultra-thin, flexible polymeric films, typically measuring 10-100 micrometers in thickness, are formulated to disintegrate or dissolve rapidly on the tongue or buccal mucosa within 30 seconds without requiring water or chewing. This patient-centric design addresses key challenges in traditional dosage forms like tablets and capsules, particularly for populations such as pediatrics, geriatrics, and those with dysphagia, by eliminating the risk of choking and enhancing compliance.

The concept of ODFs originated from non-medicinal products like breath fresheners, with Pfizer's Listerine Pocket Packs marking an early commercial entry in the late 1990s, followed by therapeutic applications such as Chloraseptic Relief Strips for sore throat relief. Over the past two decades, pharmaceutical companies have leveraged transdermal film technology to develop ODFs for systemic drug delivery, transitioning them from over-the-counter (OTC) products to prescription medications. Today, ODFs are recognized by regulatory bodies like the European Medicines Agency (EMA) as a distinct dosage form, defined by their ability to disintegrate in less than 30 seconds in less than 4 mL of saliva.

Mechanism of Action

When an orodispersible strip is placed on the tongue, the moisture from saliva immediately hydrates the surface of the strip, causing it to adhere to the mucosa. The hydrophilic film-forming polymers such as HPMC, PVA, PVP, or pullulan rapidly absorb saliva, soften, and begin to dissolve. As hydration continues, the polymer matrix undergoes dissolution and erosion, often aided by plasticizers that enhance flexibility and allow quicker penetration of saliva. In some formulations, added superdisintegrants further accelerate film break-up. As the strip dissolves within seconds, the drug is uniformly released into the saliva either in dissolved or dispersed form.

From here, a portion of the drug is absorbed directly through the buccal or sublingual mucosa, enabling partial bypass of first-pass metabolism and producing a rapid onset of action. The remaining saliva–drug mixture is swallowed and absorbed through the gastrointestinal tract by conventional mechanisms. Overall, the fast hydration, rapid film dissolution, immediate drug release, and partial mucosal absorption together contribute to the quick therapeutic effect of orodispersible strips.

Furthermore, the incorporation of Sumatriptan into an orodispersible strip system may overcome limitations associated with conventional oral tablets, particularly delayed gastric emptying during migraine attacks. Rapid disintegration and absorption through oral mucosa may provide quicker therapeutic onset, improved bioavailability, and enhanced patient convenience during acute episodes accompanied by nausea or vomiting.

Influence of Modern Lifestyle, Diet, and Environmental Stress

Lifestyle stress, poor diet quality, and environmental toxins are major contributors to hormonal dysregulation and mental imbalance. Sedentary behavior, high glycemic food intake, disrupted sleep cycles, and exposure to endocrine-disrupting chemicals (such as bisphenol A and phthalates) contribute to impaired hormonal synthesis and neurotransmitter imbalance. Chronic stress activates the hypothalamic–pituitary–adrenal (HPA) axis, resulting in elevated cortisol levels that dysregulate sex hormones and serotonin production, thereby linking endocrine instability with neurological manifestations such as migraine, anxiety, or depression. Urban living conditions further amplify these effects through air pollution, light pollution, and reduced physical activity, fostering a psychosomatic environment that predisposes individuals to both hormonal and neural dysfunction.

Limitations of Conventional Therapies

Conventional therapies for hormonal and neurological conditions typically rely on synthetic hormones, antidepressants, anxiolytics, or triptans. While effective for acute management, these therapies often have limitations related to side effects, poor tolerability, dependency potential, and low long-term compliance. For example, synthetic estrogen and progesterone therapies can cause fluid retention, weight gain, or thrombotic events, whereas neurological medications like selective serotonin reuptake inhibitors (SSRIs) and benzodiazepines are associated with withdrawal symptoms, sedation, and gastrointestinal distress. Triptans, although effective for migraine, exhibit variable absorption, delayed onset, and contraindications in cardiovascular patients. Consequently, there is a pressing need for holistic, multi-targeted interventions that mitigate hormonal and neurochemical imbalance without provoking systemic toxicity.

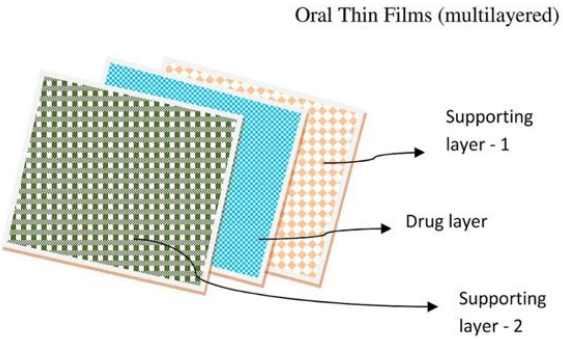
Dual-Action Herbo-Modern concept

Integrating herbal and modern pharmacological approaches provides a promising solution for comprehensive management of hormonal and neurological disorders. Herbal adaptogens such as Withania somnifera (Ashwagandha), Bacopa monnieri (Brahmi), and Curcuma longa (Turmeric) have demonstrated capabilities to regulate stress hormones, modulate serotonin and dopamine pathways, and enhance neuroplasticity. Concurrently, modern actives such as Sumatriptan deliver targeted pharmacological relief from acute migraine episodes through selective agonistic action on 5-HT1B/1D serotonin receptors, resulting in cranial vasoconstriction and inhibition of pro-inflammatory neuropeptide release. A dual-

action herbo-modern system leverages synergistic interactions between natural bioactives and conventional drugs for potentiated efficacy, reduced dose requirements, and minimized side effects. This approach aligns with the emerging focus on personalized, integrative medicine that treats the mind–body axis rather than isolated symptoms.

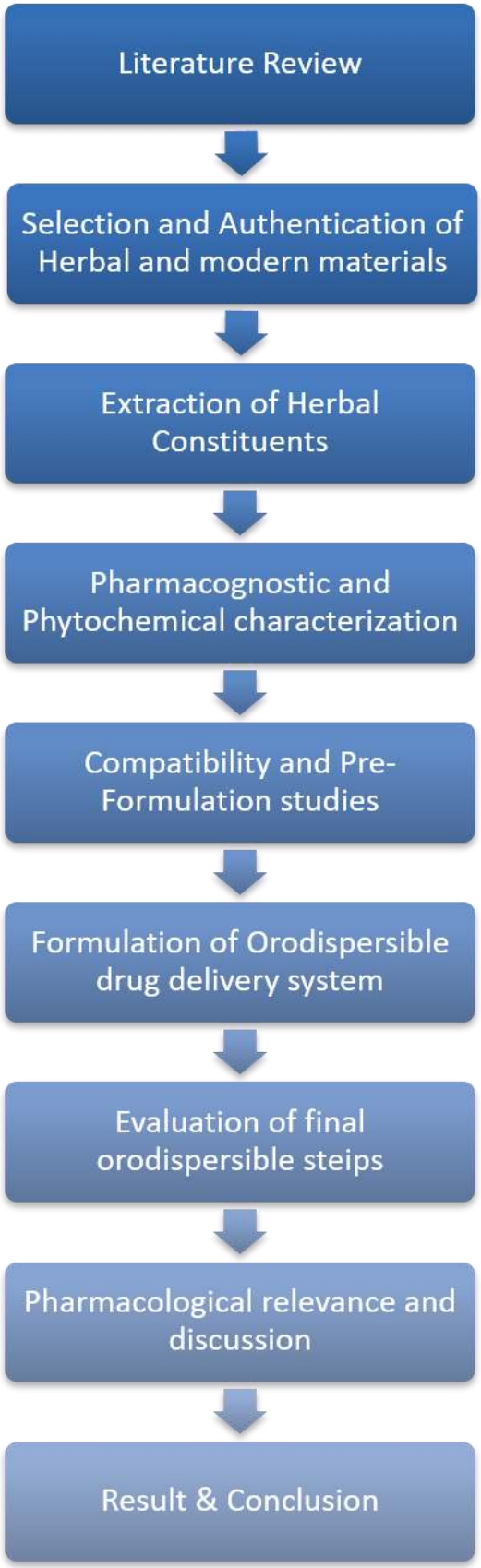
Rationale for Orodispersible Delivery System

The choice of an orodispersible delivery system further enhances the therapeutic potential of this dual-action model. Orodispersible strips (ODS) provide rapid onset of action, easy administration without water, and bypass of first-pass hepatic metabolism, ensuring higher bioavailability. This route is ideal for migraine and neurological conditions, where quick relief is essential during acute episodes. The rapid dissolution of the strip may also enhance the onset of action of Sumatriptan by promoting faster pre-gastric absorption and reducing delays associated with gastric stasis commonly observed during migraine attacks. Additionally, ODS formulations improve patient compliance, especially in populations facing difficulty swallowing tablets during nausea or severe headaches—common in migraine patients. The fast-dissolving matrix also enables combination therapy of herbal bioactives and modern antimigraine agents in a single dosage form, contributing to synergistic therapeutic action, rapid symptom relief, and improved patient adherence.



Figer No-1

3. PLAN OF WORK:



4. AIMS AND OBJECTIVES

Aim:

To develop a dual-action herbo-modern or dispersible delivery system (ODS) for migraine management by combining standardized herbal extracts with Sumatriptan to achieve rapid therapeutic action, improved bioavailability, enhanced patient compliance, and supportive modulation of hormonal and neurological imbalance associated with migraine.

Objective:

- To identify and select suitable herbal and modern actives known for their synergistic effects on hormonal regulation and neurological stability.
- To extract, standardize, and characterize the selected herbal ingredients using phytochemical and instrumental analysis.
- To perform pre-formulation and compatibility studies between herbal actives, modern agents, and film-forming polymers.
- To formulate orodispersible strips using suitable polymers, plasticizers, superdisintegrants, and flavoring agents for rapid disintegration.
- To develop optimized dual-action ODS formulations that ensure uniformity, stability, and efficient drug loading.
- To evaluate the formulated ODS for physicochemical, mechanical, and performance parameters such as thickness, tensile strength, folding endurance, pH, disintegration time, and drug release profile.
- To assess the therapeutic relevance of combining herbal and modern actives for dual-action neuro-hormonal balance.
- To compare the optimized formulation with conventional oral dosage forms in terms of onset of action, release profile, and patient convenience.
- To compile results, analyze findings, and establish the feasibility of using ODS as a fast-acting, patient-friendly delivery system for hormonal and neurological wellness.

Benefits:

1. Faster onset of action
2. Dual therapeutic action
3. Improved patient compliance
4. Enhanced Bioavailabilty
5. Better Stability
6. Reduced side effects

5. DRUG PROFILE

Active Pharmaceutical Ingredients (API)

1. Myo-Inositol

Category: Nutraceutical, Insulin sensitizer, Hormonal modulator

Molecular Formula: $C_6H_{12}O_6$

Molecular Weight: 180.16 g/mol

Description: White crystalline powder, sweet in taste

Solubility: Highly soluble in water

Mechanism of Action:

I. Acts as a second messenger in insulin signaling → improves insulin sensitivity.
II. Restores hormonal balance by regulating FSH/LH ratio.
III. Supports ovarian function and reduces androgen excess.
IV. Helps neurological balance via serotonin pathway modulation.

Therapeutic Role in Formulation:

- Regulates menstrual cycle
- Supports fertility
- Improves mood, reduces anxiety
- Balances insulin resistance and hormonal dysregulation

Dose Range in ODS: Typically 100–500 mg per strip (depending on strip thickness)

2. Sumatriptan

Category: Antimigraine agent, Selective serotonin (5-HT1B/1D) receptor agonist, Triptan class

Molecular Formula: $C_{14}H_{21}N_3O_2S$

Description: White to off-white crystalline powder

Solubility: Freely soluble in water

Mechanism of Action:

i. Selectively stimulates 5-HT1B and 5-HT1D serotonin receptors in cranial blood vessels.

ii. Produces cranial vasoconstriction, thereby relieving migraine headache.

iii. Inhibits the release of pro-inflammatory neuropeptides such as calcitonin gene-related peptide (CGRP).

iv. Reduces transmission of pain signals within the trigeminal nerve pathway.

v. Provides rapid relief from migraine-associated symptoms including nausea, photophobia, and phonophobia.

Therapeutic Role:

- Provides rapid relief from acute migraine attacks
- Reduces headache intensity and duration
- Alleviates associated symptoms such as nausea and sensitivity to light/sound
- Improves patient comfort and functional ability during migraine episodes
- Enhances effectiveness when delivered through rapid-release systems such as Orodispersible strips (ODS)

Herb: Ashwagandha

Common Name – Ashwagandha ,Indian Ginseng, Winter cherry

Botanical Name – *Withania Somnifera*

Kingdom – Plantae **Division** –. Magnoliophyta **Class** – Magnoliopsida **Order**- Solanales

Genus- Withania

Species- *W. somnifera*

Family – Solanaceae

History

Ashwagandha, often referred to as "Indian ginseng," has been used in Ayurvedic medicine for over 3,000 years. The name "Ashwagandha" translates to "smell of a horse," indicating that the herb imparts strength and vitality. Historically, it was used as a rasayana (rejuvenator), believed to promote longevity, vitality, resistance to stress, and overall well-being.

The plant is native to India, the Middle East, and parts of Africa. It is a small woody shrub with dull green leaves, yellow-green flowers, and bright red berries enclosed in papery husks. Traditionally, its

roots have been most valued for medicinal use, though leaves and berries also possess therapeutic properties.

Over centuries, Ashwagandha became popular for its role in managing stress, anxiety, inflammation, insomnia, and reproductive health. Today, it is widely studied for its adaptogenic, antioxidant, anxiolytic, and immunomodulatory properties, and is used globally in nutraceuticals and herbal formulations.

Characteristics

Here are the basic characteristics of the Neem trees-

These are deep rooted, long trees that can grow on different soils easily. Neem trees have medicinal and fungicidal properties.It is one of the fastest growing trees that can reach up to 100 ft of height.The flowers of the Neem trees are white and bisexual in nature.Neem trees are drought resistant.

Chemical Constituents

Table no .01

Withanolides	**Alkaloids**	**Steroidal Lactones**	**Saponins**
Withanolide A Withanolide D Withanolide G Withanone Withaferin A 12-Deoxywithastramonolide Withasomidienone Withanosides I–X Withanoside IV Withanoside V Withanoside VI	Withanine Somniferine Tropine Pseudotropine Anaferine Cuscohygrine Isopelletierine Ashwagandhine	Ergostane-type steroids 5-Dehydroxywithanolides Withanolide glycosides	Sitoindoside VII Sitoindoside VIII Sitoindoside IX Sitoindoside X Acyl steryl glucosides
Amino acids & Organic compounds	**Flavonoids & Phenolic compounds**	**Carbohydrates**	**Fatty acids**
Tryptophan Tyrosine Alanine Glycine Cysteine	Kaempferol Quercetin Catechins Phenolic acids	Starch Reducing sugars	Oleic acid Palmitic acid Linoleic acid

Therapeutic Uses

- Management of stress, anxiety, depression
- PCOS/PMS support (reduces cortisol-driven hormonal imbalance)
- Enhances fertility and reproductive health
- Improves memory, focus, and cognitive functions
- Supports thyroid function, especially hypothyroidism
- Boosts energy, stamina, and physical endurance
- Helps in insomnia and sleep quality improvement
- Reduces inflammation and joint pain.

ASHWAGANDHA ROOT EXTRACTION

- **METHOD USED:** Cold extraction
- **SOLVENT:** ETHANOL AND DISTILLED WATER (POLAR SOLVENT)
- **BOILING POINT:** 78 °C & 100 °C
- **TIME:** 5-7 HOURS

- **PROCEDURE:**
- The dried Ashwagandha roots are thoroughly cleaned to remove dirt and foreign matter.
- The cleaned roots are coarsely powdered using a grinder without generating excess heat.
- The powdered material is moistened with a small quantity of distilled water or hydro-alcoholic solvent to facilitate pressing.
- The moistened mass is transferred into a cold press or hydraulic press.
- Mechanical pressure is applied gradually at room temperature (below 40°C) to express the extract.
- The expressed liquid extract is collected and filtered through muslin cloth or filter paper to remove solid residues.
- The filtrate is concentrated under reduced pressure using a rotary evaporator or air-dried at room temperature to obtain a cold-pressed Ashwagandha extract.
- The extract is stored in an airtight container under refrigeration until further use

Figure no -02 Extraction setup for Ashwagandha roots Extra

PHYTOCHEMICALS CONSTITUENTS SCREENING TESTS FOR ASHWAGANDHA ROOT EXTRACTION

Phytochemical screening of Ashwagandha (Withania somnifera) root extract is carried out to identify the major bioactive groups responsible for

its adaptogenic, stress-relieving, and hormonal-balancing activities. The extract obtained after Soxhlet extraction is subjected to the following qualitative tests:

Table no-02

TEST FOR ALKALOIDS		
TEST	**PROCEDURE**	**OBSERVATION**
Mayer's Test	1 ml of extract + 2–3 drops of Mayer's reagent.	Formation of cream-colored precipitate → **Presence of alkaloids.**
Wagner's Test	1 ml extract + 2–3 drops Wagner's reagent	Reddish-brown precipitate → **Alkaloids present**
Drangendroff's Test	1 ml extract + 2–3 drops Dragendorff's reagent	Orange-brown precipitate → **Alkaloids confirmed**
TEST FOR CARBOHYDRATES		
Molisch's Test	2 ml extract + 2 drops Molisch's reagent + add conc. H_2SO_4 along the wall.	Violet ring at interface → **Carbohydrates present**
Benedict's Test	1 ml extract + 2 ml Benedict's reagent → boil for 2 minutes.	Brick-red precipitate → **Reducing sugars present**
TEST FOR SAPONINS		
Foam Test	2 ml extract + 5 ml distilled water → shake vigorously for 30 seconds	Stable persistent foam (10–15 min) → **Saponins present.**
TESTS FOR PHENOLIC COMPOUNDS & TANNINS		
Ferric Chloride Test	1 ml extract + 2–3 drops of 5% $FeCl_3$ solution.	Blue-green/black coloration → **Phenolics or tannins present.**
Lead Acetate Test	1 ml extract + 2 ml of 10%	White precipitate → **Tannins present**

	lead acetate solution.	
TESTS FOR STEROIDS / TRITERPENOIDS		
Salkowski Test	2 ml extract + 2 ml chloroform + add conc. H_2SO_4 along the wall	Reddish-brown color at interface → **Steroids present**
Liebermann–Burchard Test	2 ml extract + 2 ml acetic anhydride + conc. H_2SO_4 dropwise	lue-green or emerald green color → **Triterpenoids present.**
TEST FOR FLAVONOIDS		
Shinoda Test	1 ml extract + a small piece of magnesium ribbon + 2–3 drops conc. HCl.	Pink/red coloration → **Flavonoids present.**
Alkaline Reagent Test	1 ml extract + 2 ml 10% NaOH → then add dilute HCl.	Yellow color turning colorless → **Flavonoids confirmed.**
TEST FOR GLYCOSIDES		
Keller–Killiani Test (Cardiac glycosides)	1 ml extract + 1 ml glacial acetic acid + 1 drop $FeCl_3$ → add conc. H_2SO_4.	Brown ring at interface → **Glycosides present.**
Borntrager's Test (Anthraquinone glycosides)	2 ml extract + 2 ml dilute H_2SO_4 → boil → cool → add chloroform → add ammonia.	Pink/red color in ammoniacal layer → **Glycosides present.**
TEST FOR PROTEINS / AMINO ACIDS		
Biuret Test	2 ml extract + 2 ml Biuret reagent.	Violet coloration → **Proteins present.**
Ninhydrin Test	1 ml extract + 2–3 drops of 1% ninhydrin	Blue/purple color → **Amino acids present.**

	→ boil for 1–2 minutes	

Excipients Profile

HPMC (Hydroxypropyl Methylcellulose)

Role: Film former

Description: Off-white, odorless polymer

Solubility: Swells in water; soluble in hot water

Function in ODS:

Primary polymer forming the strip structure

Provides strength, flexibility, and smooth surface

Controls drug release & disintegration

Maltodextrin

Role: Co-film former / Bulk agent

Description: White, free-flowing powder

Solubility: Freely soluble in water

Function:

Improves film uniformity

Provides bulk and mechanical strength

Enhances quick dissolution of strip

Glycerol

Role: Plasticizer

Appearance: Clear, viscous liquid

Solubility: Miscible with water

Function:

Imparts flexibility to the strip

Prevents cracking and brittleness

Enhances softness and mouthfee

Crospovidone

Role: Superdisintegrant

Appearance: White or creamy hygroscopic powder

Solubility: Insoluble in water but swells rapidly

Function:

Promotes rapid saliva uptake

Helps the strip break instantly on the tongue

Reduces disintegration time significantly.

Stevia

Role: Natural sweetener

Appearance: White to off-white powder

Solubility: Soluble in water

Function:

Masks bitterness of herbal actives

Provides pleasant sweetness without calories

Suitable for diabetic or insulin-sensitive users

Citric Acid

Role: Saliva stimulator / Acidulant

Appearance: White crystalline powder

Solubility: Freely soluble in water

Function:

Enhances saliva secretion → speeds disintegration

Improves taste and provides slight tanginess

Adjusts micro-environmental pH for better drug stability

Peppermint Oil (Flavoring Agent)

Role: Flavor / Aroma enhancer

Description: Clear, aromatic essential oil

Solubility: Insoluble in water

Function:

Improves patient acceptability

Provides cooling, refreshing sensation

Masks herbal odor of Ashwagandha

Distilled Water

Role: Solvent / Vehicle

Function:

Used for dissolving polymers and actives

Carries excipients uniformly during casting

Ensures purity and prevents contamination.

Table no -03 Phytochemical Analysis: phytochemical analysis report

NAME OF PHYTOCHEMICALS	ASHWAGANDHA ROOT EXTRACTION
Alkaloid test	-
Carbohydrate test	-
Saponins test	-
Flavonoid	+
Anthocyanin and Betacyanin test	+
Quinones	+
Glycosides test	-
Cardiac glycosides test	-
Terpenoids test	+
Phenols	-
Acids	+
Tannins	-

Key: **Detected: +** **Not Detected: -**

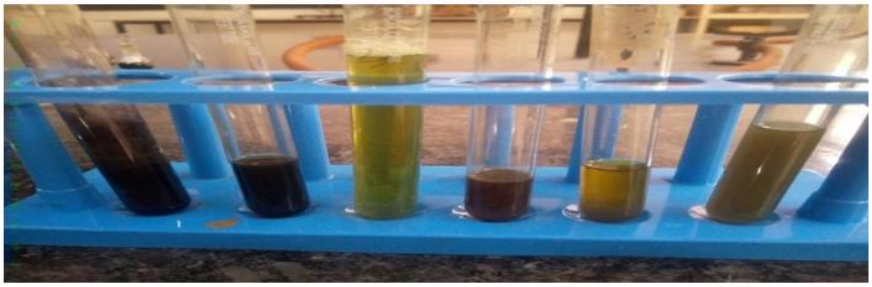


Figure No-03 Phytochemical Constituents Screening Tests for Ashwagandha root extract

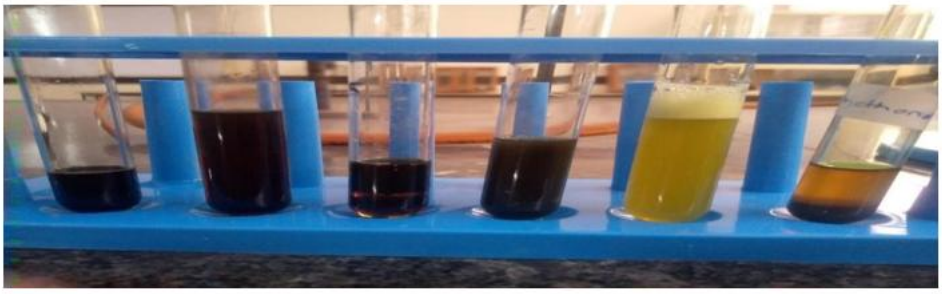


Figure No -04 Phytochemical Constituents Screening Tests for Ashwagandha root extract.

6. MATERIALS AND APPARATUS

- Beakers
- Glass rods
- Soxhlet apparatus
- Mortar & Grinder
- Heating Mantle
- Water Bath
- Volumetric flask
- Measuring cylinder
- Mechanical stirrer
- Muslin cloth
- Silver foil paper
- Whatmann paper
- Funnel
- Tripod stand
- Weighing machine
- Test tubes
- Test tubes stand
- Bunsen burner
- Burette
- Pipette
- pH meter
- Volumetric cyclinders
- Soap mould rectangular shape
- Labels,covers,marker

7. INGREDIENTS

- Sumatriptan
- Myoinositol
- Ashwagandha
- HPMC (Hydroxypropyl methylcellulose)
- Maltodextrin
- Glycerol
- Crospovidone
- Stevia
- Citric acid
- Peppermint oil
- Distilled water

8. FORMULATION TABLE

Table No -04 the formulation of Oro-dispersible strips is formulated with the required quantity of Ingredients given above in table.

INGREDIENTS	QUANTITY TAKEN (FOR 20 STRIPS)	USE
Myo-inositol	1g	Improves insulin sensitivity, ovarian function
Sumatriptan	0.50 g	Reduces stress, improves hormonal balance
Ashwagandha extract	0.20 g	Adaptogen, lowers cortisol, balances mood
HPMC E50	2.7 g	Primary film former
Maltodextrin	0.90 g	Co-film former, improves mouthfeel
Glycerol	0.90 g	Provides elasticity
Crospovidone	0.15 g	Rapid disintegration
Stevia	0.03 g	Improves taste/ sweetner
Citric acid	0.7 g	Improves saliva flow
Peppermint oil	0.1g/ 2 drops	Cooling & taste masking
Distilled water	q.s. / 40-60 mL	To make castable solution

9. METHOD OF PREPARATION

Step 1: Preparation of Polymer Base

- Accurately weigh HPMC E50 and Maltodextrin.
- In a clean beaker, add 20-40 mL of distilled water and start gentle stirring.
- Slowly sprinkle HPMC into the water to avoid lump formation.
- Allow the polymer to hydrate for 10-20 minutes until a clear viscous gel forms.
- Add Maltodextrin and continue stirring for an additional 10 minutes.

Step 2: Addition of Plasticizer

- Add Glycerol to the hydrated polymer base.
- Mix continuously to obtain a smooth and uniform polymer-plasticizer solution.

Step 3: Incorporation of Active Ingredients

- In a separate small beaker, dissolve/suspend the APIs—Myo-inositol, Sumatriptan, and Ashwagandha extract—in a small quantity of water.
- Gently add the API mixture into the polymer base with continuous stirring.

- Continue stirring for 15–20 minutes to ensure uniform dispersion.

Step 4: Addition of Excipients

- Add Crospovidone gradually and mix until uniformly dispersed.
- Add Stevia and mix thoroughly.
- Add Citric acid to enhance saliva stimulation and taste.
- Add Peppermint oil dropwise while stirring to ensure complete aroma dispersion.

Step 5: Final Homogenization

- Adjust the final volume using distilled water depending on required viscosity.
- Homogenize the mixture using a magnetic stirrer for 30 minutes to achieve a smooth casting solution.
- Allow the solution to stand for 15 minutes to remove entrapped air bubbles.

Step 6: Casting the ODS Film

- Pour the prepared solution onto a clean, leveled glass/Petri dish/plastic casting plate.
- Spread uniformly using a film applicator to maintain consistent thickness.
- Dry the film at 40–45°C in a hot-air oven or at room temperature overnight.
- Once dried, carefully peel the film from the surface.

Step 7: Cutting and Packaging

- Cut the dried film into 3 × 5 cm strips using a clean cutter blade.
- Store the finished strips in airtight aluminum pouches to prevent moisture absorption.
- Label and pack the strips for further evaluation and testing.

10. EVALUATION TEST PROCEDURES:

1. Appearance and surface uniformity

To assess the physical appearance, surface characteristics, and uniformity of the prepared orodispersible strips.

Method :

Strips were visually inspected under normal light.

Parameters observed:

- Colour
- Transparency
- Smoothness
- Presence of air bubbles
- Cracks or surface irregularities

Acceptance Criteria:

Strips should be smooth, uniform, flexible, and free from visible defects.

2. Weight Variation

To Assess uniformity of mass of individual strips.

Sample size: 20 strips.

Equipment: Analytical balance (sensitivity ±0.1 mg).

Procedure: Tare weigh boats; weigh each strip individually and record weight (g or mg).Calculate mean weight.

Calculations: Mean weight = ΣWi / 20 % Deviation of each strip = [(Wi − Mean) / Mean] × 100

Acceptance criteria: At least 18 of 20 strips within ±5% of mean; none >±10%.

3. Surface pH

To Ensure neutral/acceptable pH to avoid oral irritation.

Sample size: 3 strips.

Equipment/Reagents: pH meter (calibrated), 5 mL distilled water, glass beakers.

Procedure: Place one strip in 5 mL distilled water; allow to equilibrate for 5 minutes at 25–37 °C.

Measure pH with calibrated pH electrode, record. Repeat for 3 strips.

Acceptance criteria:

Surface pH between 5.5–7.5 (approx. neutral); adjust if too acidic/alkaline (taste or mucosal irritation concerns).

1. Folding Endurance

To Evaluate mechanical flexibility (resistance to breaking when folded).

Sample size: 3 strips.

Procedure: Fix one end of a strip between thumb and forefinger and repeatedly fold at the same point until crack or break occurs. Count number of folds to failure. Repeat for 3 strips and report mean ± SD.

Acceptance criteria: Folding endurance >100 folds (a typical target — confirm acceptable value for your polymer system).

2. Tensile Strength and % Elongation

Measure film strength and extensibility.

Sample size: 5 strips.

Equipment: Texture analyzer or Universal Testing Machine (UTM) with film grips; digital calipers for dimensions.

Procedure: Cut specimens to standard size (e.g., 30 mm length × 10 mm width). Measure thickness (t) and width (w). Record initial gauge length L0 (e.g., 20 mm).

Clamp specimen in grips, apply tensile force at 5 mm/min until break. Record Fmax (N) and extension at break (ΔL, mm). Repeat for 5 specimens.

Calculations:

Cross-sectional area A = width (mm) × thickness (mm).

Tensile Strength:

$$\text{Tensile Strength} = \frac{\text{Force at break}}{\text{Cross-sectional area}}$$

% Elongation:

$$\%\text{Elongation} = \frac{\text{Increase in length}}{\text{Original length}} \times 100$$

Acceptance criteria: Tensile strength and elongation within desired ranges for flexibility and handling (e.g., TS 5–40 MPa; % elongation 10–50% depending on polymer).

6. Disintegration Time

To determine the time required for the strip to disintegrate in the oral cavity.

Sample size: 5 strips

Equipment: USP dissolution apparatus (Type II – Paddle),

UV/Visible spectrophotometer or HPLC.

Procedure: Dissolution was performed in 900 mL phosphate buffer pH 6.8 at 37 ± 0.5°C. Paddle

speed was maintained at 50 rpm. Samples were withdrawn at 5, 10, and 15 minutes and analyzed.

Acceptance Criteria: ≤ 30–60 seconds for standard ODS. Rapid and complete drug release (>80% within 15 min)

7. Content Uniformity

Sample Size:10 strips

Equipment: UV spectrophotometer / HPLC**,** Volumetric flasks

Procedure : Each strip was dissolved in a suitable solvent. The solution was filtered and analyzed for: Myo-inositol**,** Sumatriptan, Withanolides (Ashwagandha marker)

Calculation:

$$\%\text{Drug Content} = \frac{\text{Measured amount}}{\text{Label claim}} \times 100$$

Acceptance Criteria:

85–115% of labelled claim

8. Moisture Content

Sample Size: 3 strips

Equipment: Hot air oven / Karl Fischer titrator, Desiccator

Procedure (LOD Method): Strips were weighed and dried at 105°C until constant weight was obtained.

Calculation:

$$\%\text{Moisture Content} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Acceptance Criteria: Low moisture content (<5%)

11. RESULT:

The Formulated Oro-dispersible strips showed satisfactory physiochemical and mechanical properties. The strips were smooth, flexible, and uniform in appearance with acceptable weight variation and surface pH. Folding endurance and tensile strength indicated good mechanical stability. Rapid disintegration time confirmed suitability for oral fast-dissolving delivery. Content uniformity and moisture content were found within acceptable limits, indicating uniform drug distribution and good stability characteristics.

Table No -05

SR.NO.	EVALUATION PARAMETER	RESULT
1	Appearance and surface uniformity	Smooth, Translucent , flexible strips with uniform surface and no air bubbles
2	Weight variation	102 ± 2 mg
3	Surface pH	6.7 ± 0.2
4	Folding endurance	80 ± 2 folds
5	Tensile strength	2.9 ± 0.3 N/mm^2

6	Disintegration time	24 ± 2 sec
7	Content uniformity	98.6 ± 1.4 %
8	Moisture Content	3.1 ± 0.4 %

12. CONCLUSION:

The present research successfully achieved the formulation and development of a dual-action herbo-modern orodispersible drug delivery system intended for hormonal and neurological balance. Sumatriptan and Myoinositol was effectively synthesized and incorporated along with selected herbal constituents into a polymeric orodispersible matrix.

The developed formulation demonstrated acceptable physicochemical properties, adequate mechanical strength, rapid disintegration, and efficient drug release, fulfilling the essential requirements of an orodispersible dosage form. Uniform distribution of active ingredients and satisfactory stability under accelerated and long-term conditions further validated the robustness of the formulation.

The study confirms that orodispersible systems can serve as an effective platform for combining herbal and modern therapeutic agents, offering advantages such as rapid onset of action, improved bioavailability, ease of administration, and enhanced patient compliance.

Thus, the formulated dual-action herbo-modern orodispersible system shows significant potential as a novel and patient-friendly approach for managing hormonal and neurological imbalances and may be further explored through in-vivo studies and clinical evaluation for therapeutic validation.

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HOW TO CITE: Avantika Yadhav, Akanksha Thorat, Dr. Rohit khillare*., Dual Action Herbo-Modern Orodispersible Delivery System For Migraine Management Through Hormonal And Neurological Modulation, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 9, 1541-1562. https://doi.org/ 10.5281/zenodo.22724056