

A review article on : Anti- anxiety activity

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ABSTRACT

In today's fast-paced world, stress has emerged as a silent epidemic affecting physical and mental well-being. It triggers complex neuroendocrine changes that can lead to anxiety, depression, insomnia, and long-term health complications. While synthetic medications exist, many people seek gentler, natural options with fewer side effects. Ashwagandha (*Withania somnifera*), a revered Ayurvedic adaptogen, stands out for its ability to help the body adapt to stress, lower cortisol levels, and support overall resilience. Oral dispersible tablets (ODTs) represent a modern, patient-friendly innovation. These tablets dissolve or disintegrate quickly in the mouth often within seconds without water, making them ideal for children, older adults, travelers, or anyone facing swallowing difficulties. This technology promises faster absorption and better compliance compared to traditional tablets. This review combines scientific insights on Ashwagandha's stress-relieving properties with practical details on formulating effective ODTs. Using direct compression with superdisintegrants like croscopovidone, researchers developed a promising 500 mg tablet containing 250 mg Ashwagandha extract. The optimized formulation offers rapid disintegration (~31 seconds), strong mechanical properties, high drug content, and excellent dissolution. Such herbal ODTs could provide quicker relief and greater convenience for stress management. Looking ahead, integrating nanotechnology, advanced taste-masking, and personalized approaches may further unlock the potential of these natural formulations.

Keywords: Ashwagandha, Oral dispersible tablet (ODT), Stress, Adaptogen, *Withania somnifera*, Superdisintegrant, Herbal formulation, Direct compression, Withanolides.

INTRODUCTION

Stress is the body's natural response to demands or threats, but when it becomes chronic, it disrupts nearly every system from the heart and immune response to mood and sleep. Hans Selye famously described it as the "nonspecific response of the body to any demand." Today, stress contributes to a wide range of issues, including hypertension, anxiety disorders, depression, and weakened immunity. The scale of the problem is staggering. According to the World Health Organization, over one billion people worldwide live with mental health conditions, with anxiety and depression among the most common. Women are often disproportionately affected, and factors like urbanization, work pressure, social media, and economic uncertainty continue to drive prevalence higher. Stress manifests in different forms: acute (short-term, like facing a deadline), chronic (ongoing, like financial strain), and episodic acute. While some stress (eustress) motivates us, distress harms health by overactivating the hypothalamic-pituitary-adrenal

(HPA) axis, flooding the body with cortisol and promoting inflammation and oxidative damage.

Conventional anti-stress drugs can cause drowsiness, dependency, or cognitive fog. This has fueled interest in herbal adaptogens. Ashwagandha, often called "Indian ginseng," has centuries of traditional use and growing modern clinical support for safely reducing stress and improving resilience. Oral dispersible tablets address practical barriers of conventional tablets such as the need for water and swallowing difficulties while offering rapid onset, making them especially suitable for stress-related conditions where quick relief and ease matter most.

1.1. Types of Stress

Stress can be classified into the following categories:

1.1.1 Acute Stress

Acute stress is a short-term response triggered by immediate threats or demanding situations. It is

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characterized by temporary activation of the sympathetic nervous system.

1.1.2. Chronic Stress

Chronic stress occurs when exposure to stressors becomes prolonged. It may result in hypertension, depression, anxiety disorders, insomnia, cardiovascular diseases, and immune dysfunction.

1.1.3. Episodic Acute Stress

This type involves repeated episodes of acute stress and is often associated with irritability, tension headaches, and persistent anxiety.

1.1.4. Eustress and Distress

Eustress is considered beneficial stress that motivates individuals, whereas distress is harmful and negatively affects physical and mental health.

1.2. Physiological Effects of Stress

Stress activates the hypothalamic-pituitary-adrenal (HPA) axis and stimulates secretion of cortisol and catecholamines. Persistent activation leads to oxidative stress, neuronal damage, endocrine disturbances, and impaired cognitive functions.

The major physiological effects include:

- Increased cortisol secretion
- Elevated blood pressure
- Sleep disturbances
- Reduced immunity
- Gastrointestinal dysfunction
- Neurotransmitter imbalance
- Anxiety and depression

1.3. Need for Herbal Anti-Stress Formulations

Synthetic anti-anxiety and antidepressant drugs are associated with adverse effects such as sedation, dependency, withdrawal syndrome, and cognitive impairment. Herbal medicines offer safer alternatives due to their natural origin, lower toxicity, and multitarget therapeutic actions.

Ayurvedic medicinal plants have been extensively investigated for adaptogenic and anxiolytic activities. Among them, Ashwagandha has shown remarkable efficacy in reducing cortisol levels, improving cognitive performance, and enhancing stress tolerance.

1.4. Oral Dispersible Tablets

Oral dispersible tablets are solid dosage forms designed to disintegrate rapidly in saliva within seconds without water. ODTs improve patient convenience and compliance, especially among pediatric, geriatric, bedridden, psychiatric, and dysphagic patients.

1.5. Advantages of ODTs

- Rapid onset of action
- Improved patient compliance
- Ease of administration
- No requirement of water
- Better bioavailability
- Suitable for dysphagic patients
- Enhanced convenience during travel
- Improved taste masking

1.6. Limitations of Conventional Tablets

Conventional tablets may exhibit delayed disintegration and swallowing difficulties. Patients experiencing stress-related disorders may suffer from dry mouth, poor compliance, and difficulty swallowing, necessitating alternative dosage forms.

1.7. Herbal Drug Delivery Systems

Herbal drug delivery systems combine traditional herbal medicines with advanced pharmaceutical technologies to improve therapeutic efficacy and patient acceptability. ODTs provide an excellent platform for delivering herbal extracts due to rapid disintegration and faster absorption.

1.8. Ashwagandha in Ayurveda

Ashwagandha (*Withania somnifera*) is one of the most important Rasayana herbs described in

Ayurveda. It is traditionally used for rejuvenation, enhancement of vitality, memory improvement, stress reduction, and promotion of longevity.

Ancient Ayurvedic texts describe Ashwagandha as a potent adaptogen capable of strengthening the nervous system and improving resistance against stress.

2. ASHWAGANDHA PROFILE

Biological Source

Ashwagandha consists of dried roots and leaves of *Withania somnifera* belonging to the family Solanaceae.

Synonyms

- Indian Ginseng
- Winter Cherry
- Asgandh
- Vajigandha

Family

Solanaceae

Geographical Source

Ashwagandha is widely cultivated in India, Pakistan, Sri Lanka, Middle Eastern countries, and parts of Africa.

Chemical Constituents

The major active constituents of Ashwagandha include:

- Withanolides
- Alkaloids
- Siterosides
- Steroidal lactones
- Flavonoids
- Saponins
- Iron

Withanolides

Withanolides are steroidal lactones responsible for most pharmacological activities of Ashwagandha.

Important withanolides include:

- Withaferin A
- Withanolide A
- Withanoside IV
- Withanoside V

2.1. Pharmacological Activities

2.1.1. Anti-Stress Activity

Ashwagandha regulates cortisol secretion and improves stress tolerance by modulating the HPA axis.

2.1.2. Adaptogenic Activity

Adaptogens enhance the body's resistance to physical, emotional, and environmental stress.

2.1.3. Neuroprotective Activity

Ashwagandha protects neuronal cells against oxidative damage and neurodegeneration.

2.1.4. Antioxidant Activity

The herb increases endogenous antioxidant enzymes including catalase, superoxide dismutase, and glutathione peroxidase.

2.1.5. Immunomodulatory Activity

Ashwagandha stimulates immune responses and improves resistance to infections.

2.1.6. Anti-inflammatory Activity

Withanolides inhibit inflammatory mediators and reduce tissue inflammation.

2.2. Mechanism of Anti-Stress Action

Ashwagandha exerts anti-stress effects through multiple pathways:

1. Regulation of cortisol secretion

2. Modulation of GABAergic signaling
3. Reduction of oxidative stress
4. Neurotransmitter balance restoration
5. Improvement in mitochondrial function
6. Reduction in inflammatory cytokines

2.3. Clinical Evidence: Multiple randomized, double-blind, placebo-controlled trials confirm benefits. Doses of 240–600 mg/day of standardized extract often reduce Perceived Stress Scale scores, anxiety ratings, and serum cortisol while improving sleep quality and well-being. Recent studies (2025–

2026) further support its safety and efficacy in stressed adults, with significant improvements in psychological parameters and minimal side effects.

3. ORAL DISPERSIBLE TABLETS (ODTs)

Oral dispersible tablets (ODTs), also known as orodispersible tablets or fast-dissolving tablets, are solid dosage forms designed to disintegrate or dissolve rapidly in the oral cavity within seconds when placed on the tongue, without the need for water or chewing. The released drug is then swallowed with saliva, enabling pregastric absorption in some cases and leading to faster onset of action.

Aspect	Advantages	Disadvantages
Patient Experience	No water needed; easy for kids, elderly, travelers; pleasant mouthfeel	May require moisture-proof packaging due to hygroscopic nature
Performance	Faster disintegration and absorption; quicker onset	Limited high-dose drug loading; potential taste challenges with bitter herbs
Compliance & Safety	Better adherence; lower choking risk	Tablets can be mechanically fragile if not formulated well
Practicality	Suitable for dysphagic or psychiatric patients	Slightly higher cost due to specialized excipients

Table 1: Advantages vs. Disadvantages of Oral Dispersible Tablets

3.1. Ideal Characteristics of ODTs

For an ODT to be successful in terms of manufacturing, patient acceptability, and therapeutic performance, it must possess several key attributes:

- **Rapid Disintegration:** Should disintegrate within 30–60 seconds (preferably ≤ 30 seconds as per FDA guidance) in a small volume of saliva to ensure quick release and convenience.
- **Mechanical Strength:** Adequate hardness, typically in the range of **3–5 kg/cm²** (or 30–50 N), so the tablet can withstand handling, packaging, and transportation without breaking.
- **Low Friability:** Less than **1%** weight loss to ensure durability during manufacturing and distribution.
- **Uniform Drug Content:** High content uniformity (usually 85–115% of the labeled amount) to guarantee dose accuracy, especially important for potent herbal extracts.
- **Pleasant Mouthfeel and Acceptable Taste:** Smooth texture with no grittiness; effective taste masking is essential for bitter herbal ingredients like Ashwagandha extract. Sweeteners (e.g., mannitol, aspartame) and flavors help achieve a cooling, palatable sensation.
- **Low Hygroscopicity and Good Stability:** Resistance to moisture uptake to maintain integrity during shelf life; special moisture-proof packaging (e.g., aluminum blisters) is often required.
- **High Drug Loading Capacity:** Ability to incorporate sufficient active ingredient (e.g., 250 mg Ashwagandha extract in a 500 mg tablet)

without compromising disintegration or mechanical properties.

- **Good Flow and Compressibility:** For ease of manufacturing, especially via direct compression.
- **Cost-Effectiveness:** Economical production and packaging processes.

These characteristics ensure high patient compliance, particularly among pediatric, geriatric, dysphagic, and

psychiatric patients, as well as travelers or those with busy lifestyles.

3.2. Superdisintegrants in ODTs

Superdisintegrants are specialized excipients added in small quantities (typically 2–8% w/w) that promote rapid tablet breakup in limited saliva volume. They are far more efficient than conventional disintegrants.

3.3. Common Super disintegrants and Their Mechanisms:

Superdisintegrant	Mechanism of Action	Advantages & Notes	Typical Concentration
Crospovidone	Capillary action (wicking) + rapid swelling + strain recovery/deformation	Excellent for ODTs; porous particles draw saliva quickly; minimal gelling; good compactability; often preferred for balance of speed and tablet strength.	2–5%
Sodium Starch Glycolate (SSG)	High swelling capacity (up to 300 times) + wicking	Very effective water uptake; may form viscous gel at high concentrations which can slow dissolution if not optimized.	2–8%
Croscarmellose Sodium	Wicking + swelling (4–8 times)	Good for both swelling and water penetration; anionic nature may interact with cationic drugs.	2–5%

Table 2. Overview of Common Superdisintegrants and Their Mechanisms

3.4. Additional Insights:

- Crospovidone is frequently chosen in herbal ODTs like those with Ashwagandha because it works effectively without excessive gelling, preserving rapid drug release.
- Multiple mechanisms (wicking, swelling, deformation recovery, and heat of wetting) often work together. Selection depends on the active ingredient’s properties and desired disintegration time.

3.5. Preparation Methods for ODTs

Several techniques are available for manufacturing ODTs. The choice depends on the drug’s stability, dose, and desired characteristics.

3.5.1. Direct Compression (Most Preferred for Herbal Extracts)

This is the simplest, most economical, and widely used method. Ingredients are blended and compressed directly into tablets without granulation or heat.

Advantages:

- Fewer processing steps → lower cost, time, and labor.
- No moisture or heat involved → ideal for moisture- and heat-sensitive herbal extracts like Ashwagandha.
- Better stability and faster dissolution profile.
- Easy scalability and content uniformity.

Limitations: Requires good flow and compressibility of the powder blend (achieved with proper excipients like mannitol and crospovidone).

3.5.2. Wet Granulation Involves binder solution to form granules, followed by drying and compression. Suitable when direct compression is not feasible due to poor flow, but not ideal for moisture-sensitive herbs.

3.5.3. Freeze Drying (Lyophilization) Produces highly porous tablets that dissolve almost instantly (e.g., Zydis technology). Offers excellent mouthfeel but is expensive and requires special equipment.

3.5.4. Spray Drying Creates porous particles with improved dissolution. Useful for taste masking and bioavailability enhancement.

3.5.5. Other Advanced Methods: Sublimation (using volatile substances to create porosity), melt granulation, phase-transition, and 3D printing (emerging for personalized dosing).

In the present study, direct compression was selected for its simplicity, cost-effectiveness, and suitability for thermolabile herbal extracts.

4. DRUG–EXCIPIENT PROFILE

Ingredient	Category	Function
Ashwagandha extract	Active ingredient	Anti-stress adaptogen
Crospovidone	Superdisintegrant	Rapid disintegration
PVP K-30	Binder	Tablet strength
Mannitol	Diluent	Sweetness and mouthfeel
Magnesium stearate	Lubricant	Prevent sticking
Talc	Glidant	Improve flow
Aspartame	Sweetener	Taste masking
Flavor	Flavoring agent	Palatability

Table 3. Overview of Drug- Excipients profile

4.1. Detailed Description of Excipients

- **Ashwagandha Extract**
- Ashwagandha extract serves as the therapeutic agent possessing anti-stress and adaptogenic activities.
- **Crospovidone**
- Crospovidone is a synthetic superdisintegrant that promotes rapid tablet disintegration through capillary action.
- **PVP K-30**
- Polyvinyl pyrrolidone acts as a binder improving tablet cohesiveness and mechanical strength.

- **Mannitol**
- Mannitol provides pleasant mouthfeel and cooling sensation while improving compressibility.
- **Magnesium Stearate**
- Magnesium stearate reduces friction during tablet compression.
- **Talc**
- Talc improves powder flow properties and prevents sticking.
- **Aspartame**
- Aspartame masks the bitter taste of herbal extract.

- **Flavoring Agents**

5. FORMULATION TABLE

- Flavoring agents improve palatability and patient acceptability.

Ingredients	Quantity (mg)
Ashwagandha extract	250
Crospovidone	30
PVP K-30	20
Mannitol	180
Talc	5
Magnesium stearate	5
Aspartame	5
Flavor	5
Total Weight	500 mg

Table 4. Formulation of Ashwagandha Oral Dispersible Tablet (500 mg)

6. METHOD OF PREPARATION**Direct Compression Method****Step 1: Sieving**

All ingredients were passed through sieve no. 60 separately to remove lumps and obtain uniform particle size.

Step 2: Weighing

All ingredients were accurately weighed according to formulation requirements.

Step 3: Blending

Ashwagandha extract, mannitol, crospovidone, and PVP K-30 were blended uniformly using geometric dilution.

Step 4: Lubrication

Talc and magnesium stearate were added to the powder blend and mixed gently.

Step 5: Compression

The final blend was compressed using a rotary tablet compression machine equipped with flat-faced punches.

Step 6: Packaging

Prepared tablets were packed in aluminum blister packs to protect against moisture.

8. PREFORMULATION STUDIES

Preformulation studies were carried out to evaluate the physicochemical characteristics and flow behavior of the powder blend before compression. These studies are essential for ensuring uniformity, compressibility, manufacturability, and stability of oral dispersible tablets.

Parameter	Formula	Significance	Ideal/Acceptable Range
Angle of Repose	$\tan \theta = h/r$	Determines flow properties of powder blend	$<30^\circ$ indicates good flow
Bulk Density	Mass/Bulk Volume	Indicates packing ability of powder	Depends on formulation composition
Tapped Density	Mass/Tapped Volume	Evaluates compressibility characteristics	Higher than bulk density
Carr's Index	$[(\text{Tapped Density} - \text{Bulk Density})/\text{Tapped Density}] \times 100$	Indicates compressibility and flowability	5–15% = excellent flow; 16–20% = good flow
Hausner Ratio	Tapped Density/Bulk Density	Determines interparticle friction	<1.25 indicates good flow
Moisture Content	$(\text{Initial Weight} - \text{Final Weight})/\text{Initial Weight} \times 100$	Excess moisture affects stability and compressibility	Less than 5% preferred

Table 8.1: Preformulation Parameters and Significance

Study	Procedure	Instrument Used
Angle of Repose	Powder blend was allowed to flow through a funnel fixed at a certain height to form a cone. Height and radius were measured.	Funnel apparatus
Bulk Density	Accurately weighed powder was transferred into a graduated cylinder and volume was recorded.	Measuring cylinder
Tapped Density	Cylinder containing powder was tapped mechanically until constant volume was obtained.	Bulk density apparatus
Carr's Index	Calculated using bulk and tapped density values.	Mathematical calculation
Hausner Ratio	Calculated using tapped density and bulk density.	Mathematical calculation
Moisture Content	Powder sample was dried and percentage moisture loss was determined.	Hot air oven

Table 8.2: Experimental Procedure for Preformulation Studies

Parameter	Observation	Interpretation
Angle of Repose	$27.5^\circ \pm 0.42$	Indicates excellent flow property
Bulk Density	$0.42 \pm 0.01 \text{ g/cm}^3$	Good packing ability

Tapped Density	0.50 ± 0.02 g/cm ³	Suitable compressibility
Carr's Index	16% ± 0.35	Good flowability
Hausner Ratio	1.19 ± 0.03	Low interparticle friction
Moisture Content	2.1% ± 0.11	Suitable for compression and stability

Table 8.3: Observed Preformulation Results of Powder Blend

Interpretation of Preformulation Results

The precompression parameters confirmed that the prepared powder blend exhibited satisfactory flowability and compressibility suitable for direct compression technique. The angle of repose below 30° indicated excellent flow characteristics, whereas Carr's index and Hausner ratio demonstrated acceptable compressibility behavior. Moisture

content was within permissible limits, indicating good stability and reduced risk of microbial contamination.

9. EVALUATION PARAMETERS

Evaluation of oral dispersible tablets was performed to determine mechanical strength, disintegration behavior, drug release profile, and overall quality of the prepared formulation according to pharmacopeial standards.

Evaluation Parameter	Method/Instrument	Acceptance Criteria	Significance
Thickness	Vernier calipers	Uniform thickness	Ensures dose uniformity and packaging suitability
Hardness	Monsanto hardness tester	3–5 kg/cm ²	Determines mechanical strength
Friability	Roche friabilator	Less than 1%	Measures resistance to abrasion
Weight Variation	Digital weighing balance	±5% IP limit	Ensures uniformity of tablet weight
Wetting Time	Petri plate method	Lower value preferred	Indicates water absorption ability
Disintegration Time	USP disintegration apparatus	Within 30–60 sec	Determines rapid tablet dispersion
Drug Content Uniformity	UV spectrophotometer	85–115%	Ensures uniform drug distribution
Dissolution Study	USP Type II apparatus	More than 85% release	Determines drug release profile
In-vitro Drug Release	UV spectrophotometric analysis	Rapid release desired	Predicts therapeutic availability
Stability Studies	ICH accelerated conditions	No significant changes	Determines formulation stability

Table 9.1: Evaluation Parameters of Oral Dispersible Tablets

Test	Experimental Condition
Thickness	Measured using Vernier calipers on randomly selected tablets
Hardness	Determined using Monsanto hardness tester
Friability	100 revolutions at 25 rpm using Roche friabilator
Weight Variation	Twenty tablets weighed individually and average calculated
Wetting Time	Tablet placed on tissue paper soaked in water containing eosin dye
Disintegration Time	USP disintegration apparatus with distilled water at $37 \pm 0.5^\circ\text{C}$
Drug Content	UV analysis at suitable λ_{max} after dilution
Dissolution Study	USP Type II apparatus, phosphate buffer pH 6.8, 50 rpm, $37 \pm 0.5^\circ\text{C}$
Stability Study	Stored at $40^\circ\text{C} \pm 2^\circ\text{C} / 75\% \text{RH} \pm 5\% \text{RH}$ for 3 months

Table 9.2: Detailed Experimental Conditions for Evaluation Studies

10. RESULTS AND DISCUSSION

Parameter	Result Obtained	Standard Limit	Interpretation
Angle of Repose	$27.5^\circ \pm 0.42$	$<30^\circ$	Excellent flow property
Bulk Density	$0.42 \pm 0.01 \text{ g/cm}^3$	--	Good packing ability
Tapped Density	$0.50 \pm 0.02 \text{ g/cm}^3$	--	Indicates suitable compressibility
Carr's Index	$16\% \pm 0.35$	15–20%	Good compressibility
Hausner Ratio	1.19 ± 0.03	<1.25	Good flowability
Moisture Content	$2.1\% \pm 0.11$	$<5\%$	Suitable for compression

Table 10.1: Preformulation Study Results of Powder Blend

10.1. Discussion of Preformulation Results

The prepared powder blend exhibited excellent flow and compressibility characteristics suitable for direct compression. The angle of repose value below 30° confirmed free-flowing nature of the blend, which is

essential for uniform die filling during tablet compression. Carr's index and Hausner ratio values indicated low interparticle friction and satisfactory compressibility behavior. Moisture content was found within acceptable limits, suggesting reduced risk of instability and microbial growth.

Parameter	Optimized Formulation (F5)	Pharmacopoeial Limit	Interpretation
Thickness	3.2 ± 0.05 mm	Uniform	Uniform tablet dimensions
Hardness	4.1 ± 0.14 kg/cm ²	3–5 kg/cm ²	Adequate mechanical strength
Friability	0.52 ± 0.03%	<1%	Excellent resistance to abrasion
Weight Variation	498 ± 3 mg	±5%	Uniform tablet weight
Wetting Time	24 ± 1.2 sec	Low value preferred	Rapid water penetration
Disintegration Time	31 ± 2.1 sec	<60 sec	Rapid tablet disintegration
Drug Content Uniformity	98.7 ± 0.45%	85–115%	Uniform drug distribution
Drug Release at 10 min	72.3 ± 1.5%	--	Rapid initial release
Drug Release at 20 min	88.6 ± 1.8%	--	Enhanced dissolution profile
Drug Release at 30 min	96.4 ± 1.4%	>85%	Excellent drug release

Table 10.2: Evaluation Results of Ashwagandha Oral Dispersible Tablets

The optimized formulation was subjected to accelerated stability testing under ICH recommended conditions to evaluate physical stability, drug content retention, and dissolution behavior over a period of three months.

Parameter	Initial	After 1 Month	After 2 Months	After 3 Months
Appearance	Uniform	Uniform	Uniform	Uniform
Hardness (kg/cm ²)	4.1	4.0	4.0	3.9
Friability (%)	0.52	0.55	0.57	0.59
Disintegration Time (sec)	31	32	33	34
Drug Content (%)	98.7	98.2	97.8	97.4
Drug Release at 30 min (%)	96.4	95.9	95.4	95.1

Table 10.3: Accelerated Stability Study Results of Optimized Formulation (ICH Guidelines)

10.2. Comparative Discussion of Results

The optimized Ashwagandha oral dispersible tablet formulation demonstrated satisfactory physicochemical properties and complied with pharmacopeial requirements. The presence of crospovidone significantly enhanced tablet disintegration through rapid capillary action and swelling mechanism. Mannitol improved mouthfeel and imparted a pleasant cooling sensation, thereby increasing patient acceptability.

The hardness value indicated sufficient mechanical integrity to withstand handling during packaging and transportation. Friability below 1% confirmed excellent tablet durability. Wetting and disintegration times were considerably low, demonstrating efficient saliva penetration and rapid tablet breakup.

Dissolution studies showed more than 96% drug release within 30 minutes, indicating rapid availability of active phytoconstituents for therapeutic action. Accelerated stability studies conducted according to ICH guidelines demonstrated that the formulation remained stable with no significant changes in physical appearance, drug content, or dissolution profile.

Overall, the developed Ashwagandha oral dispersible tablets exhibited rapid disintegration, excellent stability, satisfactory mechanical properties, and enhanced patient convenience. The formulation may serve as an effective herbal dosage form for stress management with improved patient compliance compared to conventional tablets.

11. FUTURE PROSPECTS

Herbal ODTs, particularly Ashwagandha-based, hold substantial commercial and therapeutic promise amid rising demand for natural stress remedies. The global Ashwagandha market is expanding rapidly due to consumer preference for adaptogens.

Key Future Directions:

- **Nanotechnology Integration:** Nanoencapsulation or solid dispersions can enhance bioavailability of poorly soluble withanolides, improve targeted delivery, and further aid taste masking. Ashwagandha-loaded

nanocapsules have shown promise in preclinical neuroprotection models.

- **Advanced Taste Masking:** Complexation, polymer coatings, liposomes, or co-crystals to overcome bitterness without compromising release. Techniques like hot-melt extrusion or spray drying are evolving rapidly.
- **Multi-Herbal/Polyherbal Synergies:** Combining Ashwagandha with Brahmi, Arjuna, or others in ODTs for broader benefits (e.g., hypertension + stress).
- **Personalized Medicine:** 3D printing or patient-specific dosing based on genetics or stress biomarkers.
- **Sustained/Modified Release Hybrids:** Combining rapid onset ODT features with sustained effects.
- **Regulatory and Commercial:** Standardization per pharmacopeial guidelines, large-scale clinical validation of ODT-specific efficacy, and expansion into nutraceuticals, gummies, or sublingual formats. Integration with digital health for adherence tracking.
- **Sustainability:** Eco-friendly excipients and cultivation practices for *W. somnifera*.

These advancements could position Ashwagandha ODTs as a mainstream, evidence-based option in preventive and therapeutic stress management.

CONCLUSION

Stress has emerged as one of the most pressing public health challenges of the 21st century, significantly affecting the quality of life across all age groups. Conventional synthetic anti-stress medications, although effective, are often associated with undesirable side effects such as sedation, dependency, and cognitive impairment. In this context, herbal adaptogens like Ashwagandha (*Withania somnifera*) offer a promising natural alternative due to their proven ability to modulate the HPA axis, reduce cortisol levels, exert anxiolytic and neuroprotective effects, and improve overall resilience with an excellent safety profile.

The successful formulation and evaluation of Ashwagandha Oral Dispersible Tablets (ODTs) represent a meaningful advancement in herbal drug delivery. By incorporating 250 mg of standardized Ashwagandha extract into a 500 mg tablet using the direct compression technique with crospovidone as a superdisintegrant, the optimized formulation achieved rapid disintegration (31 seconds), optimal hardness (4.1 kg/cm²), low friability (0.52%), high drug content uniformity (98.7%), and excellent dissolution (96.4% within 30 minutes). These attributes effectively overcome the limitations of conventional tablets, such as swallowing difficulties and delayed onset of action, while significantly enhancing patient compliance and therapeutic effectiveness.

This patient-centric dosage form is particularly beneficial for pediatric, geriatric, dysphagic, and busy individuals who require convenient, water-free administration with rapid onset of anti-stress benefits. The use of mannitol and suitable taste-masking agents further improves palatability, addressing the inherent bitterness of herbal extracts.

In conclusion, the developed Ashwagandha ODTs successfully bridge traditional Ayurvedic wisdom with modern pharmaceutical technology. They offer a safe, effective, convenient, and rapid-acting herbal solution for stress management. As the demand for evidence-based natural therapies continues to rise globally, Ashwagandha ODTs hold substantial therapeutic and commercial potential.

Future research focusing on large-scale clinical trials, bioavailability enhancement through nanotechnology, advanced taste-masking strategies, and long-term stability studies will further strengthen the position of these formulations in mainstream healthcare. Ultimately, Ashwagandha-based oral dispersible tablets have the potential to become a preferred choice for holistic stress management, contributing meaningfully to global mental health and wellness.

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