

## Pharmaceutico-Analytical Evaluation of *Ashwagandha* Tablet - A Contemporary *Ayurveda* Dosage Form commonly used in Psychiatric Disorders



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### ABSTRACT

*Ashwagandha* (*Withania somnifera*), a revered *Rasayana* herb in *Ayurveda*, is renowned for its adaptogenic, neuroprotective, and immunomodulatory properties. With the growing global interest in traditional medicine and integrative healthcare, there is an increasing demand for standardized, safe, and efficacious herbal formulations. This study presents a comprehensive pharmaceutico-analytical evaluation of an *Ashwagandha* tablet formulation developed at KLE *Ayurveda* Pharmacy, Belagavi, with the aim of assessing its quality, consistency, and therapeutic viability. The evaluation encompassed organoleptic examination, physicochemical testing, preliminary phytochemical screening, and Thin Layer Chromatography (TLC) profiling, following *Ayurvedic Pharmacopoeia* and general analytical protocols. The tablet displayed characteristic color, odor, and bitterness, correlating well with the properties of authentic *Ashwagandha* root. Physicochemical parameters, including loss on drying, ash values, extractive values, friability, disintegration time, and hardness, were within pharmaceutically acceptable limits. Phytochemical analysis revealed the presence of key secondary metabolites such as flavonoids, tannins, steroids, and glycosides, while TLC fingerprinting confirmed a consistent chemical profile. The results support the formulation's stability, purity, and potential therapeutic efficacy, especially in the management of stress-related, cognitive, and psychiatric conditions. By demonstrating compliance with both classical *Ayurvedic* and modern analytical standards, this study underscores the feasibility of integrating traditional herbal knowledge into contemporary dosage forms. The findings advocate for the continued scientific validation and standardization of *Ayurvedic* medicines to enhance their credibility and accessibility in global healthcare systems.

**KEYWORDS:** *Ashwagandha*, *Withania somnifera*, *Ayurvedic* tablet, pharmaceutico-analytical, TLC, phytochemical, *Rasayana*

### INTRODUCTION

In recent decades, the global health community has witnessed a growing interest in traditional systems of medicine, particularly those emphasizing holistic and preventive approaches to well-being. Among these, *Ayurveda*, the ancient Indian system of medicine, has garnered substantial attention for its integrative perspective on health and disease. Rooted in centuries-old philosophical, empirical, and experiential foundations, *Ayurveda* advocates a comprehensive approach to health through lifestyle modifications, regulated diet, and herbal therapeutics [1]. With the convergence of traditional wisdom and modern science, there is an increasing effort to validate and standardize *Ayurvedic* formulations to meet the expectations of evidence-based medicine.

One of the most esteemed herbs in *Ayurvedic* pharmacology is *Ashwagandha* (*Withania somnifera*), commonly referred to as "Indian Ginseng" or "Winter Cherry." Classified under the *Rasayana* category, *Ashwagandha* is renowned for

its adaptogenic, anti-stress, immunomodulatory, neuroprotective, and anti-inflammatory properties [2]. *Rasayana* drugs are traditionally used to promote longevity, enhance immunity, improve intellectual functioning, and support mental and physical health. In *Ayurvedic* texts, *Ashwagandha* is described as possessing *Tikta* (bitter) and *Kashaya* (astringent) *Rasa* (taste), *Laghu* (light) and *Snigdha* (unctuous) *Guna* (qualities), *Ushna* (hot) *Virya* (potency), and *Madhura* (sweet) *Vipaka* (post-digestive effect), with a specific *Prabhava* (action) that is *Balya* (strength-promoting) and *Rasayana* (rejuvenative) [3].

Traditionally, the root of *Ashwagandha* is most frequently used, although the leaves and seeds are also known to contain pharmacologically active constituents. The major bioactive compounds include withanolides, sitoindosides, alkaloids, flavonoids, and steroidal lactones, which are responsible for the herb's wide-ranging therapeutic effects [4]. Scientific studies have corroborated the adaptogenic and neuroprotective capabilities of

*Ashwagandha*, particularly in stress management, memory enhancement, and modulation of the hypothalamic pituitary adrenal (HPA) axis [5]. It also exerts a positive influence on endocrine health, including thyroid regulation, adrenal function, and male reproductive parameters such as testosterone levels and sperm quality [6].

In the current healthcare landscape, integrating Ayurvedic knowledge into standardized pharmaceutical dosage forms is critical for improving patient compliance, ensuring consistency in therapeutic outcomes, and enhancing global acceptability. Tablet formulations are especially advantageous in this context due to their ease of administration, prolonged shelf-life, accurate dosing, and potential for large scale production [7]. While *Ashwagandha* is traditionally used in powder or decoction forms, converting it into a tablet format aligns with contemporary pharmaceutical practices and improves accessibility in modern clinical settings.

However, challenges remain in the standardization and quality control of herbal products. Variability in raw materials due to differences in geographic origin, harvesting season, and post-harvest handling can significantly impact the phytochemical composition and efficacy of herbal formulations [8]. Additionally, the lack of consistent manufacturing protocols and inadequate analytical validation has hindered the global acceptance of many traditional products. This necessitates the adoption of pharmaceutico-analytical methods that integrate classical Ayurvedic standards with modern scientific tools.

Pharmaceutico-analytical evaluation encompasses a series of tests and observations designed to ensure the identity, purity, safety, and efficacy of a formulation. These include organoleptic analysis (macroscopy), physicochemical testing, preliminary phytochemical screening, and chromatographic profiling such as Thin Layer Chromatography (TLC) [9]. Organoleptic parameters such as color, texture, odor, and taste help in the preliminary assessment of quality and authenticity, while physicochemical tests like loss on drying, total ash, acid-insoluble ash, water-soluble extractive values, tablet hardness, friability, and disintegration time serve as indicators of formulation stability and consistency.

Preliminary phytochemical screening is essential for identifying the presence of secondary metabolites such as alkaloids, tannins, glycosides, flavonoids, and steroids compounds known for their therapeutic efficacy. TLC, a cost-effective and efficient chromatographic method, enables the visualization of phytochemical fingerprints that can be used for batch-to-batch comparison and quality control [10]. Together, these methods help bridge traditional formulations with modern

pharmaceutical standards and regulatory requirements.

In this context, the present study aims to evaluate a tablet formulation of *Ashwagandha* prepared at KLE Ayurveda Pharmacy, Belagavi, through a comprehensive pharmaceutico-analytical framework. The formulation was prepared under controlled laboratory conditions following standardized Ayurvedic and pharmacopeial protocols. Special attention was given to preserving the integrity of *Ashwagandha*'s active constituents during processing, including drying, granulation, and tablet compression, using pharmaceutically approved binders and disintegrants.

The primary objective of this study is to assess the formulation based on organoleptic parameters, physicochemical constants, preliminary phytochemical screening, and TLC analysis. These evaluations aim to establish a reproducible analytical profile that can support standardization efforts and serve as a reference for quality control. Such scientific validation is vital not only for ensuring therapeutic consistency and safety but also for enabling the integration of Ayurvedic formulations into mainstream and global healthcare systems.

Moreover, by demonstrating compliance with quality assurance protocols and pharmaceutico-analytical benchmarks, this study seeks to address ongoing concerns regarding the variability and reliability of herbal medicines. The outcome is expected to contribute to the growing body of evidence supporting the scientific basis of *Ayurveda* and enhance the credibility of its formulations in the modern pharmaceutical industry.

As global interest in integrative and complementary medicine continues to rise, the standardization and validation of classical herbal formulations will play a pivotal role in shaping the future of holistic healthcare. The case of *Ashwagandha* a time tested *Rasayana* drug exemplifies how traditional knowledge can be revitalized through modern scientific methodologies, paving the way for safe, effective, and globally accepted natural remedies.

## MATERIALS AND METHODS

The study was conducted using a standard *Ashwagandha* tablet formulation as the test sample. The tablets were prepared from KLE Ayurveda Pharmacy, Khasbag, Belagavi under standard operative procedures. Binding agent used was corn starch in the preparation of tablet. Macroscopic Evaluation, Physicochemical Evaluation, Preliminary Phytochemical Screening, Thin Layer Chromatography (TLC) evaluations were carried out in a systematic order, following both Ayurvedic Pharmacopoeia standards and general laboratory analytical guidelines.

## RESULTS

Table 1 - Description Macroscopic:

TESTS	RESULTS
Form	Tablets
Color	Creamish
Taste	Bitter
Odor	Characteristic

Table 2 - Physico-Chemical Standards:

TESTS	RESULTS
Loss on Drying at 110 C	3.717 %
Ash Value	6.410 %
Acid Insoluble Ash	1.408 %
Water Soluble Ash	2.507 %
Water Soluble Extractive	33.757 %
Alcohol Soluble Extractive	7.395 %
Friability Test	1.170 %
Disintegration Test	3 minutes
Hardness Test	3 kg/cm
Average Weight	503 mg

Table 3 - Preliminary Phytochemical Screening in Following Extracts:

TESTS	WATER	ALCOHOL
Test for Carbohydrates	Positive	Positive
Test for Reducing Sugar	Negative	Negative
Test for Monosaccharides	Negative	Negative
Test for Pentose Sugar	Negative	Positive
Test for Non-Reducing Sugar	Negative	Negative
Test for Hexose Sugar	Negative	Negative
Test for Protein	Negative	Negative
Test for Amino Acids	Negative	Negative
Test for Steroids	Negative	Positive
Test for Flavonoids	Positive	Positive
Test for Alkaloids	Negative	Negative
Test for Tannins	Positive	Negative

Table 4 - Test for Glycosides:

TESTS	WATER	ALCOHOL
Cardiac Glycosides	Positive	Positive
Antraquinone Glycosides	Negative	Positive
Saponin Glycosides	Negative	Negative

Table 5 - TLC Analysis

TESTS	RESULTS
TLC: (Alcohol Extract)	Rf Values
Mobile Phase – Toluene: Ethyl Acetate	Short Wave: 0.05, 0.32, 0.45, 0.49, 0.62, 0.86
Ratio: 7:3	Long Wave: 0.46, 0.70
	Day Light: 0.49

## DISCUSSION

The pharmaceutico-analytical evaluation of the *Ashwagandha* tablet reveals critical insights into its standardization, chemical integrity, and potential

therapeutic efficacy. Through a detailed examination of its organoleptic, physicochemical, and phytochemical features, this analysis supports the formulation's quality and aligns with the

expectations for a contemporary Ayurvedic dosage form. The macroscopic description of the tablet shows a creamish color, bitter taste, and characteristic odor. These sensory attributes correspond well with the properties of *Withania somnifera*, affirming the use of authentic raw materials. The bitterness observed is characteristic of the bioactive withanolides present in *Ashwagandha*, known for their potent pharmacological activities.

From a physicochemical perspective, the findings are within pharmaceutically acceptable limits and reflect good manufacturing practice. The loss on drying value was 3.717%, indicating that the formulation possesses optimal moisture content which aids in preserving its shelf life and prevents microbial degradation. The ash values, including total ash at 6.410%, acid-insoluble ash at 1.408%, and water-soluble ash at 2.507%, provide evidence that the tablet does not contain excessive inorganic or siliceous matter, supporting its purity and cleanliness. These values also indicate minimal contamination by adulterants or extraneous matter. The extractive values play a pivotal role in understanding the nature and extent of bioactive compounds extractable by polar and non-polar solvents. The water-soluble extractive value of 33.757% significantly surpasses the alcohol-soluble extractive value of 7.395%, demonstrating that the majority of the phytoconstituents present are hydrophilic. This finding is in accordance with *Ashwagandha*'s known content of water-soluble phytochemicals such as flavonoids and glycosides, which are responsible for many of its adaptogenic and neuroprotective effects. The mechanical attributes of the tablet further suggest good pharmaceutical integrity. The friability test result of 1.170% is slightly above the ideal limit of 1%, which may be acceptable in herbal formulations due to inherent variability in plant materials. The hardness value of 3 kg/cm<sup>2</sup> indicates sufficient structural resilience during handling and transportation, while the disintegration time of three minutes points to excellent solubility and quick onset of therapeutic action.

The preliminary phytochemical screening further substantiates the formulation's pharmacological potential. The tablet tested positive for flavonoids, tannins, steroids, and cardiac glycosides, among others. Flavonoids and tannins, being potent antioxidants, are known to scavenge free radicals and reduce oxidative stress, a key component in the pathophysiology of neurodegenerative and psychiatric disorders. The presence of steroids, most likely withanolides, is particularly significant as these are the primary bioactive components in *Ashwagandha* responsible for its adaptogenic, anti-inflammatory, and neuro-regenerative properties.

Cardiac glycosides, although requiring cautious interpretation, may contribute to cardiovascular stability, which is beneficial in managing stress-related somatic symptoms. The detection of anthraquinone glycosides in the alcohol extract also indicates the presence of compounds with mild purgative or detoxifying properties.

Notably, the tablet did not test positive for alkaloids, amino acids, or saponin glycosides. This does not diminish the formulation's therapeutic value as *Ashwagandha* is not predominantly known for these constituents. The absence of proteins and amino acids may be attributed to the extraction and processing methods which primarily preserve secondary metabolites rather than primary nutritional components.

Thin Layer Chromatography (TLC) analysis using the alcohol extract displayed a well-defined profile with multiple R<sub>f</sub> values under UV light. The detection of multiple bands under both short and long wavelengths confirms the presence of a complex array of constituents. These R<sub>f</sub> values, derived from a toluene:ethyl acetate mobile phase (7:3 ratio), serve as a fingerprint for future quality control and batch standardization, ensuring therapeutic consistency.

Beyond its analytical and pharmaceutical parameters, *Ashwagandha* holds a distinguished place in both classical Ayurvedic practice and contemporary psychiatric therapeutics. Traditionally categorized under *Rasayana*, it has been used to promote longevity (*Deerghayus*), enhance mental strength (*Medhya*), improve immunity, and build resilience against psychological stressors (*Sahasa Shamana*) [11]. In *Ayurveda*, a *Medhya Rasayana* is a rejuvenative specifically indicated for cognitive and mental health, and *Ashwagandha* has long been listed among the most potent herbs in this category.

Modern scientific investigations have increasingly substantiated these classical claims. Pharmacological studies confirm that *Ashwagandha* exerts significant effects on stress, anxiety, depression, and various neurocognitive dysfunctions [12]. One of the best-documented actions is its adaptogenic property—the capacity to enhance the body's ability to cope with physical and psychological stress. This is primarily mediated through modulation of the hypothalamic-pituitary-adrenal (HPA) axis and reduction of cortisol, the primary stress hormone, which is often elevated in chronic stress states [13]. Clinical trials have demonstrated that *Ashwagandha* root extract can significantly reduce symptoms of chronic stress and generalized anxiety disorder. In a randomized, double-blind placebo-controlled study, participants receiving high-concentration full-spectrum extract of *Ashwagandha* showed a 44% reduction in stress



levels based on perceived stress scale scores, a result comparable to standard anxiolytics, but with fewer adverse effects [14].

In psychiatric care, *Ashwagandha* exhibits dual effects as both an anxiolytic and antidepressant. Mechanistically, these effects are believed to be associated with its action on GABAergic neurotransmission and serotonergic modulation both critical pathways in mood stabilization [15]. Its interaction with GABA-A receptors and influence on monoamine oxidase inhibition may account for its calming yet non-sedative impact on the central nervous system. Patients supplemented with *Ashwagandha* have reported reductions in Hamilton Anxiety Rating Scale (HAM-A) scores, improvements in Beck Depression Inventory (BDI) scores, and overall enhancement in mood stability and emotional regulation [16]. The herb is also found to ameliorate the side effects of synthetic antidepressants, such as fatigue, sleep disturbances, and cognitive dulling symptoms that can severely impact quality of life and treatment compliance. A rapidly growing area of interest is *Ashwagandha*'s nootropic potential. The herb has been shown to support various domains of cognitive performance, including working memory, executive function, and attention span. These benefits are particularly noted in individuals with mild cognitive impairment (MCI), age-associated memory loss, and early stages of neurodegenerative diseases like Alzheimer's [17].

The underlying mechanisms involve increased dendritic branching, enhancement of synaptic plasticity, and upregulation of brain-derived neurotrophic factor (BDNF). Additionally, the antioxidant and anti-inflammatory properties of *Ashwagandha* protect neurons from oxidative stress and mitochondrial dysfunction two central features of Alzheimer's and Parkinson's disease pathology [18]. It has also shown potential in preventing beta-amyloid aggregation, a hallmark of Alzheimer's disease, and in promoting neurogenesis in hippocampal regions associated with learning and memory [19]. Sleep disturbances, particularly insomnia and sleep fragmentation, are increasingly prevalent in modern life, often linked with stress, anxiety, or depression. *Ashwagandha* has shown significant promise in managing sleep disorders by improving both sleep onset and sleep quality. This is primarily attributed to its active compound triethylene glycol, which exhibits natural sedative properties, as well as its influence on melatonin production and GABAergic signaling [20].

Studies have demonstrated improvements in Pittsburgh Sleep Quality Index (PSQI) scores in adults taking *Ashwagandha* root extract, with particular benefit noted in sleep latency, efficiency, and duration. Unlike synthetic hypnotics, *Ashwagandha* offers these benefits without inducing

morning drowsiness, making it a safe long-term option for patients suffering from chronic insomnia [21]. Another promising area is its application in paediatric neuropsychiatry, particularly in Attention-Deficit Hyperactivity Disorder (ADHD). Given the herb's calming effect on the nervous system without cognitive suppression, it offers a safer and more holistic alternative to psychostimulants like methylphenidate. Though clinical data is still emerging, preliminary studies and anecdotal reports suggest that *Ashwagandha* may help reduce hyperactivity, impulsivity, and attention deficits in children [22]. One of the most compelling aspects of *Ashwagandha* is its ability to function as an adjunctive therapy alongside standard psychotropic drugs. When combined with antidepressants or anxiolytics, it has been found to enhance therapeutic response, reduce dosage requirements, and mitigate adverse effects such as gastrointestinal disturbances, sexual dysfunction, and emotional blunting [23].

Its action on somatic symptoms of mental illness—such as fatigue, muscle tension, and digestive issues—provides a more comprehensive treatment approach, aligning with Ayurvedic principles that treat both mind (*Manas*) and body (*Sharira*). Moreover, its immunomodulatory and anti-inflammatory effects may support the emerging concept of neuroinflammation's role in psychiatric disorders, particularly in depression and bipolar disorder [24]. Overall, the tablet may be efficacious in Mental health Disorders.

## CONCLUSION

The comprehensive pharmaceutico-analytical evaluation of the *Ashwagandha* tablet underscores the significance of integrating classical Ayurvedic principles with contemporary pharmaceutical standards to ensure quality, safety, and therapeutic efficacy. The formulation was found to possess acceptable organoleptic properties and complied with most physicochemical benchmarks, including optimal moisture content, acceptable ash values, satisfactory hardness, and rapid disintegration. These attributes collectively affirm the tablet's pharmaceutical stability and user compliance. Phytochemical screening revealed the presence of key bioactive compounds such as flavonoids, tannins, steroids, and cardiac glycosides—components that align with the documented adaptogenic and neuroprotective effects of *Ashwagandha*. The absence of certain constituents like alkaloids or amino acids does not detract from its therapeutic potential, given *Ashwagandha*'s established phytochemical profile. TLC analysis further supported the integrity and consistency of the formulation, offering a reproducible chemical

fingerprint useful for standardization and quality control.

From a therapeutic standpoint, the findings not only validate the use of *Ashwagandha* in psychiatric and neurodegenerative conditions but also highlight its broader *Rasayana* benefits, such as stress reduction, immune modulation, and cognitive enhancement. As a *Medhya Rasayana*, its role in mental health management from anxiety and depression to sleep disturbances and ADHD is backed by both classical texts and modern clinical research. This study exemplifies how traditional Ayurvedic formulations, when subjected to rigorous scientific scrutiny, can meet global pharmaceutical expectations and expand their role in integrative medicine. The *Ashwagandha* tablet thus represents a promising model for modern herbal therapeutics, offering a safe, effective, and standardized alternative to synthetic drugs. Future studies may focus on long-term stability, bioavailability, and clinical efficacy to further reinforce its place in contemporary healthcare.

#### CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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