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# Ashwagandha (Withaniasomnifera) as an Adjuvant Herbal Syrup for Rare Pediatric Neurological Disorders: A Comprehensive Review

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**Abstract:** *Background: Rare pediatricneurological disorders (RPNDs) including Batten disease, Angelman syndrome, Rett syndrome, and Lennox-Gastaut syndrome remain among the most therapeutically challenging conditions in modern medicine. Curative treatments are scarce, and conventional pharmacotherapy frequently induces significant adverse effects in children. This clinical gap has prompted growing interest in evidence-based herbal adjuvants.*
*Objective: This review critically examines the scientific basis for using a standardized Ashwagandha (Withaniasomnifera) herbal syrup as a neuroprotective adjuvant in pediatric neurological management, drawing upon phytochemical, pharmacological, and formulation evidence.*
*Methods: A structured narrative review was conducted encompassing pharmacognosy, pre-clinical and clinical pharmacology of Withaniasomnifera, pediatric oral liquid formulation science, and quality evaluation data from five formulation batches (F1–F5) of an Ashwagandha herbal syrup.*
*Results: The plant's withanolides and withanamides demonstrate multi-target neuroprotective actions including cholinergic enhancement, GABAergic modulation, NF-κB inhibition, and antioxidant enzyme upregulation. Among all batches, Formulation F3 (2.0% extract, sucrose-sorbitol-glycerinbase) achieved optimal balance pH 4.5, viscosity 248 mPa·s, drug content 98.8%, and palatability score 4.1/5 with confirmed 6-month accelerated stability.*
*Conclusion: Ashwagandha herbal syrup presents a scientifically sound, safe, and patient-friendly adjuvant candidate for symptom management in rare pediatric neurological disorders. Further clinical validation through randomized controlled trials is strongly recommended..*

**Keywords:** Withaniasomnifera, Ashwagandha, pediatric neurology, herbal syrup, withanolides, neuroprotection, Batten disease, Lennox-Gastaut syndrome, phytomedicine, formulation

## I. INTRODUCTION

Pediatric neurological diseases that fall under the 'rare' umbrella present clinicians with a dilemma that is both scientific and humanitarian. These conditions Batten disease, Angelman syndrome, Rett syndrome, Lennox-Gastaut syndrome, and Niemann-Pick disease, among others collectively affect millions of children worldwide, yet individually each disorder is uncommon enough that large-scale therapeutic trials are difficult to conduct and funding remains limited [1]. What makes these disorders particularly devastating is not just their rarity but their progression. Most involve a gradual deterioration of neurological function seizures worsen, cognition declines, motor abilities regress and the

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pharmacological tools available to families and clinicians are largely palliative. Anticonvulsants, antispasmodics, and neurostimulants provide partial relief at best, and in many cases, long-term use in young patients brings its own burden: hepatotoxicity, bone marrow suppression, behavioral changes, and impaired neurodevelopment [2].

This situation has prompted a legitimate and growing scientific conversation about herbal medicine not as a replacement for modern pharmacotherapy, but as a thoughtful adjuvant. The goal is not to abandon evidence-based medicine, but to extend it into botanical science where the evidence genuinely supports it. Ayurvedic tradition has long classified a group of herbs termed MedhyaRasayanaplants that nourish the nervous system and protect cognitive function. Among these, Withaniasomnifera, commonly known as Ashwagandha, stands out as the most thoroughly studied and most promising [3].

This review synthesizes available evidence on Ashwagandha's pharmacological mechanisms, its phytochemical identity, and the formulation science behind converting it into a child-appropriate oral syrup. It draws on pre-clinical animal data, clinical trials in adults, and the findings from a structured formulation study involving five optimized batches evaluated for physicochemical, phytochemical, and stability parameters.

## II. BOTANICAL PROFILE OF WITHANIASOMNIFERA

Withaniasomnifera (L.) Dunal is a member of the Solanaceae family the same family as tomatoes, peppers, and potatoes. It grows as a small, woody shrub, typically 35–75 cm tall, in the arid and semi-arid regions of the Indian subcontinent, North Africa, and the Mediterranean basin. In India, it thrives in Rajasthan, Madhya Pradesh, Punjab, and Himachal Pradesh, often in well-drained, sandy-loam soils at altitudes up to 1500 metres [7].

The plant's medicinal history stretches back more than 3,000 years. Both the Charaka Samhita and the Sushruta Samhita foundational texts of classical Ayurvedic medicine describe Ashwagandha root as a Rasayana: a rejuvenating substance that promotes vitality, sharpens the mind, and strengthens the body against physical and mental stressors. The name itself is instructive 'Ashwa' (horse) and 'gandha' (smell) referring both to the characteristic odor of the fresh root and, symbolically, to the strength and stamina the herb was believed to confer [7].

The roots are the primary medicinal organ and remain the pharmacopoeial standard. They are thick, fleshy, and light brown externally with a creamy white interior. Standardization for pharmaceutical purposes is based on withanolide content the Ayurvedic Pharmacopoeia of India specifies a minimum of 0.3% w/w. Modern commercial extracts such as KSM-66 and Sensoril achieve standardization to much higher levels through water or hydroalcoholic extraction [6,7].

## III. PHYTOCHEMICAL COMPOSITION

### *3.1 Withanolides — The Primary Bioactives*

Withanolides are steroidal lactones unique to the genus Withania. Over 300 individual withanolides have been identified, but Withaferin A and Withanolide A have attracted the most pharmacological attention. Withaferin A is a potent anti-inflammatory and pro-apoptotic compound relevant to neuroinflammatory disease while Withanolide A has been most associated with cognitive and neuroprotective effects. Withanolide D demonstrates immunomodulatory and antitumor properties [6,8].

What makes withanolides particularly interesting from a neuroprotection standpoint is their blood-brain barrier permeability. Unlike many plant-derived compounds that are blocked at the BBB, withanolides appear to access neural tissue, making them genuinely neuroactive rather than merely peripherally bioavailable [4].

### *3.2 Alkaloids, Withanamides, and Supporting Compounds*

The alkaloid fraction principally somniferine, withanine, and isopelletierinecontributes sedative and muscle-relaxant properties, complementing the withanolide-mediated neuroprotection. Withanamides A through G are antioxidant peptide-like compounds that have demonstrated specific efficacy in protecting neurons from amyloid-beta induced oxidative stress, a pathway relevant to neurodegeneration in several pediatric conditions [8].

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Sitoindosides VII–X are water-soluble glycowithanolides particularly associated with adaptogenic effects the ability to blunt physiological stress responses. In pediatric neurological disease, where chronic stress biology is deeply intertwined with disease burden, this class of compound adds meaningful pharmacological breadth. Flavonoids including kaempferol and quercetin complete the phytochemical profile with additional antioxidant and anti-inflammatory contributions [6].

| Constituent Class | Key Compounds | Primary Action |
|---|---|---|
| Withanolides | Withaferin A, Withanolide A, D | Neuroprotection, anti-inflammatory, antitumor |
| Alkaloids | Somniferine, Withanine | Sedative, muscle relaxant, CNS modulation |
| Sitoindosides | Sitoindoside VII–X | Adaptogenic, immunomodulatory |
| Withanamides | Withanamides A–G | Antioxidant neuroprotection |
| Polyphenols | Kaempferol, Quercetin | Antioxidant, anti-inflammatory |

*Table 1: Key Phytochemical Classes of Withaniasomnifera*

## IV. PHARMACOLOGICAL MECHANISMS RELEVANT TO PEDIATRIC NEUROLOGY

### *4.1 Cholinergic System Enhancement*

The cholinergic hypothesis of cognitive dysfunction originally developed in the context of Alzheimer's disease is applicable to several rare pediatric neurological disorders where memory, attention, and learning are impaired. Bhattacharya and colleagues demonstrated that glycowithanolide fractions from Ashwagandha root reversed ibotenic acid-induced cholinergic lesions in rodent brains, restoring performance on spatial and associative memory tasks. Mechanistically, the herb inhibits acetylcholinesterasethe enzyme responsible for degrading acetylcholine thereby extending the synaptic half-life of this critical neurotransmitter [1,4].

### *4.2 GABAergic Modulation and Anticonvulsant Activity*

Perhaps the most clinically relevant mechanism for epileptic encephalopathies like Lennox-Gastaut syndrome is Ashwagandha's interaction with the GABAergic system. Kulkarni and George showed that co-administration with phenobarbitone in maximal electroshock seizure models produced synergistic anticonvulsant effects exceeding either agent alone. This implicates withanolides in enhancing GABA-A receptor function, which is the same mechanism exploited by conventional anticonvulsants [9]. The implication for polytherapy in drug-resistant epilepsy a hallmark of Lennox-Gastaut — is clinically meaningful.

### *4.3 NF-κB Inhibition and Neuroinflammation*

Neuroinflammation is increasingly recognized as a driver of disease progression in multiple pediatric neurological conditions, including Batten disease and Niemann-Pick. Withaferin A inhibits the NF-κB transcription factor pathway effectively blocking the cellular machinery that amplifies inflammatory responses. Multiple in vitro studies and animal models have confirmed significant reduction in pro-inflammatory cytokines (IL-1β, TNF-α, IL-6) following Ashwagandha treatment, with effects extending into central nervous system tissue [4,10].

### *4.4 Antioxidant Enzyme Upregulation*

Oxidative stress is a common pathological thread in neurodegeneration. Withanolides stimulate superoxide dismutase (SOD) and catalase two of the body's primary endogenous antioxidant enzymes through mechanisms that appear to involve Nrf2 pathway activation. In pediatric neurological conditions associated with mitochondrial dysfunction and reactive oxygen species accumulation, this antioxidant upregulation may translate into meaningful neuroprotection even where disease-modifying pharmacotherapy is unavailable [4,6].

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### *4.5 Adaptogenic and Stress-Axis Modulation*

Chronic neurological illness in childhood creates profound physiological stress both for the child and the family unit. Sitoindosides from Ashwagandha modulate the hypothalamic-pituitary-adrenal (HPA) axis, reducing cortisol hypersecretion and blunting chronic stress responses. Chandrasekhar et al. (2012) demonstrated in a rigorous double-blind RCT that standardized Ashwagandha extract significantly reduced serum cortisol, perceived stress scores, and anxiety ratings in adults [10]. While pediatric-specific data is limited, the underlying mechanism is biologically conserved.

## V. RATIONALE FOR HERBAL SYRUP AS A PEDIATRIC DOSAGE FORM

Choosing an appropriate dosage form is not merely a pharmaceutical technicality for pediatric patients, it is a clinical decision that directly determines whether treatment is actually administered. Children with rare neurological disorders often have swallowing difficulties (dysphagia), sensory sensitivities, tube-feeding dependency, or strong taste aversions. Solid dosage forms tablets and capsules are poorly suited to this population, presenting risks of aspiration, dose inaccuracy when crushed, and poor compliance [5].

Oral liquid formulations, particularly syrups, overcome most of these barriers. They allow dose adjustment based on body weight critical in pediatrics where dosing is never 'one size fits all.' They can be mixed into food or administered via feeding tube. Their bioavailability is often faster and more predictable than dissolution-dependent solid forms. And critically, with appropriate flavoring and sweetening, they can be made genuinely palatable a factor that transforms theoretical compliance into real-world adherence over the months and years that adjuvant therapy demands [5].

The herbal syrup formulation approach is well-established in both Ayurvedic tradition (as 'Arishtam' and 'Asavam' liquid preparations) and modern pharmaceutical practice. For Ashwagandha specifically, an aqueous decoction extraction preserves the water-soluble withanolides and alkaloids, avoids organic solvents incompatible with pediatric use, and integrates seamlessly into a sugar-based syrup vehicle [6].

## VI. FORMULATION DEVELOPMENT AND EXCIPIENT RATIONALE

### *6.1 Active Extract Preparation*

Root powder authenticated to ≥0.3% withanolide content was decocted in distilled water at 70°C for 30 minutes under continuous stirring. This temperature was selected to maximize polysaccharide and withanolide extraction while preventing degradation of thermolabile alkaloids. Double filtration through Whatman No. 1 filter paper yielded a clear extract suitable for incorporation into the syrup base [6].

### *6.2 Excipient Selection and Functional Rationale*

The syrup base was constructed from sucrose (45–55%) as the primary sweetener and viscosity builder, combined with sorbitol (10–15%) a non-cariogenic polyol that reduces the risk of dental complications in children receiving long-term liquid medication. Glycerin (5%) served dual roles as a humectant (preventing crystallization of the sucrose matrix) and a co-solvent enhancing withanolide solubility. Sodium benzoate (0.1%) was selected as the antimicrobial preservative, effective within the formulation's acidic pH range. Citric acid and sodium citrate together form a buffer system maintaining the target pH of 4.0–5.5, within which sodium benzoate achieves its maximum antimicrobial efficacy. Strawberry flavor was incorporated to mask the inherent earthy character of the Ashwagandha extract [5,6].

| Excipient | Function | Qty per 100 mL |
|---|---|---|
| Sucrose | Sweetener, viscosity builder | 45–55 g |
| Sorbitol | Non-cariogenic sweetener, humectant | 10–15 mL |
| Glycerin | Co-solvent, humectant | 5 mL |

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| | | |
|---|---|---|
| Sodium Benzoate | Antimicrobial preservative | 0.10 g |
| Citric Acid | pH modifier, taste enhancer | 0.20 g |
| Sodium Citrate | Buffering agent | 0.30 g |
| Strawberry Flavor | Palatability masking | 0.20 mL |
| Distilled Water | Vehicle | q.s. 100 mL |

*Table 2: Formulation Composition and Functional Roles*

## VII. EVALUATION METHODOLOGY AND FINDINGS

### *7.1 Phytochemical Confirmation*

Phytochemical screening of the aqueous decoction confirmed the presence of all pharmacologically critical secondary metabolite classes. The Dragendroff's test gave an orange-red precipitate confirming alkaloids; the foam test confirmed saponins; the Liebermann-Burchard reaction produced a green-blue coloration characteristic of withanolides and steroids; the Shinoda test showed pink-red coloration indicating flavonoids; and the ferric chloride test revealed trace tannins. This comprehensive positive profile validates the extraction efficiency of the decoction method and confirms that the pharmacologically active constituents were preserved through the manufacturing process.

### *7.2 Physicochemical Performance Across Batches*

Five formulation batches were evaluated for pH, viscosity, sedimentation ratio, drug content, and palatability. All batches performed within acceptable limits across all parameters, demonstrating the robustness of the manufacturing process. Key differences emerged in palatability a parameter of particular importance for a pediatricproduct where formulation F3 achieved the highest score.

| Batch | pH | Viscosity (mPa·s) | Drug Content (%) | Palatability (/5) |
|---|---|---|---|---|
| F1 | 4.2 | 182 | 96.2 | 3.2 |
| F2 | 4.4 | 215 | 97.5 | 3.8 |
| F3* | 4.5 | 248 | 98.8 | 4.1 |
| F4 | 4.6 | 260 | 99.1 | 3.6 |
| F5 | 4.8 | 274 | 97.9 | 3.4 |

*Table 3: Physicochemical Data — F1 to F5 (* = Optimized Batch)*

### *7.3 Selection of Optimized Formulation F3*

Formulation F3 emerged as the optimal batch not because it was best in every individual parameter F4 achieved marginally higher drug content at 99.1% but because it performed most consistently across all parameters combined. Its pH of 4.5 sits comfortably within the preservative efficacy window. Its viscosity of 248 mPa·s is neither too thin (which causes dose inaccuracy in spoon administration) nor too thick (which impedes pouring and dose measurement). Its sedimentation ratio of 0.98 reflects excellent physical stability. And critically, its palatability score of 4.1 out of 5 was the highest of all batches a decisive advantage for a medication intended for daily administration to children over potentially years.

The palatability advantage of F3 is attributable to the sucrose-sorbitol balance at 55% and 15% respectively. This combination delivers adequate sweetness to mask the earthy herbal extract while avoiding the excessively cloying mouthfeel associated with higher sucrose concentrations, which actually reduced acceptance in F4 and F5.

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*7.4 Stability Assessment*

Accelerated stability testing at 40°C ± 2°C and 75% ± 5% RH over six months according to ICH Q1A(R2) guidelines revealed no clinically meaningful change in pH, viscosity, drug content, or organoleptic properties at any sampling interval (0, 1, 2, 3, and 6 months). No microbial contamination was detected throughout the study, confirming the adequacy of the sodium benzoate–citric acid preservative system. These findings satisfy ICH criteria for acceptable accelerated stability and support assignment of a provisional shelf life appropriate for a market product.

## VIII. CLINICAL RELEVANCE AND SAFETY CONSIDERATIONS

The pharmacological profile of Ashwagandha maps onto the pathophysiology of rare pediatric neurological disorders with a coherence that is genuinely encouraging. GABAergic modulation addresses the epileptic dimension of conditions like Lennox-Gastaut. Cholinergic enhancement targets the cognitive impairment component seen across RPNDs. NF-κB inhibition counters the neuroinflammatory progression in Batten disease and Niemann-Pick. Antioxidant upregulation protects mitochondria-stressed neurons. And HPA-axis modulation addresses the biological correlates of chronic illness burden.

The safety profile of Withaniasomnifera, across its history of traditional use and contemporary clinical studies, is favorable. Chandrasekhar et al. (2012) and Langade et al. (2019) both reported no serious adverse events in adult populations receiving standardized extract over 8–12 weeks. Known contraindications include pregnancy, autoimmune conditions, and hypersensitivity to the Solanaceae family none of which present a systematic barrier to pediatric neurological patients [10,11].

It must be acknowledged clearly that current clinical evidence for Ashwagandha in pediatric populations specifically is limited. Most trials have been conducted in adults. The extrapolation of mechanism-based neuroprotection from adult and animal data to children while pharmacologically logical requires validation. A staged clinical development program beginning with open-label pediatric safety trials and progressing to randomized controlled efficacy studies would be the appropriate evidence-generation pathway.

## IX. FUTURE RESEARCH DIRECTIONS

Several important questions remain for future investigation. First, in vitro drug release profiling of the optimized F3 formulation would characterize the kinetics of withanolide release and absorption data that is currently absent. Second, bioavailability studies in appropriate animal models would establish the pharmacokinetic parameters (Cmax, Tmax, AUC) that are prerequisites for rational pediatric dose selection. Third, dedicated pediatric toxicity studies both acute and sub-chronic are needed to establish a safety margin specific to developing organ systems.

On the clinical side, a Phase I open-label safety and tolerability study in pediatric patients with confirmed rare neurological disorders would represent the appropriate first human study. Subject to safety confirmation, a Phase II randomized controlled trial probably with seizure frequency and quality-of-life as co-primary endpoints could provide the efficacy evidence needed for regulatory consideration. The formulation platform developed in this study would serve directly as the investigational product for such a program.

Longer-term, the formulation approach could be extended to combination herbal preparations incorporating Brahmi or Shankhapushpi alongside Ashwagandhato exploit complementary MedhyaRasayana mechanisms and potentially achieve superior outcomes through botanical synergy.

## X. CONCLUSION

This review has assembled the pharmacognostic, mechanistic, formulation, and clinical evidence surrounding Ashwagandha (Withaniasomnifera) as a herbal adjuvant for rare pediatric neurological disorders. The picture that emerges is genuinely promising. The plant's phytochemical constituents particularly its withanolides, withanamides, and sitoindosidescollectively address several of the core pathophysiological mechanisms driving neurological dysfunction in this patient population.

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The herbal syrup dosage form is both scientifically appropriate and practically optimized for pediatric administration. The optimized Formulation F3 satisfies all relevant quality benchmarks, demonstrates six-month accelerated stability, and achieves the palatability standard necessary for long-term adherence in children. It represents a well-characterized, manufacturable candidate for further clinical development.

What is needed now is not more in vitro work, but clinical commitment a willingness to take a rigorously prepared herbal formulation through the evidence-generation pathway that can transform it from a promising candidate into a validated therapeutic option for children who currently have far too few. Ashwagandha, with its millennia of documented use and growing body of modern scientific support, deserves that investment.

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