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SHODEN®

Advancing ashwagandha: Shoden®'s high-potency, low-dose advantage

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As demand for ashwagandha flourishes in both the supplements and functional F&B space, this report explores the world's most bioavailable extract, Shoden® – including the safety assurances and clinical trials that support its role in advancing health and wellbeing across a multitude of application areas.

Trust is an increasing priority for consumers of supplements – and with good reason. Although most herbal medicinal ingredients have a long history of traditional use, for a large proportion of botanicals and other raw materials, efficacy has not been clearly established in clinical trials. Safety can likewise remain a grey area, particularly as cultivation and extraction methods often vary wildly between manufacturers. Stringent quality standards and robustly designed clinical trials are therefore imperative to establish both safety and efficacy.

Nowhere is this truer than in the case of ashwagandha, which has become one of the top five best-selling natural supplements across multichannel and natural channel outlets, alongside recording 20%+ year-on-year growth in sales across mainstream channels.[1]

Amidst a surge of interest in Ayurvedic medicine, and with the global market for ashwagandha extracts set to expand at a CAGR of 10.9% from 2022–2032, broader acceptance and consumer trust in brands will hinge upon formulators opting for ashwagandha extracts that are bioavailable, effective, and safe.[2]

In this report, we explore the science behind how Arjuna Natural achieves industry-leading bioavailability in its branded ashwagandha extract Shoden®, and how studies confirming potency, efficacy, and safety are a pre-requisite for brands in selecting their supplier-partners in this flourishing market segment.

Proprietary extraction process

Drawing upon thousands of years of Ayurvedic wisdom, combined with nearly four decades of sector-leading in-house scientific expertise, Arjuna Natural has become a leader in the botanicals segment. One key advancement in this area is Shoden® – the world's most bioactive ashwagandha extract today.

© Arjuna extracting process, source-Arjuna Naturals

Considerable time and money have been invested in developing Shoden® ashwagandha, including the proprietary extraction process underpinning the innovation, with substantial resources likewise funnelled into advancing the science behind analytically testing this potent ingredient to the fullest degree. The result is a superior ashwagandha extract that boasts an industry-leading 35% withanolide glycoside content and the lowest dose advantage of 60mg per day – all backed by clinical studies confirming its safety and efficacy across an array of use cases and need states.

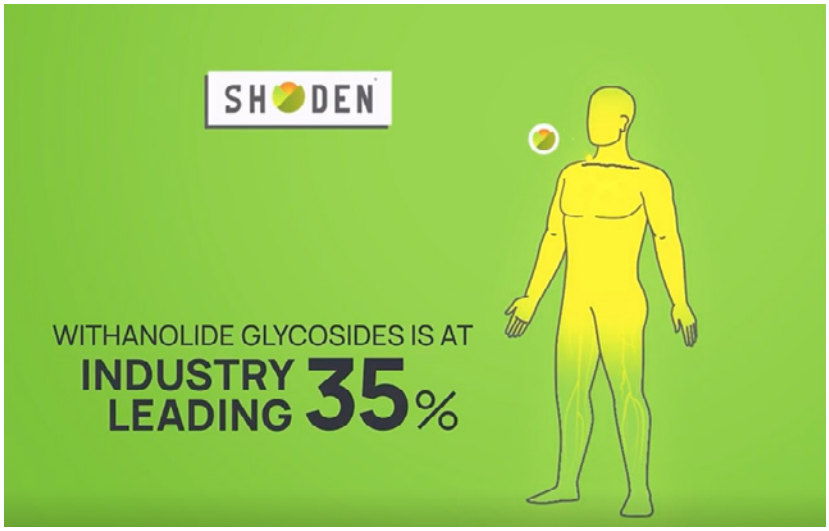
With its integrity controlled from the ground up, Shoden® is created in a clean, two-step, proprietary extraction process utilising just water and ethanol – a process that champions purity to harness the natural power of ashwagandha. Arjuna Natural's patented extraction technology is crucial to achieving Shoden®'s unique attributes, capturing the botanical's withanolide glycosides – the most active and bioavailable form of withanolides present in ashwagandha.

Withanolide glycosides are bound to sugar molecules, which can significantly enhance absorption and bioavailability of these bioactives. Key glycosides include: Withanoside IV, Withanoside V, and Withanoside VI. What makes this distinction important is that those different forms can have varying levels of bioavailability and effectiveness in the body. Indeed, recent research has shown that glycosidic forms may offer superior absorption and sustained activity compared to their aglycone counterparts.

Arjuna Natural quantifies those withanolide glycoside molecules using a validated HPLC (high-performance liquid chromatography) method. The resultant ingredient – comprising 21 different withanolide glycosides for full-spectrum support – is more bioactive and more bioavailable than any other ashwagandha extract on the market today.

The benefits of high bioavailability

Ashwagandha's bioactive molecules, withanolides, typically have a short half-life and eliminate rapidly from the body. However, a recent pharmacokinetic study demonstrated how Shoden® bucks this trend – delivering extraordinary results across multiple markers, and after just one dose.



Given ashwagandha's long history of use, alongside countless clinical trials focused on the botanical over the years, it is perhaps surprising that the human pharmacokinetics of withanolides (the active phytochemicals found in ashwagandha extracts) have not been fully evaluated until recently. Yet pharmacokinetic studies on the bioactive constituents of herbal drugs serve to provide valuable information on their metabolism, dosage form, and directions for clinical use.[3]

With limited human data hitherto generated on the bioavailability and metabolism of withanolides, in 2023 a study[4] set out to rectify that. It evaluated the oral pharmacokinetics and bioequivalence of active withanolides in human plasma after administration of a single dose of two commercial ashwagandha extracts containing equal amounts of total withanolides.

The first of the extracts, Shoden® (referred to in the study as 'WS-35') was standardised to no less than 35% withanolide glycosides specifically, while the competing 'WS-2.5' extract was standardised to 2.5% withanolides. In each extract, the clinical dosages were normalised to 185mg of total withanolide content at bioequivalent dosages.

Across various bioavailability parameters, Shoden® ('WS-35') outperformed the rival ashwagandha extract – and to a significant degree: Shoden®'s half-life, C-max, and mean residence time of total withanolide content were 5.18, 5.62, and 4.13 times higher, respectively. Shoden® exhibited lower systemic clearance than the WS-2.5 extract, while the latter delivered withanolides to the body in a quick shot, with blood levels returning to zero within six hours.

Compellingly, Shoden® was shown to be 280 times more bioavailable than the alternative ingredient. Such exceptional bioavailability appears to lie in Shoden®'s strength (as measured by withanolide content) and specifically in its industry-leading 35% content of withanolide glycosides – the botanical's most active, water-soluble molecules.

Other manufacturers have standardised their ashwagandha extracts for total withanolide content, without recognising the critical difference between glycosides and aglycones. Most extracts contain higher levels of aglycones than glycosides. This is problematic because not all withanolides are equally bioavailable or effective. An analogy is that all apples are fruits, but not all fruits are apples – similarly, all withanolide glycosides are withanolides, yet not all withanolides are withanolide glycosides[4].

HPLC – key to calculating purity and potency

The ashwagandha market is today awash with extracts claiming to contain a certain percentage of standardised withanolides. But do such extracts contain withanolide glycosides? And if not, what are they?

"Ashwagandha contains a large number of compounds, the most common of which is a group known as withanolides – including both water-soluble withanolide glycosides and water-insoluble withanolide aglycones," explains Dr Binu Kuruvilla, chief innovation officer at Arjuna Natural. "Most ashwagandha extracts are standardised to 1.5%, 2.5%, or even 5%, in terms of withanolide content – out of which the majority are water-insoluble aglycones, making them much less bioavailable and thus requiring large doses."

When Dr Kuruvilla and his team at Arjuna Natural started their research on ashwagandha, they found existing analytical methods available in the scientific space had "many limitations", including analysing only a very limited number of withanolides, as he advises. "We had to develop and validate a method using HPLC to accurately measure the active molecules in Shoden®. The resultant method uses 21 identified withanolide glycosides for calculating the percentage of purity in Shoden®.

"While other products use methods that either cover only a few withanolides or are simply unscientific and unreliable, Shoden®'s analytical method provides a more comprehensive and accurate analysis of the full spectrum of bioactive compounds in ashwagandha. And that's what Shoden® is all about – not just the product but also having a robust and scientifically validated analytical method to back it up."

Low dosage advantage for formulators

So, how does Shoden®'s industry-leading bioavailability and potency translate into opportunities for formulators?

With the highest concentration of bioactives and the lowest dose advantage in the ashwagandha extract category, Shoden® responds to numerous formulation challenges – including how to incorporate an ashwagandha extract into a product while minimising impact to taste, texture, functional properties (all clearly crucial when incorporating into functional food and beverage products).

For supplements specifically, Shoden®'s high-potency low-dosage attributes are an obvious advantage when striving to encourage higher consumer compliance. This matters, given that 'swallowing pills' was a reason given by 14% of EU consumers as to why they had never taken supplements.[5] It follows that dosage size could also be a contributory factor for consumers who cease to adhere to their health supplements regimen.

With so-called 'pill fatigue' a strengthening dynamic, how nutraceutical solutions are delivered is therefore naturally a key consideration for formulators today. The phenomenal rate of expansion observed in the gummies segment is testament to this, while smaller tablet or capsule size is clearly also preferable within this context.

Shoden®'s 'high-potency, low-dosage' advantage means easier incorporation into gummies, and smaller unit-size doses in more traditional supplement formats. As Kevin Coyne, CEO of South Africa-based natural supplements business Natroceutics, points out: "The low dose advantage is also convenient if you want to blend it into other products, because it gives you capacity within the capsule to have more fill-space. So, we've considered ideas of formulating a Shoden®-plus-multivitamin-type product, or combining Shoden® with, say, magnesium."

A renowned expert and author in the field of ashwagandha, Dr Dilip Ghosh highlights Shoden®'s key advantages from a new product development perspective: "It's water-soluble, meaning you can use it in normal food, functional food, nutraceuticals, and even what I'm seeing as a new medical food category – 'functional nutrition'. As an all-evidence-based ashwagandha product, Shoden® has huge application potential – as a beverage, tablet, capsule, sachet, powder. Because it's water-soluble and highly bioavailable, and you need only a very small dose, it's applicable for any format," he advises.

Increasingly, the challenge for formulators is in creating an experience that is, at baseline, acceptable, and ideally even enjoyable, for the consumer – thus increasing acceptance (and adherence) as part of their daily regimen. This, in turn, serves to ensure the product is efficacious and imbues the most positive health impact on the individual – with such gains encouraging repeat purchase.

Given its industry-leading bioavailability and potency, high solubility, and efficacy at a daily dose as low as 60mg (also translating into better value for formulators), Shoden® ticks all the boxes. Moreover, the branded ashwagandha extract carries the claims that matter to today's consumers, including dairy-free, Vegan, Halal, Kosher, self-affirmed GRAS, and Non-GMO Project Verified.

Addressing a broad spectrum of health needs

Strongly backed by science, Shoden® exhibits distinct benefits across numerous need states, with clinical trials demonstrating the extract's efficacy in supporting stress and anxiety relief, sleep enhancement, immunity support, energy enhancement, hormonal balance, and more.

Stress reduction

Traditionally used to reduce stress and enhance wellbeing, ashwagandha holds distinctive benefits for the modern consumer, with studies on Shoden® confirming the significant efficacy of this high-potency extract.

Amidst hectic lifestyles and an 'always on' culture, the number of stressed-out adults has been on the rise worldwide over the past decade.[6] A major exacerbating factor for hypertension and diabetes – both major killers worldwide – stress can likewise lead to long-term health issues affecting the immune system, digestive system, cardiovascular system, and mental health.[7]

One notable 60-day human study demonstrates Shoden®'s efficacy in helping physically healthy subjects who were suffering with higher stress and anxiety levels.[8] Shoden® was administered to two groups at different dosage levels – one group ('AE60') was given a 60mg/day dose and the other (AE120) consumed 120mg/day of the ashwagandha extract – while a third group took a placebo. HAMA (Hamilton Anxiety Rating Scale) scores decreased 59% in both Shoden® groups (AE60 and AE120), compared to a negligible rise (0.83%) in the placebo group. Shoden® supplementation was also associated with a dramatic drop in levels of the stress hormone serum cortisol. Specifically, morning serum cortisol levels decreased 66% in AE60 and 67% in AE120, compared to a 2.22% change in the placebo group. Another hormone key to regulating stress and energy levels is testosterone, which increased in males from both Shoden® groups (by 22% in AE60 and 33% in AE120 – versus just 4% increase in placebo group males).

The subjective experience of both Shoden® groups also improved, and to a significant degree – with Perceived Stress Scale (PSS) scores decreasing 53% (AE60 study group) and 62% (AE120), and Clinical Global Impression (CGI)-severity scores decreasing 72% (AE60) and 68% (AE120). Elsewhere, Patient Global Impression of Change (PGIC) scores improved by 60% in both Shoden®-supplemented groups.

Such results demonstrate the efficacy of Shoden® ashwagandha extract – at a dose as low as 60mg – in helping to significantly reduce high stress and anxiety in adults.

Improved sleep

In the first human study of its kind, Shoden® ashwagandha enhanced both overall sleep quality and quality of life in adult subjects suffering from non-restorative sleep (NRS).

NRS affects around 10% of people worldwide, leading to poor sleep quality, as well as physical and cognitive fatigue, alongside impacting quality of life. Recognition and treatment of NRS is therefore a priority for physicians in the field of sleep medicine, while consumers are increasingly alive to the interconnectedness of sleep with broader health benefits, ranging from mental health to energy enhancement and 'beauty from within'.

In the first human study of its kind, Shoden® ashwagandha extract (120mg/day) was evaluated in a six-week trial for its effects on improving overall sleep quality and quality of life (QOL) in adult subjects with NRS.[9]

The results were impressive: A 72% increase in self-reported sleep quality for the supplemented group (versus 29% in placebo). The Shoden® group also exhibited significant improvement in sleep efficiency, total sleep time, sleep latency, and wake after sleep onset (WASO) versus placebo after six weeks. Their scores on WHOQOL (the World Health Organization's quality of life evaluation) likewise showed significant improvement – in physical, psychological, and environment domains.

Such findings back up other human trials, alongside earlier in vitro and in vivo experimental models that demonstrate how, by enhancing the induction of sleep, GABA-mimetic action, NREM sleep, and the effects on slow-wave cycles, Shoden® boasts a calming property that improves quality of sleep.[10]

Immunomodulatory benefits

Shoden®'s ability to help modulate both innate and adaptive immune systems make it a highly useful natural ingredient in products aimed at supporting immunity.

The Covid-19 pandemic served to boost global interest in immunity-supporting supplements – and such focus has endured. The concerns of an ageing population, alongside growing consumer awareness around how natural supplements can help strengthen resistance to infectious diseases, are contributing to a projected 10.72% CAGR for the immune health supplements market from 2024– 2030.[11]

Immunomodulators of plant origin are a promising field of research, and ashwagandha has been extensively investigated in that regard. Withanolide glycosides are of particular interest when looking at the botanical's immunomodulatory action, with Shoden®'s industry-leading 35% (minimum) content of such bioactive molecules distinguishing the brand in this area.

One study on healthy adult subjects demonstrated that Shoden® supplementation (60mg/day) significantly improved the immune profile of healthy subjects at the end of the 60-day trial period, by modulating both innate and adaptive immune systems.[12]

This dual function is vital for recognising and responding appropriately to common bacteria, viruses, and allergens – boosting the immunity of people at risk of infection and during widespread infections. Certainly, the statistical significance presented in the Shoden® group across numerous analysed biomarkers suggests a role for the extract in supporting both innate and adaptive immune systems.

Such results, alongside previously reported in vivo study outcomes, demonstrate Shoden®'s immuno-stimulatory actions, thus supporting the branded botanical's value as an ingredient in immunity-boosting herbal supplements.

Enhanced vitality and vigour

Ashwagandha is commonly used to promote youthful vitality – and Shoden® supplementation has been shown to help reduce fatigue and increase vigour, as well as enhancing both sexual and psychological wellbeing.

While tiredness or fatigue varies according to case definitions, methods of assessment, and study settings, it is nonetheless one of the most frequently presenting complaints in primary care.[13] Fatigue can have a substantial impact on an individual's self-care and overall quality of life, as well as being a strong predictor of future morbidity and mortality.

Alongside increasing fatigue, reductions in steroid hormones also commonly occur as men age. Indeed, it's estimated that males experience a 1%–2% decline per annum in testosterone levels after the age of 40 years, while concentrations of dehydroepiandrosterone sulphate (DHEA-S) also drop by 1%–4% per year. Both hormones play an important role in influencing sexual health, lean body mass, mental health, cognition, bone density, cardiovascular function, metabolic activity, and more.

Given ashwagandha's long history of use in Ayurvedic medicine to promote youthful vigour and improve overall health, exploring the usefulness of high-potency Shoden® in addressing fatigue clearly holds significant value.

Within this context, a 16-week study was conducted on ageing (40–70 years), overweight men with mild-to-moderate, self-reported fatigue.[14] For the Shoden® supplemented group, improvements in fatigue, vigour, and sexual and psychological wellbeing were reported over time. Compared to placebo, Shoden® intake was also associated with a greater increase in both DHEA-S and testosterone – 18% and 14.7%, respectively.

Beyond the many beneficial impacts outlined above, a host of other interesting application areas stemming from Shoden®'s adaptogenic attributes – from cognitive health, to sports nutrition, and 'beauty from within' – speak to the myriad opportunities presented by this high-potency branded ashwagandha extract.

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Tried, tested, established, and esteemed

The safety profile of Shoden® ashwagandha has been a key pillar of its market success to date, and crucial to building trust in a vast array of customers and consumers worldwide, with well over 350 million doses sold across the globe.

In a move that serves to confirm Shoden®'s safety and efficacy, the extract is today approved by Health Canada as a Natural Health Product (NHP). Obtaining such certification required Shoden® to undergo testing for purity and potency, alongside an evaluation of its clinical studies and scientific research. Crucially, the new certification means manufacturers can add label recommendations for Shoden®'s health claims. Such claims include: 'When used over time, Shoden® helps improve sleep onset, duration, and quality'; 'Shoden® helps increase resistance to stress, helps reduce symptoms of stress, and helps reduce cortisol'; and 'In males, Shoden® helps promote healthy testosterone production'.

Benny Antony PhD, joint managing director at Arjuna Natural, said the awarding of NHP status to Shoden® underscored the company's "commitment to supplying regulatory-compliant, high-quality ingredients that consumers in Canada and internationally can trust." Such trust is grounded in convincing scientific evaluations of Shoden®'s safety – both animal studies and a new human trial.

Acute toxicity was evaluated in one animal study, which found a single dose of Shoden® (2000mg/kg body weight – bw) fed to rats resulted in no clinical signs of abnormality or mortality. Likewise, a 90-day sub-chronic toxicity study on rats – in which the animals were fed Shoden® at 100, 500, and 1000mg/kg bw – resulted in no mortality or clinical signs of toxicity. The haematology and biochemistry profile of the treated subjects was similar to the control, while the histopathology of major organs was normal in all control and treated animals.[15]

Bolstering such evaluations is a ground-breaking new 90-day human clinical study – the first human safety trial to be conducted by any ashwagandha brand to date. Currently under publication, the trial sees Shoden® consumed by healthy adult participants at a dose of 480mg daily.[16] Results clearly demonstrate Shoden® is safe and well tolerated among healthy participants – showing stable safety parameters and no adverse effects.

Clearly, with quality control and safety more crucial than ever for today's consumers, Arjuna Natural offers supplement brands "peace of mind," says Kevin Coyne of Natroceutics. "As a brand owner, we can only go so far – we rely on reputable partners. And we've always had peace of mind working with Arjuna Natural, knowing we're getting the highest quality ingredients – and that all the testing, all the procedures, everything that's required to produce a quality product, is backed up by Arjuna. In all our years of working with Arjuna, we've never had an issue, which speaks to the quality of what they're producing."

Drawing upon a rich legacy of knowledge gifted through Ayurveda, combined with the enduring focus on scientific discovery and innovation, award-winning Arjuna Natural represents a quality- and innovation-focused partner for formulators looking to differentiate their products and gain an edge in the market, while high-potency and high-purity Shoden® ashwagandha provides the safety and efficacy assurances so crucial to such brands in building consumer trust.

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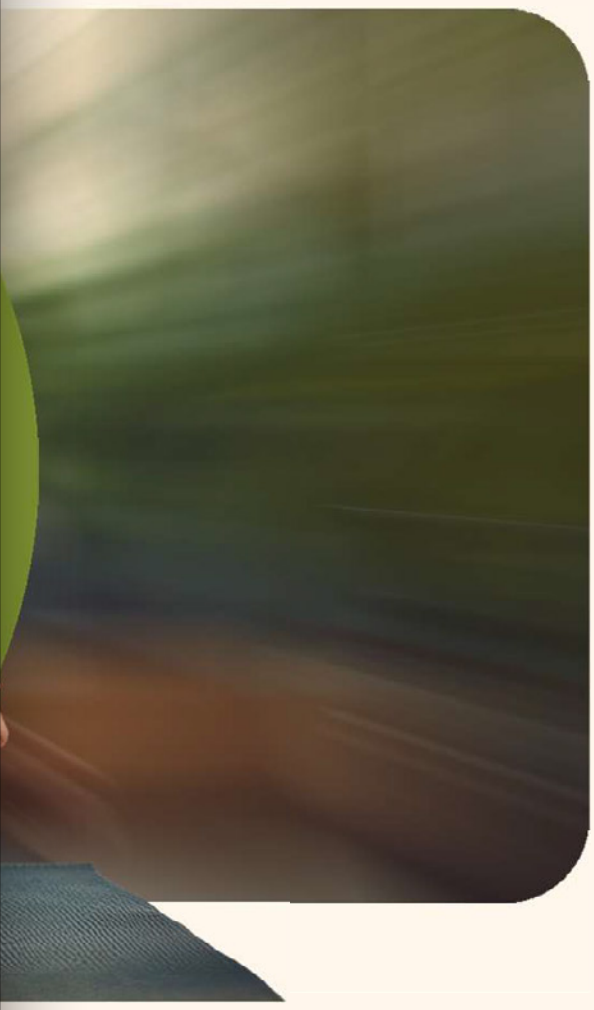

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