KSM-66 Ashwagandha®
WORLD'S BEST ASHWAGANDHA
PAID CONTENT

ROOT-ONLY ASHWAGANDHA: THE SAFETY STANDARD





Why standard testing can't detect adulteration, and the authentication framework that ensures root-only ashwagandha integrity

The ashwagandha market has experienced explosive growth, with U.S. mainstream retail sales surging from $7.5 million in 2018 to $335 million by 2023, according to SPINS. But this meteoric rise has exposed a critical quality control challenge that threatens both consumer safety and brand integrity: the inability of standard testing methods to distinguish between ashwagandha roots and aerial plant parts.

Ashwagandha roots and aerial components—leaves, stems and flowers—have dramatically different chemical compositions and vastly different levels of safety validation. Yet conventional laboratory testing measures only total withanolide content, the primary active compounds present in all plant parts. This creates a dangerous blind spot: products can meet withanolide specifications while containing undeclared aerial components with different safety profiles, different regulatory status and no long-term clinical validation.[1] This isn't merely a supply chain issue—it's an authentication crisis requiring plant-part-specific verification that goes far beyond standard withanolide testing.

For manufacturers, formulators and retailers navigating this complex landscape, understanding the critical differences between root and aerial materials—and the testing limitations that enable adulteration—is essential for product safety, regulatory compliance and consumer protection. True market leadership requires an authentication framework that refuses to trade consumer safety for economic shortcuts.

Rooted in tradition, backed by modern science

For thousands of years, ashwagandha *(Withania somnifera)* has been a mainstay of Ayurvedic medicine, revered for its use across a broad range of traditional indications. Historically, only ashwagandha roots were considered safe for internal use, and Ayurvedic physicians relied exclusively on roots for formulating therapeutic remedies. The aerial parts of the plant—the above-ground biomass, including stalks, stems, flowers



and leaves—were treated under a separate protocol. Leaves were relegated to external applications, like topical poultices for burns or skin conditions. They were not recommended for internal use.[2]

Published randomized controlled trials show that ashwagandha root can:

- Regulate cortisol levels, alleviate anxiety and soothe stress[3]
- Significantly improve multiple sleep parameters and enhance overall sleep quality[4]
- Increase sexual desire, performance, outcomes and satisfaction in both women and men[5, 6, 7]
- Promote skin and hair quality, with significant improvements in skin- and hair-related parameters[8]
- Minimize stress and stress- related food cravings[9]
- Ease menopausal changes, including hot flashes, stress and sleep disruptions[10]
- Support athletic performance, strength and muscle recovery after exertion[11, 12, 13]
- Improve general health, physical fitness and quality of life in elderly men and women[14]



WHY WITHANOLIDE TESTING **ISN'T ENOUGH**

Standard quality control in the ashwagandha industry relies on measuring total withanolide content—the primary active compounds. However, this approach has a critical blind spot: Withanolides are present in both roots and aerial parts. Because leaves contain withanolide concentrations higher than roots for certain compounds, adding even small amounts of leaf material can artificially boost total withanolide levels. A product can meet withanolide specifications while containing undeclared aerial components—components with different chemical profiles, different safety data and different regulatory status.



The evidence of widespread adulteration is compelling:

- In the only published survey of its kind, eight of ten commercial extracts labeled as root carried flavonol glycoside markers of aerial material[15]
- HPTLC screening of 584 incoming batches of commercial root extract found one in five was not solely authentic root, and 14% contained leaf material[16]

The solution requires plant-part-specific authentication:

- Flavonol glycoside marker testing to detect aerial components
- Microscopic analysis to identify leaf debris
- Complete supply chain traceability from verified root-only cultivation
- Third-party verification of authentication protocols

KSM-66® ashwagandha employs comprehensive plant-part-specific authentication protocols, including flavonol glycoside marker testing and microscopic analysis, to ensure 100% root-only composition. With complete supply chain traceability from verified cultivation through extraction, KSM-66® provides third-party verified assurance that products contain exclusively ashwagandha root, not undeclared aerial components.

However, this extensive clinical validation applies specifically to authenticated root extracts. Aerial parts lack equivalent long-term safety data and contain markedly different chemical profiles. The distinction between plant parts isn't merely botanical—it's a fundamental safety and efficacy consideration that standard withanolide testing cannot verify.

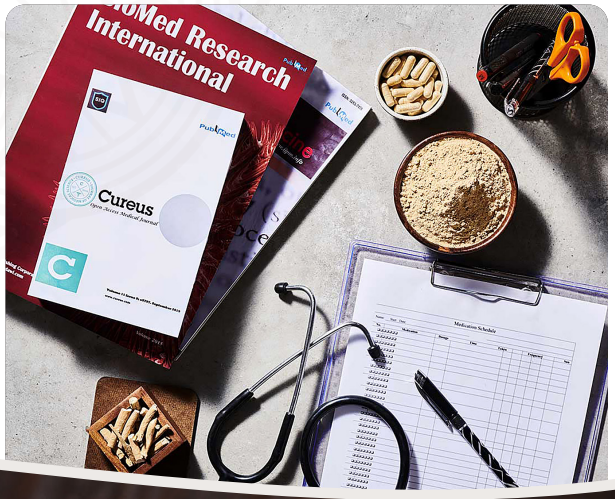
The intersection of traditional wisdom and clinical proof informs the core philosophy of KSM-66® Ashwagandha. Made from 100% authenticated roots, never leaves, KSM-66® preserves historical practices while addressing the modern authentication challenge, merging traditional applications with cutting-edge verification methods and establishing itself as the industry's leader in plant-part-specific quality assurance.

Roots vs. leaves—a critical safety distinction

Traditional Ayurvedic medicine considered ashwagandha roots the appropriate part for internal consumption, with leaves reserved for external applications. And while both parts come from the same plant, modern testing and analyses confirm historical practices while revealing that roots and aerial parts have vastly different physical characteristics and chemical makeup.

The core safety issue stems from the concentration of withanolides, the primary active compounds responsible for ashwagandha's adaptogenic effects. The root naturally possesses a balanced blend of these potent constituents shown to support stress adaptation and restore the body's equilibrium.[17]

The leaves and aerial parts of the plant, on the other hand, contain elevated levels of other withanolides, most notably withaferin A and withanone. Reported leaf-to-root ratios for withaferin A run from roughly twentyfold to, in one





varietal comparison, several hundredfold. Even at the conservative end, a small amount of leaf moves the assay, raising concerns about long-term safety at supplemental doses. At elevated concentrations, research indicates the compound may affect human liver and reproductive cells. Withanone concentrates in the leaf and is largely absent from the root. In laboratory studies it caused DNA damage in cultured human liver cells, which the authors proposed as a mechanism for liver toxicity reported with some ashwagandha products.[18]

In nine of 14 published hepatotoxicity cases the specific product could not be identified, so the plant part was never established. That is the accountability gap. Where sourcing is traceable and the plant part is verified, the question is answerable.

> *Roots command premium prices while leaves are essentially agricultural byproducts,* ***prompting some suppliers to spike root extracts with cheaper aerial components.***

Research suggests withanone may cause DNA damage and cellular stress specifically within human liver cells, potentially representing a primary mechanism underlying liver toxicity attributed to ashwagandha usage.

Economic pressures create powerful incentives for adulteration. Roots command premium prices while leaves are essentially agricultural



byproducts, prompting some suppliers to spike root extracts with cheaper aerial components. Because leaves are concentrated in withanolides, blending them into root extracts bypasses standard testing methods. But hidden adulteration exposes unsuspecting consumers to elevated doses of compounds that would not be found in a traditional, root-only preparation—compounds that lack long-term safety validation.

The scope of this authentication problem is documented in published research. HPLC-UV analysis of 10 commercial ashwagandha extracts labeled "derived from the roots" found that only two samples lacked chemical markers for aerial component adulteration—indicating that 80% of tested products contained undeclared aerial parts.[15] A separate study using HPTLC analyzed 584 batches of commercial root extract raw materials, finding that 14.0% were rejected due to leaf debris and 20.4% contained incomplete root material.[16]

Despite the dearth of long-term safety data on leaf material—and documented cases of product adulteration—confusion still abounds. Plenty of consumer health blogs and websites ignore the difference between roots and aerial parts, praising the benefits of ashwagandha leaves. For manufacturers, formulators, retailers and practitioners, the question isn't just about withanolide potency—it's about verifiable plant-part authentication. Root-only extracts like KSM-66® Ashwagandha represent the industry standard for safety and transparency in a market where standard testing cannot detect adulteration.



The changing regulatory landscape

Regulatory bodies worldwide increasingly recognize that roots and aerial parts are not interchangeable—a distinction that standard withanolide testing alone cannot verify. Because the chemical profiles of the root and leaf are so distinct, global regulatory frameworks do not view them as equivalent ingredients. This has driven a rapid shift towards stricter measures regarding ashwagandha leaf in consumer products.

The most decisive action comes from the herb's country of origin. On 15 April 2026 the Ministry of Ayush directed that only ashwagandha root be used and that leaf, in crude, extract or any other form, is strictly prohibited in Ayush drugs and products (F. No. T-13020/4/2022-DCC). FSSAI extended the restriction to health supplements and nutraceuticals the following day, stating that traditional use and safety validation belong exclusively to the root. Parts of the order are under interim stay pending litigation brought by affected manufacturers. The stays are procedural and limited to the petitioners; the safety rationale has not been set aside.

European lawmakers are also tightening regulations: Poland has set maximum daily levels of around 3g root powder and 10mg withanolides per daily portion rather than a plant-part rule. Denmark removed ashwagandha from its supplement market in 2023 and used the RASFF network to flag products across the single market. France's ANSES advised against use by people with thyroid, liver or cardiac conditions, by pregnant women and by those taking sedatives. In June 2024 the EU Heads of Food Safety Agencies shortlisted ashwagandha for an Article 8



procedure under Regulation 1925/2006. The UK FSA opened a call for evidence in 2024 feeding a COT risk assessment, and Germany's BfR recommended Article 8 inclusion in 2013. In the Netherlands, where RIVM advised against use in spring 2024, a new draft regulation proposes prohibiting ashwagandha preparations derived from plant parts other than the root. Root preparations would remain permitted, subject to specified safety labeling requirements. The proposal underscores the growing regulatory importance of botanical identity—not simply withanolide concentrations—in distinguishing between ashwagandha ingredients.

This regional crackdown aligns with the world's most credible medical and quality monographs. International pharmacopoeia standards—including the USP, the British Pharmacopoeia and the Ayurvedic Pharmacopoeia of India—define the article as Withania somnifera root. Respected organizations like the American Botanical Council have been highly vocal about the specific issue of leaf-to-root adulteration.

These regulatory distinctions underscore a critical point: compliance requires not just withanolide standardization, but plant-part-specific authentication that confirms root-only sourcing. By combining a commitment to root-only formulations with supply chain traceability, advanced testing methods that detect aerial components and superior quality control, KSM-66® establishes a clear blueprint for product safety, regulatory compliance—and consumer trust.



Cultivating quality

The true value of ashwagandha begins long before the root ever reaches an extraction facility. In an era where traceability and authentication are critical, comprehensive quality control starts with knowing exactly what plant material enters the supply chain—and where it comes from.

KSM-66®'s vertical integration begins at cultivation, with dedicated farms in Rajasthan, one of the two principal growing regions for ashwagandha in India. This controlled sourcing provides the foundation for authentication: complete ownership and management of the growing process, from seed selection to harvest.

Farmers cultivate crops naturally, selecting only premium pieces of root. Only first-harvest roots meeting set criteria for texture, color and size enter the process. This field-level curation guarantees a consistently potent, pristine raw material that sets the foundation for product integrity and enables the forward and backward traceability essential for plant-part verification.

Supply chain pressures

In an industry where economic pressures incentivize shortcuts and standard testing cannot detect adulteration, KSM-66® Ashwagandha addresses the authentication challenge at every level. By



GLOBAL REGULATIONS **AT A GLANCE**

India's stance: Formal government advisories prohibit or warn against the internal use of leaf material. The directive also requires compliance with Rule 161 of the Drugs Rules, 1945, which requires the plant parts used to be stated on the label.

EU restrictions: European countries have adopted varying approaches to ashwagandha, including restrictions, safety advisories and proposed plant-part-specific regulations.

Monograph consensus: USP, British and Ayurvedic Pharmacopoeia of India monographs uniformly exclude leaf from standard definitions.

Netherlands proposal: A draft regulation would prohibit ashwagandha preparations derived from plant parts other than the root. Root preparations would remain permitted, subject to specified safety labeling requirements.

Australia's TGA carve-out: Since March 2020, listed medicines containing Withania somnifera require a pregnancy warning unless the product uses root only, is an extract made with water, ethanol or methanol and stays at or under 12g dry root equivalent per maximum daily dose.

Domestic: U.S. law already requires the plant part: 21 CFR 101.4(h)(1) requires the common or usual name of a botanical ingredient to state the part of the plant—root or leaves—and 21 CFR 101.36 carries it into the Supplement Facts panel. A product declaring root extract that contains aerial material is misbranded today.

maintaining complete vertical integration—from seed selection in Rajasthan's optimal growing regions to final extract—KSM-66® eliminates the vulnerabilities that plague conventional supply chains. Every batch undergoes rigorous multi-stage testing, including advanced authentication methods that detect leaf contamination through flavonol glycoside marker analysis and microscopic examination.

With more than 48 independent third-party certifications and adherence to the world's strictest quality standards, KSM-66® doesn't just meet industry benchmarks—it defines them. For brands committed to consumer safety and product integrity, the question isn't just about withanolide potency—it's about verifiable plant-part authentication. KSM-66® provides both: root-only, fully traceable, scientifically validated ashwagandha backed by an authentication framework that ensures every batch contains exactly what the label claims.

With more than 48 independent third-party certifications and adherence to the world's strictest quality standards, ***KSM-66® doesn't just meet industry benchmarks—it defines them.***

KSM-66®'S AUTHENTICATION FRAMEWORK

Complete vertical integration: Ownership of the entire production cycle from seed to extract eliminates third-party vulnerabilities and enables complete forward and backward supply chain traceability—knowing exactly what plant material is used at every stage.

100% pure-root protocol: The manufacturing protocol mandates using only the mature roots of organically cultivated ashwagandha, excluding all aerial parts. Multi-stage testing detects even trace amounts of leaf contamination.

Advanced authentication methods: Beyond standard withanolide testing, KSM-66® employs plant-part-specific analytical techniques, including flavonol glycoside marker testing to detect aerial components, microscopic analysis to identify leaf debris and comprehensive botanical authentication.

Green chemistry processing: The proprietary extraction method runs on green chemistry principles, using no alcohol or chemical solvent.

Rigorous verification: Advanced in-house laboratories execute multi-stage testing and verification on all raw and finished materials. Quality protocols incorporate organoleptic checks, microbiological and aflatoxin testing, batch-wide analysis for heavy metals and pesticides and a suite of botanical authentications.

Third-party validation: More than 48 independent certifications including GMP clearances from the USP, NSF International and UL verify authentication protocols and manufacturing standards.

Clinical validation on authenticated material: KSM-66® is one of the most extensively researched ashwagandha extracts available, with dozens of randomized controlled trials, and additional open-label work, all on verified root-only extract.

Clean-label compliance: The ingredient's certifications include USDA Organic, Non-GMO Project Verified, GFCO certified gluten-free, Kosher, Halal and others, as well as compliance with several international sustainability standards.

Authentication as the foundation of quality

The ashwagandha industry stands at a critical juncture. As demand continues to surge, the gap between consumer expectations and supply chain realities widens. Standard withanolide testing—the industry's primary quality metric—cannot distinguish between roots and aerial parts, creating opportunities for adulteration that compromise both safety and regulatory compliance.

The solution requires a fundamental shift from potency-focused testing to comprehensive authentication. **This means:**

- **Plant-part-specific analytical methods** that detect aerial component markers
- **Complete supply chain traceability** from verified root-only cultivation
- **Multi-stage verification protocols** that go beyond basic withanolide analysis
- **Third-party validation** of authentication procedures
- **Clinical research conducted on authenticated material** to ensure safety data applies to the actual product

KSM-66® Ashwagandha demonstrates that this authentication framework is not only possible—it's the new standard for ingredient integrity in a market where consumer safety and regulatory compliance depend on knowing exactly what's in the bottle.



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