

# KSM-66 ASHWAGANDHA'S GOLD-STANDARD COMMITMENT TO SAFETY

## PART OF THE ASHWAGANDHA EXPERIENCE



As the world's most certified branded botanical, the leading root-only KSM-66 Ashwagandha extract is trusted by consumers and formulators across the globe. Its safety is supported by extensive human clinical research and comprehensive toxicological evaluations.

Trust forms the backbone of every successful relationship and this holds especially true for the natural supplements industry and its consumers. For formulators, rigorous quality assurance is non-negotiable, and they depend heavily on the integrity of their ingredient partners to consistently deliver materials that meet the highest safety and quality benchmarks.

Unfortunately, the recent "gold rush" surrounding ashwagandha has led some low-quality extract manufacturers to dilute their products with inferior leaf material and other aerial parts of the plant. Given that ashwagandha leaves sell for only a small fraction of the cost of roots, sometimes up to 100 times less per kilogram, the incentive for such practices is evident. This so-called "leaf adulteration" raises serious concerns around both safety and effectiveness, while also undermining the reputation of a botanical whose roots have been respected in Ayurvedic medicine for more than 4,000 years.

Amid this climate of ambiguity, where trust has become more critical than ever, KSM-66 Ashwagandha has established itself as a clear benchmark. Its high-purity, organic, root-only extract is backed by multiple human clinical trials and toxicological studies that consistently confirm its safety for human consumption.

### Built on Science and Long-Term R&D

Developed through more than 14 years of dedicated research and development, KSM-66 Ashwagandha is produced by a fully vertically integrated manufacturer, Ixoreal Biomed. Significant investments have been made to ensure both the safety and efficacy of this market-leading extract.

Since its launch just over 12 years ago, KSM-66 has grown into the world's leading ashwagandha root extract. It is now sold in 52 markets worldwide and featured in more than 4,500 products, including formulations from Pfizer, Walmart, Mars, Nature's Bounty, GNC, GSK, CVS, Nestlé, Unilever, and Bayer.

While global brands routinely conduct their own assessments of the ingredients used in their products, KSM-66 has further supported this process by building a strong scientific foundation for its extract. Although classical Ayurvedic texts describe ashwagandha as both safe and effective, KSM-66 has taken significant steps to validate these traditional claims through modern scientific research for today's health-conscious consumers.

## Strong Human and Toxicological Safety Evidence

A comprehensive portfolio of GLP-compliant toxicology studies demonstrates the safety of KSM-66 Ashwagandha across multiple models. These studies include evaluations of acute toxicity, sub-acute toxicity, 90-day repeated-dose toxicity, mutagenicity and genotoxicity, as well as reproductive and prenatal developmental toxicity. These laboratory findings are further reinforced by multiple human clinical trials that establish KSM-66's safety profile.

A recently published study evaluated the long-term safety of KSM-66 Ashwagandha root extract at 300mg twice daily over a 12-months in healthy participants aged 18 to 65. The study reported no clinically significant changes in the vital signs, liver parameters or thyroid function and no serious adverse events were observed, thus confirming its safety for long term use.<sup>1</sup>

In addition, a 2021 randomized, placebo-controlled study evaluated the safety of KSM-66 in healthy volunteers. Participants received either 300 mg of KSM-66 or a placebo twice daily for eight weeks. The study reported no clinically significant changes in vital signs, blood parameters, or thyroid function in either group, and no adverse events were observed confirming the extract's safety in both male and female participants.<sup>2</sup>

A second eight-week study conducted in 2023 assessed the effects of KSM-66 on body composition and blood health markers in professional wrestlers receiving 300 mg twice daily. No significant changes were observed in laboratory parameters, confirming the extract's stable safety profile and demonstrating that it was well tolerated by the participants.<sup>3</sup>

Further reinforcing this safety record, a study currently under peer review evaluates KSM-66 at a high dosage of 2,000 mg per day over 12 weeks in healthy adults and continues to demonstrate a stable safety profile.<sup>4</sup>

## Safety Begins at the Root

When it comes to the safety of ashwagandha extracts, the makers of KSM-66 alongside a broad base of independent researchers, consistently emphasize the importance of differentiating between the plant's roots and its less valuable, potentially less safe leaf material.

From its inception, KSM-66 has used only premium-grade roots that are organically cultivated and processed without solvents or alcohol. The plant's leaves are returned to the soil as compost to naturally enrich the following season's crop.

By sharing its growing body of evidence-based research with academics, healthcare professionals, researchers, regulators, and consumers, KSM-66 aims to empower informed decision-making rooted in safety, quality, and efficacy, bringing greater transparency and trust to the marketplace.

## REFERENCES

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2. Verma N, Gupta SK, Tiwari S, Mishra AK. Safety of Ashwagandha Root Extract: A Randomized, Placebo-Controlled Study in Healthy Volunteers. *Complement Ther Med*. 2021 Mar;57:102642. doi: 10.1016/j.ctim.2020.102642. Epub 2020 Dec 15. PMID: 33338583.
3. Effects of Ashwagandha (Withania somnifera) Supplementation on Body Composition and Blood Health Indices in Professional Wrestlers. December 2023. *Polish Journal of Sport and Tourism*. 30(4):26–32. DOI: 10.2478/pjst-2023-0022.
4. Safety and Efficacy of Ashwagandha (Withania somnifera) Root Extract (2000 mg/day) in Healthy Adults: A Prospective, Non-comparative Study (Under peer review).