

# Ashwagandha Advantage

July 2020

## Case Study

# Selecting the Right Ashwagandha Supplier

Key considerations to drive the process



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<b>KEY FACTORS</b> .....	3
1: RESEARCH INVESTMENT .....	3
2: SUPPLY CHAIN OVERSIGHT .....	4
3: QUALITY COUNTS .....	4
4: PRODUCTION COMPLIANCE .....	4
5: SINGULAR FOCUS .....	4
6: CORPORATE SOCIAL RESPONSIBILITY .....	4
7: SYNERGY OF SCIENCE .....	5
8: GLOBAL DISTRIBUTION.....	5
9: ACTIVE SALES ORGANISATION .....	5
<b>GRADING KSM-66</b> .....	6
1: RESEARCH INVESTMENT .....	6
2: SUPPLY CHAIN OVERSIGHT .....	7
3: QUALITY COUNTS .....	8
4: PRODUCTION COMPLIANCE .....	9
5: SINGULAR FOCUS .....	9
6: CORPORATE SOCIAL RESPONSIBILITY .....	10
7: SYNERGY OF SCIENCE .....	10
8: GLOBAL DISTRIBUTION.....	11
9: ACTIVE SALES ORGANISATION .....	11



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**A**shwagandha (*Withania somnifera Dunal*) is the most popular Indian botanical plant and has been in use in Ayurveda, the more than 4,000-year-old Indian system of medicine, as a rejuvenative and a daily tonic for many centuries. Ashwagandha embodies the very essence of the preventative and curative approach to health in Ayurveda. The name Ashwagandha is from the Sanskrit language and is a combination of the word *ashva*, meaning horse, and *gandha*, meaning smell; the root has a strong aroma that is described as “horse-like.”

Ashwagandha is referred to as the “Prince of Herbs” in Ayurveda because it has an impressively broad range of therapeutic effects. Such a broad range of effects arises perhaps because ashwagandha is one of the more complex herbs with many phytochemical constituents in it. Ashwagandha operates at the level of the overall body system by helping maintain balance in the substances and processes running in the human body. It raises an individual’s resistance to physical, chemical and biological stressors, operating on the neural, immune, endocrinal and energy production systems.

As formulators and manufacturers are increasingly seeing the value of incorporating ashwagandha into their finished products, the next step is selecting the right supplier that can deliver a consistent, quality ingredient. With continued discussion in the industry regarding supply chain traceability, quality control, substantiation and more, it’s important to understand the top considerations for choosing an ingredient supplier.

## KEY FACTORS

### 1: RESEARCH INVESTMENT

In today’s “no nonsense” era, consumers want more evidence and validation of the claims they see on their products. There is a demand for clarity, but also a desire for scientific research that is easy to understand. This presupposes that there is a robust amount of high-quality scientific research into the ingredients that does substantiate the purported health effects. When looking at ashwagandha, this means: has research been conducted on this actual ingredient, with results presented in a transparent way?



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techniques, such as organic, kosher or Halal.

**Understanding the types of certifications a company holds can give insight into what it values and where it is investing.**



## 2: SUPPLY CHAIN OVERSIGHT

International regulatory agencies place great importance on supply chain traceability, and recent laws make it more important than ever that companies can be transparent throughout the supply chain. In terms of botanicals, understanding where and how the ingredients are sourced and processed is particularly important, as it can affect the bioactivity and efficacy. In terms of ashwagandha, different geographic locations determine the amounts and ratios of bio-active compounds in the root. Depending on soil conditions, the withanolide content in ashwagandha can vary. Can your supplier trace its ingredient from the field to your door?

## 3: QUALITY COUNTS

Quality certifications provide some assurance that a company is committed to best practices in its production and supply chain. Some certifications focus on production techniques, such as organic, kosher or Halal. Understanding the types of certifications a company holds can give insight into what it values and where it is investing.

## 4: PRODUCTION COMPLIANCE

While quality certifications such as organic, kosher and Halal do touch on production techniques and have requirements, there are additional production requirements involved in meeting international government standards. Good manufacturing practices (GMPs) ensure the consistency of production, while international consensus-based standards from ISO (International Organization for Standardization) support innovation across the production chain. What evidence of compliance can you receive?

## 5: SINGULAR FOCUS

The botanical supply chain includes myriad companies that offer a broad range of ingredients. Some are geographically focused, providing many ingredients from a particular area. Others serve as a warehouse of ingredients, branded or generic, around a single health issue or category. And still others help expedite ingredients through the supply chain, linking producers with buyers around the world. Buyers must decide about the types of suppliers they will use for different ingredients, looking at efficiency, quality and value.

## 6: CORPORATE SOCIAL RESPONSIBILITY

Corporate social responsibility, or CSR, has become an increasingly critical issue for companies around the globe. Consumers and industry are looking to build partnerships with organisations that are committed to more than just the bottom line. Empirical studies point to correlations between CSR efforts and customer loyalty; a 2019 study published in the *Journal of Global Marketing*

(DOI:10.1080/08911762.2018.1528652) polled consumers across 57 countries and found CSR impacts commitment to purchase intent, particularly when purchasing online.

## 7: SYNERGY OF SCIENCE

For more than 4,000 years, Ayurvedic practitioners have used ashwagandha root extract to promote human health. Even as modern clinical science substantiates the health effects—and uncovers the mechanisms of action—turning to traditional wisdom provides a basis of knowledge that can inform future areas of discovery.

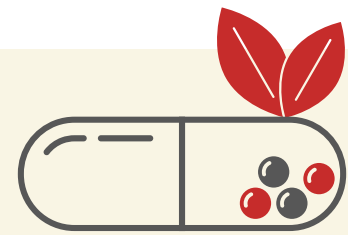
Botanicals are complex substances with many constituents. With many botanicals, modern research has proven clinically beneficial effects, but often has not been able to definitively identify which specific constituents in the botanicals cause the effects. Many herbalists and scientists believe that, with ashwagandha and several other herbs, it is not just one or two constituents that cause the clinical effects, but rather it is the combination and synergy of several constituents that gives the clinical effects.

## 8: GLOBAL DISTRIBUTION

While just-in-time production has been recognised as a standard of efficiency in the past, the impact of the COVID-19 pandemic on the supply chain has forced a re-examination of this standard. Manufacturers and producers that placed an emphasis on minimal warehousing times are now considering whether greater stocks could be an appropriate investment in product security. As such, suppliers are forced to consider myriad options including working with local distributors in different geographies, housing material in key markets, or committing to direct supply to optimise support of key customers and geographies.

## 9: ACTIVE SALES ORGANISATION

Companies are constantly looking for an “edge” in today’s competitive market, which often means seeking out new partnerships and connecting with suppliers to discuss the latest information on



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ingredients. Outside of major industry events, those personal connections are built by informed, dedicated sales professionals, who have the company and ingredient knowledge that buyers are seeking.

## GRADING KSM-66

As formulators and buyers look to source ashwagandha, they can use these key factors to drive their decision process. In this report, we use the market leading KSM-66 from Ixoreal Biomed as a case study against the key factors.

### 1: RESEARCH INVESTMENT

Ixoreal's clinical trials program is overseen by Prof. Anand Bodapati, University of California Los Angeles; Dr. Kaj Winther from the University of Copenhagen actively engages in the design and approval of study protocols. KSM-66 has been evaluated in 18 human clinical trials with an additional four human trials in progress; four animal efficacy studies have also been completed. Ixoreal collaborates with major academic and research institutes. The clinical studies follow gold standards of substantiation: randomised, double-blind, placebo-controlled designs.

Kartikeya Baldwa of Ixoreal said, "Ashwagandha has been advocated for a wide range of applications by practitioners and traditional texts. However, for many of these applications, there is inadequate supporting evidence in the modern scientific literature. Ixoreal has been a significant force in bringing a rigorous clinical lens to many of the claims."

The studies are conducted by reputable physicians and scientists in major research centers and academic institutions with a history of publication. Priority is placed on publication of results in peer-reviewed journals that are indexed in PubMed, which is a database maintained by the U. S. Government's National Library of Medicine incorporating articles published in what academics consider to be high-quality biomedical journals. Ixoreal is the industry leader in clinical trials investigating the effectiveness of ashwagandha, and KSM-66 is the ashwagandha extract with the most extensive set of research studies.

Another important consideration is the applicability of research results to the ability to make claims to consumers. As dietary supplements are designed to bolster general health and wellness, and not to treat, mitigate or cure disease, studies conducted in clinically compromised populations may not be useful when developing a substantiation dossier. Broadly speaking, because of the physiological law of diminishing marginal improvements, it is easier for a drug or ingredient to achieve improvements





The state of **Rajasthan** in India is one of the most suited terrains known to grow the best quality ashwagandha in the world and **that is where Ixoreal's ashwagandha farms are located.**



in clinically compromised populations than in normal healthy applications; for example, it is relatively easier for an obese person who weighs 300 pounds to lose 5 pounds than it is for a healthy person who weighs 150 pounds to lose 5 pounds.

The makers of KSM-66 have taken great pains to ensure KSM-66's clinical studies are all on normal healthy populations having no pre-existing clinically adverse conditions. Recruiting people from normal healthy populations is frequently difficult because they are less interested in participating in clinical studies. However, Ixoreal Biomed prefers clinical trials on KSM-66 Ashwagandha be on normal healthy people, because most of its customers target their end-products at normal healthy people who want to develop some extra function or strength.

## 2: SUPPLY CHAIN OVERSIGHT

Ixoreal Biomed has its own farms, production facilities, testing laboratories, research center and distribution facility, allowing full control of the supply chain. Not only does this permit traceability, but underscores a commitment to quality.

At Ixoreal, only high-grade ashwagandha roots from the best geographic location are sourced. The herb requires well drained, sandy loamy or light red soils with pH of 7.5 to 8.0. Ashwagandha is a late rainy season crop and requires a relatively dry season. The state of Rajasthan in India is one of the most suited terrains known to grow the best quality ashwagandha in the world and that is where Ixoreal's ashwagandha farms are located. The roots of ashwagandha are cultivated organically, and no old root stock is used.

At the farm, the use of good agricultural and collection practices (GACP) ensures the highest-quality ingredients enter the supply chain. Only special or High A-grade root pieces are used for the extraction. These roots are solid and bright, up to 7 centimeters, approximately and with a diameter of 1 to 1.5 centimeters. Quality root is not inexpensive, but is the key to producing an efficacious finished extract that is in line with traditional Ayurvedic practice; in addition, the control of supply chain avoids any possibility of the inclusion of leaves, which are significantly less expensive and have been used to bolster content of certain marker compounds without being labeled—a form of economic adulteration that misleads consumers and harms the market.

The roots are dried in the shade (not exposed to the sun, an important Ayurvedic requirement), and then transported in special protective covering to extraction facilities. Inspections and validation are done through the transportation process. Once at the extraction facility, the raw material is inspected again before extraction commences. After the extraction, the extract is tested for bioactives and safety, then packaged into drums for export of out India. These activities and processes are inspected by independent auditors so Ixoreal can provide all the critical documentation to manufacturers who source from the United States and be fully compliant with federal regulatory requirements, including those related to Foreign Supplier Verification.

### 3: QUALITY COUNTS

Ixoreal Biomed has 30 different quality certifications, the most of any supplier in the industry, with another two in process. The certifications support its clients' needs as they develop products for different target markets.

For example, companies looking for organic ashwagandha take comfort in the multiple organic certifications from EU Organic, USDA Organic, Canada Organic and India Organic. These certifications are renewed on an annual basis by highly trained individuals who ensure the growing, cultivation and production standards do not use any type of banned materials and are in line with all stated requirements. While Ixoreal Biomed continues to expand its farm properties in Rajasthan, it is a three-year transition to full, certified organic production, and the company remains committed to upholding those standards.

Additional standards are sought by consumers following strict dietary guidelines or practices. For example, kosher laws are complex and extensive, and involve certification that a food or ingredient is permitted to be eaten per Jewish law. Similarly, halal means a food or food ingredient is permissible per Islamic law. With increasing interest in healthy foods and supplements across new geographies—and a wide perception by consumers that Kosher, Halal, Non-GMO, Gluten free certifications indicate high quality and safety—Ixoreal Biomed also invested in these certifications, working with Star K, JK Kosher, GFCO, FCID and Halal India. Further, Ixoreal has strong science and testing in place to validate and substantiate its claims and quality, which is supported by its certification as BSCG (Banned Substance Control Group)-Drug Free for Sport; its Friend of the Earth certification speaks to a focus on sustainability and supply chain traceability.

Ixoreal Biomed also supports industry quality initiatives. The company “adopted” ashwagandha via the American Botanical Council’s (ABC) “Adopt an Herb” program. Each adopting organisation helps ensure the most current information on their herb is available in HerbMedPro, an interactive, electronic herbal database that provides hyperlinked access to the scientific data underlying the use of herbs for health. This enables consumers, researchers, educators, media, health practitioners, government agencies and industry to have easy access to abstracts of the latest scientific and clinical publications on the many aspects, properties and benefits of the adopted herb. The company is also an underwriter of the Botanical Adulterants Prevention Program, an industry initiative dedicated to addressing continued challenges around adulteration of herbs in the supply chain; and ABC’s Sustainable Herbs Program, focused on sustainability initiatives for the global botanical market.







This focus on quality has been recognised internationally, with KSM-66 receiving awards from Nutraingredients Asia as Sports Nutrition Ingredient of the Year 2018; the Society for Ethnopharmacology as Herbal Industry Leader 2016; Product Innovation in Botanicals 2014 from Frost & Sullivan; and Best Botanical Ingredient 2013 at Engredea/Natural Products Expo West.

#### 4: PRODUCTION COMPLIANCE

Ixoreal stringently follows World Health Organization (WHO) and U.S. FDA guidelines on GMPs. The company has been GMP registered with NSF International, and is GMP certified by the U.S. Pharmacopoeia (USP), U.L., Natural Products Association (NPA) and the Govt. of Telangana in southern India. It has also been certified compliant with ISO 22000 (food safety), ISO 14001 (environment), ISO 9001 (quality management) and OHSAS 18001 (health and safety).

And while KSM-66 Ashwagandha is widely used in food supplements and foods, it is produced in a state-of-the-art manufacturing unit, located at the Government of Telangana (India) allocated pharma zone, underscoring the company's dedication to pharma-level quality standards. Processing of the ashwagandha is done in exclusively designed clean room systems. Internal manufacturing controls provide documented proof that correct procedures are consistently followed at each step of processing and every time a batch extraction is made. Extensive controls cover the sanitation and hygiene of Ixoreal's facilities, personnel, utensils and machinery. Controls are also in place for handling materials throughout each step of the production process, such as work sheets, assuring consistency from batch-to-batch, easy monitoring and averting any chances of contamination and adulteration.

In addition, Ixoreal Biomed places a heavy emphasis on quality testing. All raw and finished material is inspected by the in-house quality control unit. Freshness labeling guidelines are followed, and trained and qualified personnel handle all the material, from raw stock to finished product. Testing includes organoleptic, identity, moisture content analysis, microscopy, microbiological, ash, pH, aflatoxin, heavy metal analysis, pesticide analysis and potency. Based on client requirements, Ixoreal also offers to get its product tested in independent testing laboratories anywhere in the world. Every sample and every dispatched batch is accompanied by certificate of analysis (COA).

#### 5: SINGULAR FOCUS

Ixoreal Biomed has been offering its KSM-66 Ashwagandha for about eight years, after spending nearly 14 years perfecting the production process and investing in scientific research to substantiate the health benefits. The company's singular focus on ashwagandha has allowed it to incrementally scale globally, working actively to develop relationships from the farm through the supply chain, and with academic institutions and governments.



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Just over half of the ashwagandha exports from India are KSM-66 Ashwagandha, making it the best-selling ashwagandha extract on the world market. It is currently included in more than 750 products across 40 countries including those from European market leaders such as KeyPharm, PureHealth, Wild Nutrition and more.

This dedication to KSM-66 Ashwagandha means the research and development (R&D) team at Ixoreal Biomed has great familiarity with the ingredient and how it acts in myriad matrices. Companies looking to develop innovative formulations or new delivery formats can work in partnership with Ixoreal Biomed's team, based in high-tech Hyderabad, India. In addition, regulatory experts at Ixoreal Biomed are not only familiar with the market restrictions and opportunities around the globe, but are working proactively to continue to open new geographies to ensure consumers worldwide can benefit from the health-promoting properties of KSM-66 Ashwagandha.

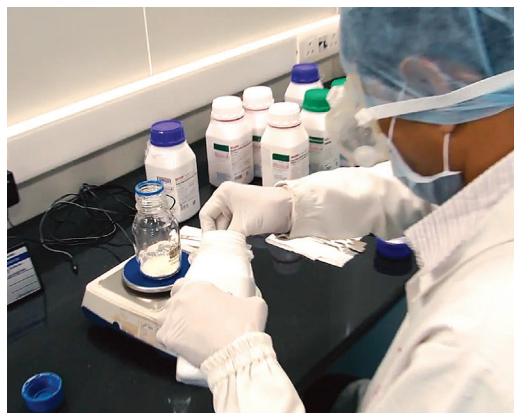
## 6: CORPORATE SOCIAL RESPONSIBILITY

Ixoreal Biomed is part of the Baldwa Group of companies, which is universally committed to philanthropy and social causes. Ixoreal has specifically focused its CSR efforts in India, particularly in the province of Rajasthan, where its high-quality ashwagandha is grown. The company has invested in schools, and placed an emphasis on building long-term relationships with local harvesters to build their own economic stability.

Ixoreal believes its key resources are in its farms and labs and in the workers and scientists who operate them. Ixoreal is part of a family business group, with an expansive notion of "family," which includes not just the owners but also the employees and their relatives and the people living in the towns and communities where the company operates. Ixoreal's management team believes a company's productivity is greatly increased if it is in happy, thriving communities. Baldwa commented: "We believe making our communities happier makes our employees happier, which makes them work better, which leads to Ixoreal's products becoming better, which leads to our customers being happier." For this reason, Ixoreal is very enthusiastic about supporting human capital and traditional livelihoods in the areas it operates in, and has supported schools, hospitals, colleges, building of roads, parks and community centers.

## 7: SYNERGY OF SCIENCE

Ixoreal Biomed spent years developing KSM-66, focusing on the traditional Ayurvedic uses and pharmacopoeia as a guide. KSM-66 Ashwagandha is a "full-spectrum" extract, maintaining





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the balance of the various constituents as in the original herb, without over-representing any one constituent. KSM-66 Ashwagandha differs from other hydro-alcoholic extracts because its innovative extraction process does not upset the delicate balance of various constituents found in crude ashwagandha root; rather, it retains and potentiates the synergism in the whole root.

Further, Ixoreal Biomed found that traditional Ayurvedic textbooks, as well as standard references including the Indian, British and U.S. Pharmacopoeias, refer to the exclusive use of ashwagandha root when producing an extract for internal use. In addition, some regulatory authorities have disapproved the use of ashwagandha extracts that incorporate leaves, allowing solely root-only extracts. Therefore, KSM-66 Ashwagandha is produced only from high quality root; leaves are never incorporated into the extract. As the price of ashwagandha leaves can be one-fifteenth that of quality root, there are concerns about economically motivated adulteration to use the cheaper plant part to boost levels of marker compounds without being labeled as containing leaves; testing and working with a trusted supplier can help mitigate concerns.

## 8: GLOBAL DISTRIBUTION

KSM-66 made a deliberate decision to optimise its production processes in India, and ships directly to customers when orders are received. While this may not fit with the just-in-time focus, the company notes that it has had the ability to address the supply challenges with the pandemic by working directly with its customers. In addition, by shipping larger orders directly from India, customers are assured of the freshest possible stock.

## 9: ACTIVE SALES ORGANISATION

Ixoreal does not have a dedicated sales team to sell KSM-66. They prefer an approach focused on science, education and technical marketing rather than on traditional salesforce tactics. While dedicated sales professionals can offer an organisation active outreach into the market, they also have set performance indicators and goals to achieve, regardless of whether their ingredient or service truly meets the needs of the potential lead. Instead of this type of “push” strategy, Ixoreal Biomed has invested in a “pull” strategy, putting its investments into science, product development and innovation, and looks instead to educate the market in a proactive manner, building interest in and demand for ashwagandha globally. This “rising tide” theory has resulted in greater awareness of ashwagandha throughout the supply chain, and into the consumer market. Ixoreal Biomed further supports the development of content online and in person that spreads the word about ashwagandha, and provides resources for formulators and buyers to make educated decisions when they source material.