

Quality Cultivation and Standardization of *Withania somnifera*: Comprehensive Agro-Practices and Regulatory Approach

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ABSTRACT

Background: The rising demand for *Withania somnifera* requires strict adherence to regulatory guidelines to ensure quality and efficacy. However, batch-to-batch variations, heavy metal residues, and contamination threaten the stability of the herbal drug industry. Objectives: This study evaluated *Withania somnifera* as a model plant of cultural, medicinal, and ecological importance, assessing cultivation and processing practices through quality risk assessment and compliance with global pharmacopoeial standards. **Materials and Methods:** Material attributes and process parameters were examined via literature review, expert consultations, and field trials. Risks were categorized to optimize soil quality, irrigation, seed selection, and agrochemical application. Macroscopic, microscopic, physicochemical, and toxicity tests were reviewed against standards from the WHO, Indian Pharmacopoeia, Ayurvedic Pharmacopoeia, and the Food Safety and Standards Authority of India. **Results:** Results showed that optimized cultivation and harvesting methods increased withanolide content and reduced contamination risks. **Conclusion:** The findings support standardized protocols that enhance commercial viability, ensure regulatory compliance, and improve therapeutic efficacy. This framework promotes collaboration among regulators, researchers, and farmers to achieve homogeneous quality standards and global acceptance of *Withania somnifera* in herbal medicine.

Keywords: Cultivation, Medicinal plants, Quality cultivation, Quality Control, Standardization, *Withania somnifera*.

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INTRODUCTION

The complexities of herbal manufacturing pose serious challenges. The herbal manufacturing is a fine art that incorporates several variables and therefore suffers from variability of batches from one to the other (Kapoor *et al.*, 2019). Weather changes, soil condition changes, or biodiversity in natural plant constituents can produce these changes. Managing these natural variations becomes a major hurdle in maintaining consistency across different batches (A. Kumar *et al.*, 2020; Reyer *et al.*, 2013). Moreover, the challenge posed by heavy metal residue in the manufacturing process further complicates matters (Carolin *et al.*, 2017). Heavy metals can be

absorbed by plants from the soil or the surrounding environment and may pose a health risk, necessitating monitoring and control in herbal products. The *Withania somnifera* (*W. somnifera*) plant is reported to respond vegetatively and biochemically in various ways to heavy metal exposure, with an increased accumulation of heavy metals affecting important metabolites and diminishing the plants' efficacy and possibly creating health concerns, while stressing the need for continued vigilance and maintenance of standards in herbal products (Banadka and Nagella, 2023). Therefore, it becomes imperative from the point of view of quality control that these traces must remain as residuals within limits prescribed by regulatory authorities. Hence, the very nature of the herbal manufacturing, together with batch variations, heavy metal residues, etc., demands that considerable attention be paid in strictly adhering to quality control measures in order to address the legal regulatory requirements and, therefore, to ensure safety and efficacy for herbal products (M. Ibrahim *et al.*, 2024). Owing to its esteem and recognized significance worldwide, *W. somnifera*



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has gained approval as a medicinal herb in various countries. The high use rate of *W. somnifera* across Africa and the world at large indicates its significance. More importantly, it features among the 85 top traded African medicinal plant species at an international scale, with a wealth of research publications totaling only a little over 1767 between the last decade (Van Wyk, 2015). Belonging to the family of plants named Solanaceae, which includes some 3000 species dispersed over 84 genera worldwide (Mirjalili *et al.*, 2009), While having ecological importance, *W. somnifera* is also of economic worth. As far back as history allows for the delineating of its passage into the annals of complete understanding, it has since obtained the status of an Ayurvedic agent, coming to be operated in Mediterranean regions and Orientalis. It is widespread in all continents except Antarctica and is mostly found in Asia, Europe, Africa, and Australia. In India, it grows in cultivation and thrives naturally, thus making it easy to locate. The plant has therefore been used in bioremediation because of its roles in phyto-extraction (Abhilash *et al.*, 2008; G. Singh and Kumar, 2011). This global recognition, together with the history as well as ecological versatility of *W. somnifera* presents a reason for its approval and endorsement as a medicinal herb in different countries of the world.

Where standardized quality control criteria to assess chemical constituents for *W. somnifera* are concerned, these criteria should be all the more highlighted because of the risk of hormonal imbalance if replaced by its adulterants. Moreover, a due stress on the significance of applying Good Agricultural and Collection Practices (GACP) is pretty much within this point, focusing on awareness, farm-to-facility production programs, and sustainable harvesting techniques for *W. somnifera* (Speers *et al.*, 2021).

This research follows two main lines: regulatory bounded analysis, providing thorough knowledge on common parameters under which *W. somnifera* can be grown; and agricultural aspects where GACP are effectively implemented along with quality risk management. Here, the production of *W. somnifera* is divided into three phases, that is pre-agriculture, agro-practice, and post-harvesting phases. Critical points affecting quality parameters have been identified through earlier study, field-based evaluations, and feedback from the farmers who are already into cultivation. With the constant scrutiny of these critical factors during cultivation, uniformity of quality, therefore, exists to satisfy industries that employ raw herbs in their assemblages.

Background of Research

Market value depends primarily on morphological characters, root texture, and medicinal importance, which depends on the quantity and ratio of bioactive constituents (Kumar *et al.*, 2012). The variation in yield possibly arises from the absence of proper morphological and microscopical identification, leading to defects in the differentiation of varieties, which could substantially affect yield and amounts of bioactive constituents (Ibrahim *et al.*, 2013).

Variation in the chemical composition might contribute greatly to toxicity issues (Kelly and Fussell, 2012). *Withania* is recognized globally for its versatile uses and is among the most sought-after herbs. To ensure market value nowadays, scientific evaluations and validation of high-yielding *Withania* cultivars are essential (Ahmad *et al.*, 2023). Additionally, awareness-raising programs may want to promote high-yielding, improved varieties among farmers in order to raise market value and plant for sustainability (Jelliffe *et al.*, 2018). Collaboration among industry, research institutes, and farmers could maintain uniform and high-quality raw materials needed by *Withania* and other medicinal plants through public-private partnerships or contractual farming arrangements (Maiti and Geetha, 2013).

W. somnifera, with a crocheted history of over 3,000 years through diverse traditional medicinal applications, finds its application ranging from Persian, Ayurvedic, and Oriental medicine to therapeutic options such as immune-modulators, antineoplastics, and antioxidants. This versatile plant has been used in ethnic medicine by minority groups in India, South Africa, and Egypt, primarily for antimicrobial and anti-neurodegenerative effects. Withanolides are the primary active ingredients responsible, at least in part, for its pharmacological activities, including anti-anxiety and anticancer actions. Sustainable cultivation is therefore all the more important to ensure adequate supplies of these bioactive compounds for possible pharmaceutical use.

Regulatory bodies, such as FSSAI, IP, API, also WHO, play a vital role in setting and maintaining quality standards for the herbal industry (Chandra and Narayana, 2023). The increase in demand for herbal products, including the various kinds of supplements, cosmetics, and healthcare formulations in the world market, has put added pressure on medicinal plant resources (Sen *et al.*, 2011). Inside India, unregulated cottage-level units and registered herbal companies depend on the uninterrupted supply of medicinal plants (Ravi and Bharadvaja, 2019). The NMPB in India imparts agro-techniques and guidelines to maintain quality, including proper field collection techniques and the GAP Standard for medicinal plants (Kala and Sajwan, 2007). It also admits that agronomic requirements are likely to vary among agroclimatic zones and, consequently, cause a variation in the yield of medicinal plants (Singh *et al.*, 2021a). In India, the existence of some standard reference books like an IP and an API hardly provides data on a few medicinal plants leaving a great gap in knowledge (Chandra and Narayana, 2023). This is the research that addresses this gap by putting forward an extensive study discussing the quality standards by aggregating and contradicting data from several sources including the standard reference books and scientific literature (Wong *et al.*, 2013). The challenge to the industry, particularly in herbal formulations, lies in inconsistency in therapeutic and pharmacological properties of the plant material from batch to batch (Dhami and Mishra, 2015). The industry is responding to this challenge by establishing different

quality standards to ensure products become aligned with the purity, quality, and potency requirements established in advance (Calixto, 2000). This research tackles the problem pertaining to the herbal industry regarding production modalities of herbal products to meet the increasing world demand. Regulatory bodies, including IP, API, FSSAI, and WHO, actively establish and uphold these standards (Chandra and Narayana, 2023). *W. somnifera*, or Ashwagandha in Hindi, or Indian ginseng or winter cherry in English, is generally used with a great value in Ayurveda and other traditional medical systems (Saiyed et al., 2016). It occupies an important position in Ayurveda for its ability to pacify the 'Vata' dosha, and thus it is regarded as one of the most useful herbs according to ancient texts (Rhoda, 2014). It has raised quite a bit of interest in pharmacological research in recent times because of the wide range of potential medicinal properties it exhibits (John, 2014). Pharmacological studies have shown that *W. somnifera* possesses not only nervous system-acting properties but also anticancer, adaptogenic, immunomodulatory, anti-convulsant, and antioxidative effects (Kalra and Kaushik, 2017). These features make it a very strong candidate for a variety of therapeutic uses (Karthikeyan et al., 2020). It is believed that *W. somnifera* is effective in the treatment of problems associated with the elderly, arthritis, behavioral disorders, and problems related to stress (Speers et al., 2021). Withaferin A inhibits cyclooxygenase-2, which may be an example of an anti-inflammatory and anticarcinogenic agent with a low risk of ulcerogenic side effects (Davison et al., 2010). It also exhibits an immunosuppressive effect on B lymphocyte proliferation (Alhakeem et al., 2017). Other withanolides, including glycosylated ones, which are also present in *W. somnifera*, have been reported to possess immunomodulatory, antioxidant, and other beneficial activities (Wang and Weller, 2006). Some of the withanolides are known to confer protective effects against chemical carcinogenesis, thus highlighting their potentials in cancer prevention (Vyas and Singh, 2014). *W. somnifera* is available in a variety of forms, including mono- and poly-herbal preparations that are sold commercially in India (Bhargavi and Shankar, 2021). However, a lack of standardization of quality-profiling parameters in pharmacopoeia makes it difficult for the consumer to know the chemical content (Bansal et al., 2014). It emphasizes that developing standardized quality assessment protocols is a prerequisite to ensuring the effectiveness and safety of products based on *W. somnifera* for herbal and functional food production. Figure 1 illustrates various health benefits of *W. somnifera* herb.

Quality Criteria for *W. somnifera*: Regulatory and Textual Insights

Different international Pharmacopoeias render guidelines regarding the quality of plants and herbal products for example, API, United States Herbal pharmacopoeia, British Herbal pharmacopoeia, Chinese Herbal pharmacopoeia, and Japanese

Standards for Herbal Medicine (Alamgir and Alamgir, 2017). API Works under the auspices of the Indian government and plays a key role by specifying the quality attributes for ayurvedic medicines used mostly (Ali et al., 2020). It is divided into two sections: pure medicinal substances from plants, and compound formulations referred to from traditional texts of Ayurveda (Chopra and Nayar, 1956). The WHO has a global standard for quality control in the medicinal plant materials describing such parameters as acceptable levels of pesticide residues and heavy metals (Joshi et al., 2017; Organization, 1998). In addition to *W. somnifera*, the FSSAI also sets quality standards in order to maintain safety and quality in several food products, for both imports and domestic consumption (Patel et al., 2022). Figure 2 illustrates diverse quality assessment parameters for *W. somnifera* as outlined in various standard references.

MATERIALS AND METHODS

Quality and Safety Profiling of *W. somnifera*

Data for *W. somnifera* was compiled from the key parameters from standard literature; all processes used respective regulatory limits. Organoleptic properties, including color, fragrance, shape, size and taste, were noted, respectively, using references such as the API, the Indian Standards of Medicinal Plants, and the IP. Microscopic features, including transverse and longitudinal sections, were detailed in powder microscopy. This included laboratory analysis of physicochemical parameters, including moisture content, foreign matter and values of ash. Information on chromatographic profiling (TLC and HPTLC) was given to estimate withaferin A and B. Toxicological data was reviewed for heavy metals, pesticide residues and aflatoxins in human safety evaluation.

Methodology of Quality Risk Assessment

The study employed a systematic approach to identify and evaluate variables affecting the quality of *W. somnifera* through a comprehensive review of cultivation, processing, and environmental practices. Pre-harvested factors that influence soil preparation, sowing techniques, and nutrient application were evaluated in relation to root development and withanolide concentrations. Agro-practices during cultivation were analyzed for their influence on phytochemical profile and plant health, including irrigation management, balanced fertilizer application, and weeding. Harvesting time and methods were studied to establish the right root maturity and preservation of medicinal properties. Post-harvest treatments like washing, cutting, drying, sorting, grading, and packaging have been evaluated for their role in helping to maintain product integrity, microbial safety, and moisture control. Environmental variables such as climate, soil type, and pest management were considered in terms of their interaction with material attributes and processing parameters. Risk analysis was performed to prioritize the relevance of these variables toward critical quality attributes like withanolide

content, root integrity, and microbial contamination into high, moderate, and low-ranking risks. Findings will be synthesized to highlight the best practices for cultivating high-quality *W. somnifera* in line with pharmaceutical standards.

RESULTS AND DISCUSSION

Quality and Safety Profiling of *W. somnifera*

Organoleptic and Macroscopic Evaluations of *W. somnifera*

The organoleptic analysis involved analyzing some of the characteristics of the plant material by evaluating its other aspects, namely, the colour, odor, size, shape, and taste. These qualities represent its overall visual properties: special features like fracture, texture, and odor of the medicinal plant (Rao *et al.*, 2022). The evaluation remains the first step in confirming the authenticity of medicinal plants. This assessment is carried out by trained professionals, who inspect the part of the plant with the naked eye or with the help of a magnifying glass (Senanayake *et al.*, 2020). Table 1 shows the official ranges for various sensory and visual parameters of *W. somnifera* as given in the API and other standard literature sources.

Microscopic Evaluation of *W. somnifera*

Identifying herbs under a microscope is crucial for detecting contaminants like fungi, mold, insects, or animal waste, and for recognizing characteristic tissue features. Staining techniques, such as phloroglucinol and concentrated hydrochloric acid for lignin, reveal unique tissue structures (I. Ahmad, Ahmad Khan, *et al.*, 2006). Microscopic evaluation includes Transverse and Longitudinal Sections (TS/LS), as well as powder microscopy, with stains like safranin used to observe components such as

starch and fixed oils (Ahmed and Hasan, 2015). Table 2 outlines several specific microscopic features observed in the TS/LS and powdered samples of *W. somnifera*.

Physicochemical Parameters of *W. somnifera*

Physicochemical parameters denote a set of evaluations utilized to assess the efficacy of medicinal plants (Adhikari *et al.*, 2007). These parameters include assessing moisture content and detecting foreign matter, both crucial indicators (Juszczak *et al.*, 2009). Furthermore, ash value analysis helps differentiate between physiological and non-physiological ash, unveiling the silica content within the plant material (Nagalakshmi and Anand, 2022; S. Sharma *et al.*, 2025). Table 3 outlines the specific allowable thresholds of physicochemical parameters for *W. somnifera*.

Qualitative and Quantitative Estimation of *W. somnifera*

Chromatographic profiling, through various TLC methods, is very vital in qualitative assessment of primary active constituents in the medicinal plant. The prime active constituents of *W. somnifera* are withaferin A and B (Sangwan *et al.*, 2014). This profiling is followed by quantitative tests, namely HPLC and HPTLC, which aim to accurately evaluate the concentration of these major active principles. In this evaluation, withaferin A and B have been analyzed by measuring their respective amounts (Meena *et al.*, 2021). It seems to play an important role in identifying the possible adulteration of *Withania somnifera* by lower-grade species or exhausted plant parts (Cooper *et al.*, 2017). Table 4 provides detailed information, including Rf values and quantitative ranges for withaferin A, as well as the methodology outlined in various standard texts.



Figure 1: Multifaceted therapeutic properties of *W. somnifera*.

Table 1: Organoleptic and morphological characters of *W. somnifera*.

Organoleptic analysis	API (Joshi et al., 2017b)	Indian Standards of Medicinal Plants (Gupta, 2003)	IP (Pharmacopoeia and Commission, 2010)
Shape	Cylindrical, green with longitudinal wrinkles	Wrinkled and wiry brittle	n.d.
Size	Short and uneven	Conical to cylindrical	n.d.
Colour	Buff to grey, yellow	Externally buff, internally white	Buff to grey yellow
Odour	Characteristic	Characteristic	n.d.
Taste	Bitter and Acrid	Slightly sweet	Slightly mucilaginous, bitter and acrid
Morphological characters			
Root	Direct and without branching. Thickness changes with maturity. Produces fibrous secondary roots. Outer surface appears buff to grey-yellow. Exhibits longitudinal wrinkles.	The dried root is conical to cylindrical, 20-30 cm long and 1-2.5 cm in diameter, rough with longitudinal wrinkles and occasional lenticels. It has wiry brittle rootlets or scars from removal, and breaks with a short, starchy fracture.	The main roots exhibit either a straight, conical, or finger-like shape, which varies in thickness as they mature. Secondary roots are slender and fibrous. The outer surface appears buff to greyish yellow with longitudinal wrinkles.
Stem	Cylindrical, green wrinkles, 2-6 stem base remains, variable stem base thickness, nodes visible on petiole side.	n.d.	n.d.

n.d. = No data available.

Ranges of Toxicity Indicators in *W. somnifera*

Indicators of toxicity within *W. somnifera* encompass more than just plant characteristics affecting medicinal quality; they also pose potential risks to human health when consumed. These indicators include the presence of heavy metals, pesticide residues, and aflatoxin levels (Resmi et al., 2022). Problematic conditions, such as areas prone to mold growth, can foster the production of carcinogenic aflatoxins in the soil. Additionally, uncertain soil histories and unreliable irrigation sources may contribute to elevated pesticide and heavy metal levels (Tian et al., 2022), presenting a significant challenge within the herbal industry. Excessive concentrations of these contaminants in *W. somnifera* can lead to the rejection of entire batches (Ahmad, Aqil, et al., 2006). Specific details on the range of toxicity indicators can be found in Table 5, referencing various standard sources.

Quality Risk Assessment

Identifying variables affecting the quality of *W. somnifera*

W. somnifera recognized for its medicinal properties, demands extra care from planting to preparation for obtaining better quality. Many factors influence its quality, beginning with pre-cultivation factors.

Methods for cultivating the crop play a major role, proper sowing techniques provide uniformity and sound development of roots.

Supporting plant growth with bamboo canes prevents bending and ensures better root formation. The correct planting time, usually late rainy season, corresponds with natural growth cycles and is ideal for water availability while limiting waterlogging dangers that can cause root rot. Preparation of the soil is equally important—flat land allows for even water distribution and nutrient availability and harrowing and deep plowing (to depths of 2-3 cm) promote soil aeration and root penetration. The addition of well-rotted organic manure enriches the soil with basic nutrients and microbial activity for healthy plant growth, i.e., 1 ton cow dung per acre. Optimum spacing between the plants (60 cm × 60 cm or 45 cm × 30 cm) facilitates better nutrient uptake, less competition, and more air circulation, which lowers the risk of fungal infection. Intercropping *W. somnifera* with sesame or other compatible crops gives better use of the land while controlling pests and ensuring a more sustainable cropping system (Banik, 1985; Guo et al., 2025; Zhou et al., 2025).

Agricultural practices during the growing period exercise a great influence on the yield and phytochemical profile of *W. somnifera*. Fertilizer management is important—be balanced in your application of nutrients like Nitrogen, Phosphorus, and Potassium (N-P-K). Better root growth and better withanolide concentration is the positive outcome of balanced application of these nutrients. Overusing chemical fertilizers, however, may significantly lower the amounts of bioactive compounds. Irrigation is again a key

Table 2: Microscopic characters of *W. somnifera*.

Type of microscopy	API (Joshi et al., 2017b)	Indian Standards of Medicinal Plants (Gupta, 2003)	IP
TS of wood			
Cork Structure	Exfoliated or crushed cork, which is isodiametric and lacks lignification, is characteristic of cork material. The cork cambium typically comprises 2-4 dispersed rows of cells.	n.d.	n.d.
Cork cells	n.d.	Outermost 4 to 8 rows. Occasionally interrupted by lenticels	n.d.
Secondary Cortex	About twenty layers of compact parenchymatous cells.	n.d.	n.d.
Phloem Composition	Sieve tubes, companion cells, and phloem parenchyma.	Narrow parenchymatous. Contains starch grains	n.d.
Secondary Xylem	It generates solid tissue, forming a closed vascular ring, and is divided by multiseriate medullary rays.	Broad. Contains isolated vessels or occasional groups of 2 to 3 vessels. Encased within thin-walled fibers. Dominates the majority of the wood space.	n.d.
Cortical Parenchyma	n.d.	15 to 20 layers. Loaded with starch grains and calcium oxalate crystals	Microcrystals present in parenchyma cells.
Medullary Rays	n.d.	Uni- to multiseriate. Continue into the xylem beneath. Bent in places. Especially when running alongside vessels.	n.d.
Xylem Parenchyma	A few xylem parenchyma cells present	n.d.	n.d.
Starch Grains	n.d.	Abundant starch grains observed. Starch grains are simple, mostly spherical, reniform-oval with a central hilum	n.d.

n.d. = No data available.

Table 3: Physicochemical parameters of *W. somnifera*.

Physico-chemical parameters	API (Joshi et al., 2017b)	Indian Standards of Medicinal Plants (Gupta, 2003)	IP (Pharmacopoeia and Commission, 2010)	Industrial Standards
Foreign matter	< 2%	< 1%	< 2%	As per API
Total ash	< 7%	< 8%	< 7%	
Alcohol insoluble ash	< 1%	< 2%	< 1.2%	
Alcohol soluble extractive	> 15%	> 18%	> 10.0%	
Water soluble extractive	n.d.	> 22%	> 15%	

n.d. = No data available. < = not more than; > = not less than.

factor too; provide irrigation synchronized with rainfall so as to prevent waterlogging as well as nutrient leaching while helping to maintain the proper moisture level for proper root development. Usually, two cycles of irrigation during the period of growth are sufficient. Regular weeding minimizes competition for resources and prevents germination of contaminating plants, and ensures healthy growth. The time of harvest is the point where the medicinal potency of *W. somnifera* roots is secured (Pandey and

Hembram, 2025). The correct period for harvest is between 150 and 180 days after sowing, whereby the roots are fully matured and contain maximum levels of bioactive compounds. Modes of harvesting also affect quality-mildly unearthing the roots with minimal damage will ensure that the medicinal properties remain. Using clean implements such as power tillers or country ploughs lessens chances of contamination and maintains the integrity of the roots.

The postharvest stage is equally important as it relates to the impact during storage, efficacy, and marketability of *W. somnifera*. Proper peeling and washing of roots with clean water prevents microbial contamination and guarantees a clean product for further processing. Tree roots are cut down to small pieces of 7 to 10 cm to ensure uniform drying so that they are microbial free during storage. Drying is an essential thing in retaining the active compounds in Ashwagandha roots. Ashwagandha roots should be dried to 10-12% moisture level to inhibit fungal growth and keep longer. If the drying is not uniform, molds might occur and the bioactive properties might get lost, rendering the product useless for medicinal purposes. The last bit of sorting brings not only uniformity among the roots concerning size, shape, and quality but also increases market value charges. Grading them for the market value and therapeutic utility in terms of color and withanolide concentration gives an idea of the pricing, therefore, the efficacy. Due to their higher concentration, high-grade roots are preferred for pharmaceutical purposes. Packaging is the final but most important for: Escalating quality-a moisture-tight bag to avoid moisture ingress to the dried roots, dust, and the

outside environment, thus ensuring effectiveness in storage and transport. Proper labeling and storage ensure traceability which builds confidence in the consumer (Mahato *et al.*, 2025; Roy *et al.*, 2025).

Besides these major stages of the process, a few other external factors like environmental conditions, soil type, and pest management practices also influence the quality of *W. somnifera*. The plant prefers to grow in semi-arid regions with moderate temperatures ranging between 20°C and 35°C. Prolonged exposure to extreme weather such as drought and frost will have a detrimental impact on root quality. Assuredly, the soil must be well-drained sandy loam with a pH between 7.5 and 8.0, which promotes optimum nutrient uptake and root growth. The soil must be tested before the commencement of the cultivation of *W. somnifera* for the identification of deficiencies and corrective measures. Infection of the roots is caused by root beetles and aphids, while disease initiation and causation like root rot and leaf blight both lead to a decrease in yield and quality. Several eco-friendly pest control measures are crop rotation and natural

Table 4: Qualitative and quantitative ranges of Withaferin A in *W. somnifera*.

Method	API (Joshi <i>et al.</i> , 2017b)	Indian Standards of Medicinal Plants (Gupta, 2003)	IP (Pharmacopoeia and Commission, 2010)	General method of experimentation
TLC	n.d.	R_f is 0.43 corresponding to withaferin A	n.d.	Quality standards of medicinal plants Solvent for extraction reflux condenser: methanol The solvent system consists of Ethyl acetate, Toluene, and acetic acid in a ratio of 9:1.1:0.6, with visualization achieved using anisaldehyde sulfuric acid. For detailed method, refer “Quality standards of Indian medicinal plant”.
HPTLC	n.d.	R_f is 4.5 corresponding to withaferin A	n.d.	Quality standards of medicinal plants Solvent mixture for HPTLC analysis of Eugenol: Ethyl acetate: Toluene: Acetic acid: (9:1.1:0.6). Detection carried out at 214 nm. For detailed method, refer “Quality standards of Indian medicinal plant”.
Liquid Chromatographic	n.d.	n.d.	R_t of withanolide A is 1.0	IP, 2010 Solvent for extraction using reflux condenser: acetonitrile o-phosphoric acid buffer (ph 2.8): acetonitrile (gradient flow) For detailed method, refer “Indian Pharmacopoeia, 2010”.

n.d. = No data available.

pest deterrents to minimize crop loss from pest damage and to ensure the sustainable nature of farming. Rounding up on other attributes of pre-plant, agro-process, and post-harvest factors affecting the quality of Ashwagandha, conscious consideration and reviewing of each stage is needed in order to produce roots appreciably rich in medicinal properties such as withanolide. The decisions surrounding timing of planting, scientific methods of sowing, fertilizer use, irrigation, and harvesting techniques will impact directly on the pharmacological value of the plant. The active principles are preserved during the storage of roots when proper harvesting, drying, sorting-grading, and packaging in air-tight storage are carried out. Climate, soil type, and pest management must also be tackled if quality is ever to be achieved. Appropriately applying science, endorsing the environment, and functioning best on agri-practices by farmers and stakeholders will seamlessly allow to produce quality *W. somnifera* based on the market demands and preserves its ancient therapeutic legacy.

Material Attributes

W. somnifera quality is contingent not only on the attribute landscape across cultivation and processing activities, but also on really poorly executed on-farm practices, which can diminish the quality of *W. somnifera*. Materials attributes in the pre-cultivation stage like scientific sowing, planting should be done in late rainy season, proper land preparation-harrowing, deep plowing, leveling, organic manure application, optimum spacing, intercropping with sesame-all these are important for the healthy

growth of *W. somnifera*. Agro-practices like balanced fertilizers (N-P-K application), synchronized irrigation, weeding, harvests between 150 and 180 days, and routine handling were taken to be important in the maintenance of plant quality. The final stage relates to post-harvest practices, such as washing in pure water, cutting roots into uniform pieces, drying to a 10-12% moisture content, sorting, grading, airtight packaging, all of which are important in the preservation of medicinal properties of roots. Additionally, environmental factors in terms of semi-arid climate, sandy loam soil (pH 7.5-8.0), and eco-friendly pest management play key roles in the production of good quality *W. somnifera* suited for pharmaceutical uses.

Table 5: Toxicity indicators of *W. somnifera*.

Parameter	Limits	Reference
Alcoholic extract	1260 mg/kg Inter-peritoneal (LD ₅₀ Dose)	WHO, 2011,1998
Crude extract	100 mg/kg oral administration for 180 days	
Lead	2.5 mg/kg (Food not specified)	(Food Safety and Standards: Contaminants, Toxins and Residues) Regulations, 2011-FSSAI
Copper	30 mg/kg	
Arsenic	1.1 mg/kg	
Cadmium	1.5 mg/kg	
Mercury	1.0 mg/kg	

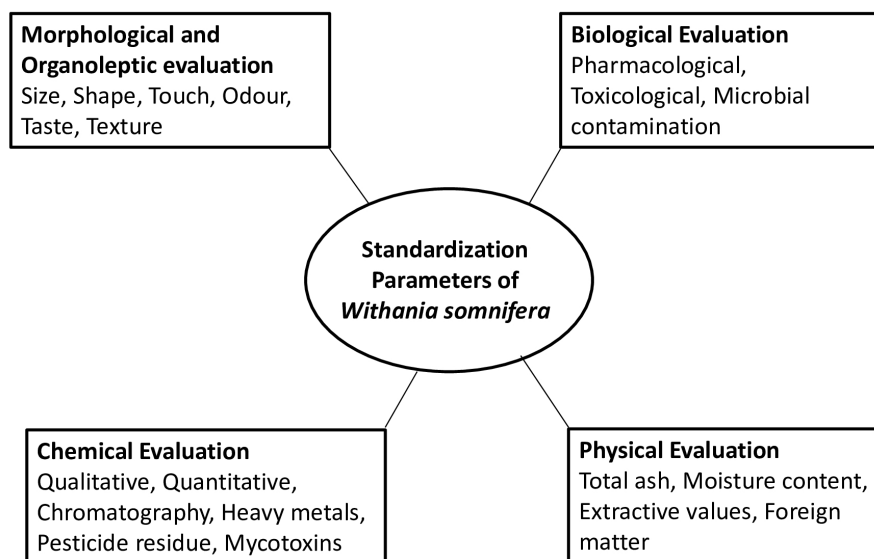


Figure 2: Quality parameters of *W. somnifera*.

Process Parameters

Essentially, pre-planting parameters-wise, ensuring that the cultivation and processing steps are followed at each stage guarantees good-quality *W. somnifera*. Pre-cultivational operations shall include leveling, harrowing, and deep plowing for adequate aeration of the soil to allow almost equal water distribution, followed by planting at a depth of 2-3 cm and spacing of 60 cm x 60 cm or 45 cm x 30 cm for cobbing the roots. During cultivation, the application of properly balanced fertilizers, irrigation as per rainfall, and timely weeding must be carried out to ensure healthy growth. The yield should be harvested around 150-180 days after sowing, using minimal disturbance roots unearthing techniques and clean tools to prevent damage to roots. The post-harvest procedures include clean water washing, cutting roots into small 7-10 cm pieces, drying at 10-12% moisture content, and sorting and grading according to quality standards parameters that assure retention of medicinal properties in roots. Proper airtight packaging protects the dried roots from contamination and moisture, thus preserving their efficacy during storage and transport.

Identify the target quality product profile or quality attributes

The target quality product profile or quality attributes of *W. somnifera* cultivation are ensuring high medicinal potency, uniformity, and compliance with pharmaceutical standards. Some of these attributes are:

- 1. High Withanolide Content:** This means the roots must contain high concentrations of bioactive compounds, particularly withanolides, which are the major therapeutic agents.
- 2. Root Integrity:** The roots should remain intact and free from physical damage or contamination at the time of harvesting and during processing.
- 3. Size and Shape:** Uniformity in root size during harvesting (preferably 7 to 10 cm after cutting) ensures uniformity in drying and quality. Low Moisture Content: Dried roots should have a

moisture content of 10-12% to prevent fungal growth and ensure longevity during storage.

4. Microbial Contamination: The roots must be free from microbial contamination, heavy metals, pesticide residues, and other impurities.

By maintaining these quality attributes, the cultivation process ensures *W. somnifera* roots meet the therapeutic, commercial, and pharmaceutical requirements effectively.

Identifying risk factors

As per the methodology for the quality risk assessment for the cultivation of the *W. somnifera* identification of the risk factors involved and prioritizing into process parameters and materials attributes which could affect the quality of the *W. somnifera* in terms of yield, high withanolide content, root integrity, optimal size and shape, low moisture content and free from any microbial contamination.

Risk analysis

Based on the reviewed literature, farmer's prior knowledge of cultivation process, various material attributes and critical process parameters are identified. These material attributes and process parameters played a crucial role in the determining the final quality attributes of the *W. somnifera*. Risk analysis includes the determining the impact of the material attributes and process parameters on final quality attributes and classified on the three scales of the impact 'High', 'Low' and 'Moderate'. Classification of material attributes on the risk analysis scales are shown in Table 6.

Various material attributes such as climatic conditions, seed quality, cultivation methods, and soil pH have a high impact on the final quality attributes, such as the withanolide content, integrity, size, shape, moisture levels, and microbiological contamination. Quality attributes are, to a large extent, influenced by the climate, the semi-arid region with steady temperatures of about 20-35°C and appropriate sunshine allowing for the ideal growth of the plant, thus enhancing withanolide biosynthesis and improving

Table 6: Risk assessment of impact of material attributes on the final quality attributes for the quality production of *W. somnifera*.

MA QA	Climatic condition	Seed	Water	Soil	Nutrients	Agrochemicals	Agricultural process equipment
Final withanolide content	High	High	High	High	High	Moderate	Less
Root Integrity	High	High	Moderate	High	Moderate	High	Less
Optimal Size and Shape	High	Moderate	High	High	High	High	Less
Low Moisture Content	Less	Less	High	Moderate	Less	High	Less
Microbial Contamination	Less	Less	Less	High	Less	High	Less

the size and shape of the roots—all this while reducing moisture retention, which can cause microbial growth. The quality of the seeds also matters, since high-quality seeds mean better genetic potential, which leads directly to higher withanolide content, integrity of the roots, and uniformity in size and shape. About water and irrigation, the withanolide level, the ideal size, and moisture can be significantly determined by the amount of water available and its effective management, since accurate irrigation reduces stress on the plant while overirrigation usually lowers the integrity of the root structure or causes microbial contamination. Among other properties of soil, pH (7.5-8.0) and texture (sandy loam) have a pronounced influence on the integrity and health of the root system to absorb nutrients and preserve the essential physical structure for optimal shape and size. Though excessive nutrients may lead to secondary growth problems that will increase the risk of losses of root integrity, the content of organic matter and the N-P-K fertilizers have a high influence on both biosynthetic processes and root development. Agrochemicals may moderately assist growth by controlling pests and diseases, but care must be exercised in their usage to minimize the likelihood of persistent chemical residues. Agricultural process machinery exerts a less significant influence on biosynthesis, although it

is not without some indirect contributions by ensuring precise sowing, uniformity in spacing, and gentle harvesting, enabling maintenance of the root structure. These material attributes work in a synergistic manner to compliment the Ashwagandha in terms of high medicinal potency, optimum physical characteristics, and microbial safety, thus adhering to the pharmaceutical standards for quality. Table 7 represents the impact of process parameters on final quality attributes and classification on three scales of risk.

Risk assessment for the process parameters in *W. somnifera* cultivation, as shown in the table, illustrates the extent to which the parameters affect the final quality attributes. The risk elements for high withanolide content include climatic conditions, seed quality, and soil characteristics, which are of high impact due to their direct role in biosynthesis. Another aspect is water and nutrient availability, which presents high risk if badly managed. Moderately and slightly significant risks arise from agrochemicals and agricultural machinery. Root integrity is greatly affected by climate conditions, seed quality, and characteristics of the soil—improper handling or bad conditions could compromise structural quality. Water and agrochemicals here present moderate to high risks when improper irrigation or overuse of chemicals is involved. The factors influencing root size and shape

Table 7: Risk analysis of process parameters on the final quality attributes.

Pre-cultivation phase				
PP QA	Seed treatment	Site treatment	Soil treatment	Water treatment
Final withanolide content	High	High	High	High
Root Integrity	Less	Moderate	High	Moderate
Optimal Size and Shape	High	Less	Less	High
Low Moisture Content	Less	Less	Less	Less
Microbial Contamination	Moderate	High	Moderate	Less
Agro-practice phase				
PP QA	Sowing	Plant management	Nutrition	Harvest
Final withanolide content	High	High	High	Less
Root Integrity	Moderate	Less	Moderate	Less
Optimal Size and Shape	High	Less	Less	Moderate
Low Moisture Content	Less	Moderate	Less	Less
Microbial Contamination	Less	Less	Less	Less
Post-harvest phase				
CPP CQA	Collection	Drying	Storage	Handling
Final withanolide content	Moderate	Less	Less	Less
Root Integrity	Moderate	High	Moderate	High
Optimal Size and Shape	High	Less	High	Less
Low Moisture Content	Less	Less	Less	Less
Microbial Contamination	Less	Less	Less	Less

shall include climatic conditions, water, nutrients, and soil, with the risk derived from improper irrigation, nutrient imbalance, or soil compaction, whereas agrochemical process equipment should have less impact. Low moisture maintenance relies heavily on water management and post-harvest treatment; too much water can promote contamination by fungi or other harmful organisms. Mainly, the risk of microbial contamination arises from soil and water quality, where agrochemicals and improper handling might also be important. The overall risk assessment highlights the importance of closely controlling climatic, irrigation, soil, and nutrient parameters to reduce risks and help produce quality *W. somnifera* in compliance with industry standards.

CONCLUSION

Cultivation and quality assessment of *W. somnifera* will require a multidisciplinary approach involving the integration of agricultural practices with regulatory compliance (Sharma et al., 2024). Adherence to standardized agro-techniques-such as planting time, soil enrichment, irrigation management-was shown to greatly increase plant yield and withanolide content (Patel et al., 2022). Quality risk assessment further emphasizes the need for systematic monitoring of environmental and process parameters to minimize risks of contamination (Singh and Baldi, 2023). The research provided valuable insight for farmers, regulatory bodies, and the herbal industry towards producing established quality for *W. somnifera* pharmaceutical applications. Regulatory authorities form a major part in assuring the quality and safety of medicinal plants like *W. somnifera* for commercial acceptability (Sharma et al., 2024). The research deliberated on the multifaceted therapeutic potential of *W. somnifera* and points to the existing gap in knowledge regarding its varied quality parameters and their acceptable limits. This, in turn, poses challenges to the industry wherein maintenance of consistent quality standards is challenged due to variabilities that come in the therapeutic and pharmacological characteristics of medicinal plants case after case. Additionally, toxicity due to unequal yield is a major concern. The standards laid down by diverse national and global regulatory authorities provide the necessary yardsticks to ensure that the products adhere to pre-set parameters related to purity, potency, and effectiveness. This compilation intends to streamline and consolidate all relevant knowledge on *W. somnifera* into one unified document that represents this ongoing effort. This study does much more than ask academic questions; it has direct significance for farmers engaged in the cultivation of *W. somnifera*. By furnishing a famed repository of information, this research empowers farmers to certify and test their crops towards the enhancement of commercial acceptability of the quality-based medicinal plant produce. For instance, herbal scientists are investigating *Curcuma longa* for managing the pandemic, in view of the great demand for medicinal plants arising post-COVID-19, due to their diverse health properties. The authors discuss concerns regarding species adulteration

and the need for one comprehensive document that will outline standard quality parameters, drawing from sources such as API, WHO, and FSSAI (S. Sharma et al., 2024; P. A. Singh et al., 2021b). This, in turn, supports the industry's resolve to sustain consistent quality standards to meet regulatory requirements. This research plays a key role in bridging the information gap, acting as a pillar both for supporting farmers and enhancing the industry commitment to producing high-quality medicinal plants. Collaboration among regulatory authorities, scientific research, and the agriculture sector is emphasized to maintain the therapeutic properties of medicinal plants such as *W. somnifera* and, ultimately, the well-being of the consumers.

ABBREVIATIONS

API: Active Pharmaceutical Ingredient; **WHO:** World Health Organization; **FSSAI:** Food Safety and Standards Authority of India; **HPLC:** High-Performance Liquid Chromatography; **HPTLC:** High-Performance Thin-Layer Chromatography; **IP:** Indian Pharmacopoeia; **GACP:** Good Agricultural and Collection Practices.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHOR'S CONTRIBUTION

Baldi A conceptualized the research, provided guidance, revised the manuscript and handled the submission and communication with the journal. Sharma S, Naman S, Kaur R performed an extensive literature review, writing, field related research, and drafted the manuscript. Dwivedi J, Ashawat MS and Chauhan NS supervised the writing and Chandan A provided sources for ground data.

SUMMARY

This research highlights the importance of having a cohesive system which joins field practices with regulatory expectations for the sustainable production of quality *W. somnifera*. Quality oversight for major agronomic and operational procedures provides consistency, uniformity and removes unwanted contaminants. The work adds value by organizing scattered knowledge, facilitating evidence-based decisions by producers and reinforcing the supply chain for raw materials of medicinal plants. More reliable, traceable and safe use of *W. somnifera* will come from strengthened partnerships among research bodies, farming communities and regulatory authorities.

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