

# Raising the Standard: Continuing a Tradition of Quality

Manufacturing Excellence and the  
Wellness Works Nutraceutical  
Line



# Manufacturing Excellence

- Wellness Works' manufacturer has been a leader in manufacturing quality dietary supplements for more than five decades.
- Their rigorous manufacturing practices and procedures are designed to monitor and verify quality throughout every step of the production process.
- Detailed written Standard Operating Procedures and cGMPs (current Good Manufacturing Practices) in accordance with USP 31
- Laboratories are ISO 9001 certified and 17025 accredited
- Manufacturing facilities have received GMP registration from NSF International
- In-house laboratories, under the supervision of staff PhDs, constantly monitor quality
- Veri-Match, electronic label match to formula system to ensure content accuracy
- Vendor Certification Program ensures raw material quality
- Compliance with Public Health Security and Bioterrorism Preparedness Response Act
- Compliant with the Adverse Events Reporting (AER) enacted in 2007

# Quality Raw Materials

- All raw materials that our manufacturer receives are quarantined until they successfully undergo testing and are released by the Quality Control Department.
- Only after Quality Control approval has been granted can the raw material be released for use in a product.
- Our manufacturer has a rigorous process (Vendor Certification Program) for qualifying raw material suppliers, as companies must demonstrate that they operate under strict SOPs and GMPs and have valid FDA registration numbers. Our manufacturer will not work with any supplier that cannot document the specific steps that it takes to ensure the quality and safety of the ingredients that it supplies.

# Quality Manufacturing and Production

- The manufacturing process itself is performed under tight controls by a team of highly skilled, dedicated staff, who strictly adhere to written Standard Operating Procedures (SOPs) prepared in accordance with Good Manufacturing Practices (GMPs), as listed under Nutritional Supplements in the USP 31.
- Good Manufacturing Practices are guidelines that provide a system of processes, procedures, and documentation to assure the product produced has the identity, strength, composition, quality, and purity that it is represented to possess.
- NSF GMP registration demonstrates commitment to quality. NSF is an independent company that audits our manufacturer's facility against a strict set of manufacturing practices.

# Quality Assurance

- All manufacturing takes place in temperature and humidity controlled conditions, and is under constant supervision. To further ensure precision and accountability, our manufacturer electronically follows the entire manufacturing process, from the receipt of the raw material to the finished product. This allows our manufacturer to track the progress of a product at all points through the production process and allows the various departments that work on the product to better interact, ensuring a quality supplement.

# Laboratories Ensure Quality

- Testing is conducted on raw materials before manufacturing to assure purity. Products are also tested during and after the manufacturing process to ensure potency and quality.

- **Physical Analysis Laboratory**

Tests the weight, thickness, hardness, and disintegration of finished products, making certain that capsules and tablets disintegrate and release their nutrients in a timely manner.

- **Microbiology Laboratory**

Tests all raw materials and products for yeast, mold, and bacterial purity in accordance with USP 31.

- **Chemical Analysis Laboratory**

Uses highly sophisticated analytical instruments, including HPLC (High Performance Liquid Chromatography), ICP (Inductively Coupled Plasma spectrophotometer, used for mineral analysis), GFAA (graphite furnace atomic absorption spectrophotometer, used for heavy metals testing) and an FT-IR (Fourier Transform Infrared spectrophotometer).

Findings from our manufacturer's laboratories have been compared to independent lab reports on many occasions and have been consistently on target.

# What is ISO?

- The International Organization for Standardization (ISO) is a worldwide federation of 111 national standards bodies whose primary objective is to promote the development of manufacturing, trade and communication among business organizations worldwide through the development of standards.
- The term “**ISO 9001**” refers to a detailed set of quality management standards that a company must adhere to in order to meet the conditions of certification.
- The more rigorous “**ISO 17025**” provides a third-party accreditation of our manufacturer’s laboratories, which serves to demonstrate that their laboratory has the technical and managerial capabilities to perform specific tests and measurements using correct, validated procedures and equipment specific tests and measurements using correct, validated procedures and equipment.

# ISO 17025

This accreditation demonstrates a number of important factors including:

- Personnel are competent and have the applicable theoretical and practical backgrounds to properly perform their work.
- Written procedures are used for the sampling, handling, transport, storage, and preparation of items to be tested.
- When applicable, testing methods are those published as international or national standards.
- Testing methodology is validated to confirm that it is appropriate for each particular test.
- It is the validation of the method and the adherence to a set of tightly controlled procedures that is the key to being assured of accuracy and reproducibility.
- Strict maintenance and calibration schedules are also in place for analytical instruments.
- Our manufacturer's ISO certification and accreditation mean that they have developed and validated quality control procedures in accordance with an internationally recognized set of standards.

# Wellness Works Commitment to Quality

Our manufacturer takes great pride in an uncompromising approach to providing you with products that meet the highest levels of quality. They are constantly evaluating evolving technologies to incorporate into the development and manufacture of new and existing products. Our manufacturer's unparalleled quality, manufacturing flexibility, five decade of experience, breadth of product line and cutting-edge technology are indeed raising the standard by which to measure dietary supplements within the industry.

# A Commitment to Excellence

- ISO 9001 Certified Manufacturer
- ISO 17025 Accredited Laboratories
- NSF GMP Registration
- Health Canada
- European Union GMP Certified
- FDA Audit Compliant

