

## Simplexity Health's Quality Assurance Program

In our efforts to provide the highest quality finished products, we have designed a Quality Assurance (QA) program that ensures the quality and safety of our products, from harvesting and processing of the algae itself to the testing of ingredients from suppliers. By reviewing the following information, customers develop ever greater confidence in the superiority of products purchased from Simplexity.

### Quality Assurance for Harvesting & Processing *Aphanizomenon flos-aquae* from Upper Klamath Lake

#### Testing Before and After the Harvest

- **Pre-harvest scouting** involves collecting algae samples from potential harvest locations. Samples are tested either directly on the Lake Harvester or in our onshore laboratory.
- **Pre-harvest testing** includes microscopic analysis to determine the species of algae present, biomass evaluation to establish the amount of algae available, and thorough examination to assess the purity of the algae.
- **Post-harvest analysis** involves microscopic in-house examination to verify the purity of each batch and to confirm that we meet state guidelines. Chlorophyll and other pigment testing further ascertains the raw product quality.
- **Post-harvest independent testing** is also crucial. Each harvest season we send random samples of every batch for independent testing to world-renowned algologists Dr. Don Anderson of Woods Hole Oceanographic Institute and Dr. Wayne Carmichael of Wright State University. This independent testing verifies in-house analyses and serves as our final test results.

#### Low-Temperature Drying

Once we have received test results from the independent laboratories, we can proceed with the drying process, using a low-temperature spray-drying technique called BioActive Dehydration™. The proprietary Oxy-Guard™ system prevents oxidation during drying, which is extremely important, as oxidation causes the algae to deteriorate.

Testing has shown that sensitive chlorophyll and enzyme levels remain high for algae spray-dried via this method. Our drying system also meets the stringent guidelines for both organic certification and kosher certification.

#### AFA Powder Analyses

After drying, each batch of algae goes through yet another round of testing by independent laboratories.

1. Dr. Don Anderson's lab **analyzes for chlorophyll and other pigments**. This is important because pigments are fragile; intact pigments signal a product with all other nutrients also intact.
2. A certified food lab tests for:
  - a. Microbial levels of aerobic bacteria, coliforms, *Escherichia coli*, yeasts, molds, *Salmonella*, *Listeria*, *Shigella*, and *Staphylococcus*.
  - b. **Heavy metals** such as arsenic, mercury, cadmium, selenium, chromium, and lead.
  - c. **Pesticides** including organophosphates, organochlorides, and carbamates.

#### Certificate of Analysis

After each batch of algae has passed all quality assurance testing, a Certificate of Analysis is issued and that batch is released for use in the production of dietary supplements and foods.

#### Quality Assurance for Finished Products from Vendors

We are one of the few companies that also run regular QA testing on all our vendor's products.

Shipments of finished products are placed in quarantine before being inspected and sampled by our Quality Control department. Review of the product includes the following:

1. Inspection of the bottle, the label, and the integrity of the cap and seal.
2. Testing of samples from random bottles, using the same criteria as that for raw materials, which includes testing for microbes, appearance, flavor, aroma, texture, disintegration, and friability (tablet stability).
3. Verification that the average capsule or tablet weight, the bottle count, and the net weight are within specifications.
4. Review of the Certificate of Analysis from the vendor for accuracy.

A sealed sample of each lot of material is saved for one year beyond the shelf life as a Quality Control retainer.

### **Good Manufacturing Practices (GMP)**

Simplexity Health's manufacturing facility is officially registered for the FDA's Current Good Manufacturing Practices (GMP), **including GMP Registration and GMP for Sport™ Registration**, through NSF International's dietary supplements registration program.

This program is designed to reduce the risk of product contamination by strict adherence to their standards.

Standard operating procedures have been established for all sectors and current approved methods are carefully followed.

GMP Registration for our facility applies to practices in the following areas:

- **Personnel are thoroughly trained**; they wear GMP-approved garments, including hair and beard nets; eating, drinking, and tobacco use in GMP areas are prohibited.
- **Manufacturing plant and grounds** have adequate cleaning and litter removal procedures, pest control, water supply, sewage and drainage systems, hand-washing protocols, self-closing doors, and parking lot maintenance procedures.
- **Equipment and utensils** are food-grade, non-toxic, and well-maintained, and utilize properly calibrated instruments.
- **Optimum methods** are employed for raw materials inspection, testing, and storage, as well as for processing steps such as encapsulation and bottling.
- **Warehouse configuration** protects food from contamination.
- **Returns and complaints** are promptly investigated; if necessary, corrective actions are taken.
- **Recall and traceability** procedures are utilized.
- **Production control systems** include maintaining master manufacturing and batch records, component specifications, a supplier approval program, and quality controls for packaging and labels.
- **Holding and distribution** procedures protect food from contamination and assure product quality and safety



GMP Registered



Certified for Sport®

**The result:** Our edible microalgae is the most nutrient-intact & safe algae on the market.