dotFIT™ Product Manufacturing and Testing

Reliance Vitamin Company
Manufacturer of solid-dose dietary supplements including tablets, capsules and powders

Reliance has a strong industry reputation for producing innovative, value-added supplements with a high rate of on-time delivery. The company has an impressive selection of 450+ always-in-stock private label products, and the ability to manufacture many others on a contract basis. Their 34 years of experience has allowed them to build an innovative Product Development team, a strong Quality and Regulatory Department, an in-house laboratory, and an industry-leading Customer Service Department.

Product Development Team
The development team is led by a Ph.D. formulator, and includes a nutritionist, Quality Assurance personnel, and others with significant industrial formulations experience. They offer particular expertise in highly-stable probiotics and protein powder formulation and manufacturing. Among other tools, they have access to an ultra-low humidity environment. It is this team that can play an advisory role on regulatory, legal, and international export issues.

Quality
Since Reliance is regulated by local, state, and federal agencies such as the FTC, the NJ Department of Health, and FDA; they have built large Quality Assurance and Quality Control departments. Their teams have developed and follow an extensive system of Standard Operating Procedures (SOPs) and Good Manufacturing Practices (GMPs) that ensure regulatory compliance at all levels. A critical part of the Quality team’s responsibilities is to control the complex processes of the manufacturing systems including:

- Development and/or participation of product formulations with strict adherence to dotFIT’s evidence based guidelines
- Specification development
- Materials procurement
- Raw material receipt, testing and release
- All in-process manufacturing systems
- Sample retention
- Document and records control
- Laboratory oversight
- Physical and analytical testing
- Batch reconciliation
- Finished product review and release
- Internal audits
- Personnel training for compliance with internal SOPs and GMPs
- Compliance with all local, state and federal government regulations
- Compliance with NSF Certified for Sport (NSFCS) unique requirements
  - See below under “About NSF” for more on NSF & NSFCS

Additional 3rd Party Audits
The Reliance quality teams have also been central to the company’s compliance with the standards and system controls required by external programs such as the Natural Products Association’s GMP certification, and NSF GMP certification. These are important third-party organizations that provide external measures of quality assurance and compliance.
Note: The FDA conducted a full audit in 2015 which yielded Reliance Vitamin Company the highest classification possible.

Analytical and Physical Testing
Reliance conducts physical and analytical tests throughout the entire manufacturing process. Our in-house laboratory completes the following tests for each material and/or batch:

- Physical testing
  - Tablet hardness
  - Tablet thickness
  - Tablet friability
  - Weight variation
  - Color matching
  - Moisture analysis
  - Tap density
  - Disintegration

- Analytical Testing for Identity and/or Potency
  - Raw material identity through FTNIR spectra matching
  - Finished product analytical testing using
    - HPLC
    - Atomic Absorption
    - Titration
    - NIR
    - UV-Vis

- Microbial Testing
  - Absence of E. coli
  - Absence of Staphylococcus
  - Absence of Salmonella
  - Total Plate Count

Third Party Product Testing
All products undergo third Party testing by Covance, LA Analytical & Chemical Solutions. Additional third party testing required by a specific line of dotFIT products is performed by the NSF Certified for Sport (NSFCS) program and Health Canada (see below for more on NSFCS banned substance testing). The accredited third-party laboratories confirm the potencies of:

- Botanical extract actives
- Water-soluble vitamins
- Fat-soluble vitamins
- Trace minerals
- Macro minerals
- Enzymes
- Amino acids
- ORAC value
- Antioxidants
- Fatty acids
- Specialty compounds
- Nutritional content (carbs, proteins, fats, cholesterol, sodium, etc.)
And the presence/absence of:

- Heavy metals
- Genetically Modified Organisms (PCR)

**Regulatory Advisement**

The Reliance Quality, Regulatory and Product Development teams can assist with international registration, and regulatory compliance for label claims and advertising.

**Capstone Nutrition**

*Primary powder formulation manufacturer for dotFIT.*

**Raw Material to Finish Product Testing**

Capstone maintains a strict quality program on all raw materials and finished products. All incoming raw materials undergo microbiological testing, heavy metals testing, contaminant testing and analysis for assay if applicable. For protein products in particular, all incoming raw materials are specifically tested to ensure protein content is attained in accordance with the specifications. All finished products are tested again for micro and heavy metals along with assays based on the type of product. This is all done via in-house equipment and varies by ingredient. Capstone currently has the following equipment to perform these tests: HPLC, FTIR, ICP-MS, GC-MS and more. In-process testing is also conducted via FTIR and HPLC to ensure that a proper blend has been achieved. FTIR provides a fingerprint of the blend, whereas HPLC provides specific detail on an analyte. Certified Certificates of Analysis (C of As) accompany every product batch delivery to dotFIT.

**Third Party Quality Controls**

Good Manufacturing Practices (cGMPs) are regulatory requirements that provide guidelines for necessary processes, procedures and documentation, assuring the product produced has the identity, strength, composition, quality and purity it is represented to possess on the product label. NSF conducts regular plant audits of Capstone’s facility to verify compliance with GMPs. GMPs for the current NSF Dietary Supplements Program are included in NSF American National Standard 173-Dietary Supplements, the only American National Standard for Dietary Supplements, and are consistent with the requirements that FDA has laid out in 21 CFR § 111.

**Third Party Product Testing**

Following the in-house testing and 3rd party audits listed above, specific dotFIT products produced by Capstone are sent for additional 3rd Party testing performed by Health Canada and the NSFCs program as shown below.

**The NSFCs Testing and Certification program (see below “About NSF” for more details)**

- APPLICATION
  - Formulation
  - Label
  - Ingredient supplier’s information
  - Manufacturing facility’s information
- TOXICOLOGY REVIEW
  - Label and formulation review and comparison
  - Ingredient review
  - Determine product testing
FACILITY INSPECTION
- Good Manufacturing Practices (GMP) audits of production facilities
- Observations of in-house laboratories
- Sourcing and traceability procedures
- Schedule of ingredient supplier audits based on number of suppliers

ANNUAL LABORATORY TESTING/ANALYSIS
- Microbiological
- Heavy metals
- Pesticides/herbicides
- Label content verification
- Disintegration
- Banned substances testing based on number of lots

PRODUCT CERTIFICATION/LISTING
- Monitor formulation/ingredient supplier changes
- Unannounced follow-up audits
- Marketplace sampling

Additional information can be found here:

Garden State Nutritionals

Manufacturer of tablets, capsules, powders, liquids (shots to multi-serving containers), creams, gels, soft chews and gummies.

Garden State Nutritionals (GSN) is one of the largest custom contract manufacturers of nutritional supplements in the United States. GSN has built a reputation over three decades as a trusted leader in the formulation, development and manufacture of custom dietary supplements. GSN also has an international reputation, supplying dietary supplements to more than 35 countries around the world. GSN is one of a select group of manufacturers to have received certification and approval from Australia’s Therapeutic Goods Administration (TGA). As dietary supplements for the Australian market must be manufactured to pharmaceutical standards, TGA approval is the ultimate confirmation of superior quality.

Product Development Team
In addition to GSN’s own highly skilled Product Development group, the company also maintains a Scientific Advisory Board. This multidisciplinary team includes leading research scientists, molecular biologists, physicians, pharmacists, clinical nutritionists, herbalists, food technologists, and sports physiologists.

In-house and Third Party Quality Controls
GSN’s FDA regularly inspected facility operates under strict Good Manufacturing Practices (GMPs). Their kosher-approved facilities have been audited and approved by leading independent bodies as well. The Quality Control/Analytical Development Department of GSN consists of a highly trained staff of 15 degreed chemists under the supervision of our resident Ph.D.
From raw material analysis to final product inspection, every production step is carefully monitored and documented, with full accountability and in-process controls. GSN’s ongoing commitment to superior quality is backed up by rigorous analysis of products in our own in-house testing laboratories as well as additional third party testing required for specific dotFIT products.

Auditing, Testing & Documentation
The department performs testing and inspection pertaining to the approval and release of all incoming raw materials and finished products. GSN’s Quality Assurance Department has broad responsibilities and authority in the following areas:

- Quality Improvement — Quality improvement is based on the premise that all work activities can be planned, performed, measured, and improved.
- Personnel GMP Training and Qualification — all employees who come into contact with products must begin GMP training within the first month of employment. GMP training continues on a regular basis throughout the length of employment. Tests are given to monitor the effectiveness of training.
- Internal Audits — QA inspectors monitor all phases of production to assess performance and adherence to GMP and to the SOPs of each department.
- External Audits — QA oversees and supervises inspections and audits of facilities by domestic and international regulatory bodies, as well as by customers and independent auditing firms.
- Supplier Qualification — GSN maintains an audit program to verify suppliers’ ability to provide consistent products that meet strict quality requirements.
- Document and Record Control — QA is responsible for maintaining all documents, records and Standard Operating Procedures, making sure that they are up to date.
- Inspection and Acceptance Testing — QA has the authority to release and reject any component or finished product that does not meet specifications.
- Non-Conformances — QA handles the identification, documentation, control, investigation and disposition of all non-conforming materials, components and final products.
- Maintenance of NSF and NSFCS compliancy (see below, “About NSF”, for more on NSF programs)

GSN’s Laboratory Equipment and Capabilities Include:

Chemical Analysis (guarantees label claims for potency)
- Fourier Transform Infrared (FT-IR) and Near Infrared (N-IR) Spectrometers — for positive identification fingerprinting of incoming raw materials.
- High Performance Liquid Chromatography (HPLC) — for accurate quantitative analysis of vitamins, amino acids and botanical actives. The 7 Waters HPLC Instruments are all interfaced to a Millennium 32 Client/Server System for seamless data integration.
- Perkin-Elmer Inductively Coupled Plasma Emission Spectrometer (ICP) — for precise analysis of nutrient minerals and heavy metals.
- Beckman UV/Visible Spectrometer — for quantitative analysis by light absorption.
- Brinkmann Automatic Titrator — for wet chemical assays.
- Tablet Dissolution/Disintegration equipment — to guarantee conformance with rigid USP specifications.

Physical Analysis (guarantees consistency and uniformity)
- Physical testing equipment determines tablet weight, hardness, thickness, and friability, as well as tap density and particle size of powders.
Practitioner Dietary Supplement Reference Guide 2015 Update

Microbiological Analysis (guarantees purity)
- A complete Microbiology Lab guarantees that raw materials and finished products comply with strict USP requirements.

Stability Analysis (guarantees shelf life)
- Accelerated shelf-stability testing is performed in a range of humidified and non-humidified chambers.

GSN is a fully compliant GMP manufacturing and packaging facility. The company is duly licensed and regularly inspected by State and Federal health authorities. Additionally, GSN undergoes frequent GMP audits by their clients, who confirm our GMP compliance either with their own teams or by engaging independent auditors.

Third Party Product Testing
Following the in-house testing and third party audits listed above, specific dotFIT products produced by GSN are sent for additional third party testing performed by Health Canada and the NSFCS program. See, “The NSFCS Testing and Certification Program” described above under Reliance Vitamin Company. Also see below, “About NSF”, for more details.

Regulatory Assistance
Since the passage of the Dietary Supplements Health and Education Act in 1994, regulatory compliance has become increasingly complex. The GSN Regulatory Affairs and Information Services team offers the following services:

- Full label review - ensures accuracy and regulatory compliance
- International registration assistance
- Formula modifications — to adapt to the requirements of each country
- Full-time Health Canada consultant — to keep pace with the rapidly changing regulatory environment
- Full service testing, including microbiological and stability studies

Quality Control Laboratory Services and Capabilities
The GSN Quality Control Laboratory performs analytical testing of raw materials, in-process samples, and finished goods in a cGMP/GLP compliant facility.

CHEMISTRY CAPABILITIES

Methods
- USP/NF, BP, AOAC, in-house, and client supplied methods are utilized.

Tests Performed
- Vitamin and Dietary Supplement Assays
- Dissolution and Disintegration according to USP and compendia procedures.
- Elemental analysis of minerals
- Physical Testing including Partial Size, Friability, Hardness, and Weight Variation.
- Moisture analysis via Loss on Drying and Karl Fischer techniques.
- Identification via spectroscopy
- Wet Chemical Analysis
- Organic Volatile Impurities (OVI)
- Pesticides Analysis
Heavy Metals Testing for various Regulatory Compliance

Instrumentation
- HPLC / UPLC systems equipped with UV/VIS, PDA, RI, and ELSD detectors.
- UPLC/MS/MS system with ESI and APCI modes.
- GC system with PID, FID, ECD, detection and headspace auto sampling.
- FTIR and NIR spectroscopy systems
- ICP/MS – inductively coupled plasma spectroscopy
- Automated Disintegration and Dissolution apparatus
- Automated Titration equipment
- Automated Moisture Determination equipment

MICROBIOLOGY CAPABILITIES

Methods
- USP/NF, BP, AOAC, FDA-BAM, and client supplied methods are utilized.

Tests Performed
- Microbial Limits
- Probiotic Assays
- Antimicrobial Effectiveness Testing (AEI)
- Tests for Specified Organisms
- Water and Environmental Monitoring

Instrumentation
- Viteck automated Microbial Identification System
- Tempo automated Microbial Assay system

ADDITIONAL LABORATORY SERVICES

- Stability Testing according to ICH guidelines and customized storage conditions.
- Method Development and Validation
- Technology transfer of analytical methodology.

FACILITY AND STAFF

- State-of-the-Art laboratory staffed with 20+ highly qualified professionals all with extensive industry experience.
- Integrated LIMS system

Bakery Barn
Manufacturer of protein sticks and meal replacement bars for dotFIT

Bakery Barn’s 30,000 square foot facility is NSF certified. They recently added a 400 ft. high-speed production line. The new production line has slab and slit capabilities, along with baking and decorating capabilities.
Quality Control Including Third Party Testing
During the production process, a sample unit is pulled from the packaging line every hour. All the collected bars are sent to an independent lab for microbiological testing. Bakery Barn currently utilizes Microbac Labs for microbiological testing. The category of testing that they analyze for (and our limits) include: Coliform (<100 cfu/g), Escherichia Coli (<10/g), Salmonella (Negative/25g), Standard Plate Count (<10,000 cfu/g), Staphylococcus Aureus (<10 cfu/g), Yeast Count (<1,000 cfu/g), Mold Count (<1,000 cfu/g) and Listeria Monocytogenes (Negative/25g). Bakery Barn uses a very strict standard of 10,000 or under for an acceptable measuring for Aerobic Plate Count.

Micro samples: Bakery Barn has a standard of <10,000 CFU/g for Total (Aerobic) Plate Count. There is no “industry standard”, “safe”, or “unsafe” level of Aerobic Plate Count; it is simply a measure. For micro samples, they take four samples at the beginning, four samples in the middle, and four samples at the end of a lot for micro testing. Bakery Barn maintains an extensive "Retains" program where random samples selected throughout the day for every lot are retained on site for a minimum of 90 days after the expiration date of the lot. In the event of a broad range of situations ranging from a major ingredient recall to a consumer question regarding the pattern of icing on a particular product, we can pull actual samples from the same lot for further examination and/or testing.

NSF Certification for Sport Program (NSFCS)
Although all dotFIT (dF) products are formulated and manufactured with the same rigor as described above, a select group of dF products go thru an additional test and 3rd party Certification for another type of assurance. A complete line of dotFIT NSF Certified for Sport (NSFCS) products can be found [here](#). In addition to the dF standard of evidence-based programming, formulas, and 3rd party testing, the addition of the NSFCS process ensures collegiate and professional athletes that they are protected from unwarranted suspensions due to banned substances in supplements. Therefore, not only are the contents tested to match the label, the program includes a test for banned substances that can creep into products during the manufacturing process because of unprotected, non-segregated mixing rooms or worse, deliberate spiking of illegal ingredients. Collegiate, professional, other drug-tested athletes and their team managements require this assurance (NSFCS seal) in order to protect themselves from tainted products commonly found in commercially available dietary supplements in mass-market outlets.1,2,3,4,5

About NSF
To meet the growing demands of athletes, coaches and all those concerned about safety and banned substances in sports supplements, NSF International created the NSF Certified for Sport® Program. The program's objective is to certify that participating sports supplement manufacturers have met NSF's stringent independent certification process guidelines, which were developed through a consensus process involving regulatory, sports industry and consumer groups. This program, which focuses primarily on the sports supplement manufacturing and sourcing process, provides key preventive measures to:
- Protect against adulteration of products
- Verify label claims against product contents
- Identify athletic banned substances in the finished product or ingredients

NSF developed and maintains the only accredited American National Standard to certify dietary supplements, NSF/ANSI Standard 173. NSF's history of independence led to a partnership with the National Football League (NFL) and the NFL Players Association (NFLPA) to develop and administer the NFL/NFLPA Supplement Certification Program, specifically for professional football but used across all sports.

The NSF Prohibited Substances List includes banned substances, identified by leading sports organizations, such as the World Anti-Doping Agency (WADA), the NFL and Major League Baseball (MLB). The NSF Certified for Sport™ Program certifies products and inspects facilities for a range of substances. Click the [here](#) for more on NSF Certification program.
Products by Manufacturer and 3rd Party Testing

**Reliance**
All products are 3rd party tested by Covance Labs, LA Analytical or Chemical Solutions. Additional 3rd party testing by NSF and Health Canada are listed next to their respective products.

- ActiveMV™ - Multivitamin & Mineral Formula - **NSF, Health Canada**
- Women’sMV™ - Multivitamin & Mineral Formula
- Over50MV™ - Multivitamin & Mineral Formula
- SuperiorAntioxidant™ - **NSF, Health Canada**
- Advanced Brain Health™
- SuperCalcium+™
- WeightLoss & LiverSupport™ - **Health Canada**
- CarbRepel®
- ThermAccel™
- CreatineXXL™ - **Health Canada**
- MuscleDefender™ - L-Glutamine - **NSF**
- All Natural Whey Smooth
- Best Plant Protein

**Capstone**
Finished products not marked with “NSF” or “Health Canada” are tested in house and Certificate of Analysis (CofAs) are available upon request.

- Creatine Monohydrate - Raspberry Lemonade - **NSF**
- Recover&Build™ - BCAA’s
- WorkoutExtreme™
- First String Chocolate Blast - **NSF**
- First String Vanilla Blast - **NSF**
- Pre/Post Workout Formula & Meal Replacement Creamy Chocolate – **Health Canada**
- Pre/Post Workout Formula & Meal Replacement Creamy Vanilla - **Health Canada**
- Pre/Post Workout Formula & Meal Replacement Strawberry Banana
- Whey Smooth Chocolate Creme – **NSF, Health Canada**
- Whey Smooth Vanilla Creme – **NSF, Health Canada**
- LeanMR - Vanilla
- LeanMR - Chocolate

**CapTek**

- SuperOmega-3 Fish Oil - **NSF, Health Canada**

**Garden State**
Finished products not marked with “NSF” or “Health Canada” are tested in house and Certificate of Analysis (CofAs) are available upon request.

- AminoBoost XXL - **NSF, Health Canada**
• Kid's MV
• NO7 Rage

**GMP Labs**
3rd party tested by Covance Labs, Chemical Solutions, ABC Labs, Silliker Labs, Micro Quality Labs. Additional 3rd party testing by NSF and Health Canada are listed next to their respective products.

• JointFlexPlus - **Health Canada**
References