

## Practitioner Dietary Supplement Reference Guide – 3<sup>rd</sup> Edition

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### 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 41 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 (NSFCFS) unique requirements
  - See below under "About NSF" [for more on NSF & NSFCFS](#)

#### Additional 3<sup>rd</sup> 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.

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*Note: The FDA conducted a full audit in 2018 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.)

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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 3<sup>rd</sup> party audits listed above, specific dotFIT products produced by Capstone are sent for additional 3<sup>rd</sup> 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

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- 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:

[http://www.nsf.org/business/athletic\\_banned\\_substances/index.asp?program=AthleticBanSub](http://www.nsf.org/business/athletic_banned_substances/index.asp?program=AthleticBanSub)

### Bakery Barn

#### Manufacturer of protein sticks and meal replacement bars for dotFIT

Bakery Barn’s 30,000 square foot facility is NSF certified. This includes a 400 ft. high-speed production line that 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.

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### 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 3<sup>rd</sup> 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 3<sup>rd</sup> 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.<sup>1,2,3,4,5</sup>

### 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 3<sup>rd</sup> Party Testing

#### Reliance

All products are 3<sup>rd</sup> party tested by Covance Labs, LA Analytical or Chemical Solutions. Additional 3<sup>rd</sup> 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**
- SuperCalcium+™ - **NSF**
- Recover&Build™ - BCAA's
- WeightLoss & LiverSupport™
- CarbRepel®

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- 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.

- AminoBoostXXL – Lemonade, Blue Raspberry, Watermelon, Grape - **NSF**
- Creatine Monohydrate - Raspberry Lemonade - **NSF**
- ExtremeCreatineXXXL+ - Raspberry Lemonade – **NSF**
- WorkoutExtreme™
- ThermAccel™
- DigetiveEnzymes
- 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

Quality Control & Assurance - <https://capteksoftgel.com/quality/>

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

### GMP Labs

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

- JointFlexPlus – **NSF**

### RobinsonPharma

Certifications - <https://robinsonpharma.com/page.php?pageID=certifications>

Quality Assurance - <https://robinsonpharma.com/page.php?pageID=qualityassurance>

- AdvancedBrainHealth

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### References

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- <sup>1</sup> <http://mikeha77.com/fda-finds-problems-at-62-of-supplement-manufactures/>
- <sup>2</sup> <http://www.neogaf.com/forum/showthread.php?t=479530> Bodybuilding.com found guilty of spiking supplements with steroids
- <sup>3</sup> <http://www.forbes.com/sites/alexmorrell/2015/03/12/lawsuits-say-protein-powders-lack-protein-ripping-off-athletes/> [9/9/2015 12:05:21 PM]
- <sup>4</sup> <http://well.blogs.nytimes.com/2015/02/03/new-york-attorney-general-targets-supplements-at-major-retailers/>
- <sup>5</sup> <http://www.wsj.com/articles/oregon-sues-gnc-alleging-supplements-contained-illegal-ingredients-1445543143>