USP Verification Services

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Senior Director, Verification Programs
USP Verification

Program for Dietary Ingredients & Supplements

A best-in-class service offering

Advancing quality to help build a healthier world
USP Verification Services

USP Dietary Supplement Verification
Launched 2002

USP Dietary Ingredient Verification
Launched 2004 - Relaunched 2017

USP GMP Audit Program
Launched 2015
6 Quality System Inspection Model

1. Quality Management
2. Facilities and Equipment
3. Materials
4. Production
5. Packaging and Labeling
6. Laboratory Controls
# GMP Facility Audit

## DIVP vs DSVP Audit Criteria

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<th>Audit Standard</th>
<th>Dietary Ingredients</th>
<th>Dietary Supplements</th>
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<td><strong>USP–NF General Chapter &lt;2750&gt;</strong></td>
<td><em>Manufacturing Practices for Dietary Supplements</em></td>
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<tr>
<td><strong>21 CFR Part 117</strong></td>
<td><em>Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food</em></td>
<td><em>21 CFR Part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements</em></td>
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<tr>
<td><strong>USP–NF General Chapter &lt;2740&gt;</strong></td>
<td><em>Manufacturing Practices for Dietary Ingredients</em> (coming soon!)</td>
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GMP Audit Company Participants:

Ingredients:
- Golden Biotechnology Corp.
- Sami Labs Limited (Nelamangala, Kunigal, Dobaspet, & Hyderabad)
- Shri Kartikeya Pharma
- Sino Siam Biotechnique Co., Ltd.
- Yantai Dongcheng Biochemicals Co. Ltd.

Supplements:
- Captek Softgel International
- Formulation Technology, Inc.
- Lallemand Health Solutions (Harmonium & Institut Rosell)
- Metagenics, Inc.
- Nutribiotech USA, Inc.
- Premier Research Labs
- Quality Nutrition Labs
- Usana Health Sciences, Inc.

ISO 17020 Accreditation (in process)
Sami-Sabina's Biotech site achieves USP GMP audited status

13 April 2019 | Correspondent

The Sami-Sabina Group's Nellamangala biotechnology site in Bengaluru, India has been audited by the United States Pharmacopoeia (USP) and received a GMP compliance certificate on February 25, 2019. The certificate recognizes that the site operates GMP quality systems which meet the requirements set forth in 21 CFR Part 117 Current Good Manufacturing Practices, Hazard Analysis and Risk-Based Preventive Controls for Human Food, and USP-Pharmacopeial-<2750> Manufacturing Practices for Dietary Supplements for Dietary Ingredient Manufacturing.

This site produces peroxide, enzyme blends as well as Supercritical Fluid extraction of various botanicals. "All of our facilities have undergone many inspections and certifications through the years and will continue to do so" said Sami-Sabina founder Dr. Muhammad Majed. "While we always encourage customers to visit us in India and see our manufacturing facilities for themselves, we realize that's not possible for everyone. Participating in the USP GMP audit program is another way we can assure customers of our unwavering commitment to producing quality ingredients. Our other facilities are scheduled for USP auditing in the near future."

"USP is pleased to recognize Sabina's successful completion of the USP Quality Systems GMP Audit Program for this site," said John Ahweter, Senior Director of USP Verification Services. "This demonstrates Sabina's commitment to quality and to operating GMP quality systems for the manufacture of dietary ingredients in compliance with officially recognized requirements.

USP's GMP audit program helps dietary ingredient manufacturers ensure compliance with GMP requirements and reduce risk while also providing them with a way to differentiate and qualify their manufacturing facilities and operations for their customers, finished product manufacturers, in an increasingly competitive global market. USP's GMP audit program includes annual audits of a manufacturing site's quality systems compliances with GMPs. Having received recognition from USP, Sabina has earned a USP Quality Systems GMP Audited Certificate, and was added to USP's website www.usp.org/verification-services/gmp-audit-program, a resource for finished product manufacturers to identify ingredient manufacturers who have earned the right to use the USP Audited Good Manufacturing Practices Mark.
Products that meet the DIVP / DSVP program requirements are awarded the use of a USP Verified Mark on their label.

USP has tested and verified ingredients, potency, and manufacturing process.

USP sets official standards for dietary supplements. See www.uspverified.org
USP Standards Form the Foundation of DIVP & DSVP

Documentary Standards
For Dietary Supplements

Chemical Reference Standards
For Dietary Supplements
Both verification programs follow the same process with different GMPs.

Start Program:
- Product Eligibility

Pre-approval Verification Phase:
1. GMP Facility Audit
2. Product QCM Documentation Review
3. Product Sample Testing

Mark Approval:

Post-approval Verification Phase:
- Label Review
- Continuous surveillance
Dietary Ingredient Verification Participants

Manufactured by AstaReal, Inc.
- AstaReal® L10

Manufactured by Balchem Corporation
- Choline Bitartrate Regular
- Choline Bitartrate Conditioned 20M
- Choline Bitartrate Conditioned 40M
- Choline Bitartrate Conditioned Regular
- Choline Bitartrate (intermediate)
- Choline Chloride
- Choline Chloride 1%

Manufactured by Inner Mongolia Kingdomway Pharmaceutical Ltd.
- Ubidecarenone (Coenzyme Q10)

Manufactured by DSM Nutritional Products Canada Inc.
- DSM Marine Lipids Peru S.A.C.
  - Natural Fish Oils (NF) - 5
  - Natural Fish Oil Concentrates (NFC) - 1
  - Triglycerides Concentrates (TGC) – 13
  - Ethyl Esters Concentrates (EEC) - 22

Manufactured by PuraPharm International (HK) Limited
- Fructus Crataegi Formula Granules
- ONCO-Z Coriolus Versicolor Extract
- Radix Astragali Formula Granules

Manufactured by Balchem Corporation

Manufactured by E.I.D. PARRY (India) Limited, Parry Nutraceuticals
- Organic Spirulina (Arthrospira Platensis) Powder

Manufactured by Huaian MDC Chemistry Co. Ltd.
- Chondroitin Sulfate Sodium

Manufactured by Inner Mongolia Kingdomway Pharmaceutical Ltd.
- Ubidecarenone (Coenzyme Q10)

Manufactured by Shenzhou Biology & Technology Co., Ltd.
- Ubidecarenone (Coenzyme Q10)

Manufactured by OmniActive Health Technologies
- CurcuWIN Curcumin DNS Powder 20%, HB Powder 20%
- Lutemax® Free Lutein Vegetarian Beadlets 5%, 10%, 20%, 25%
- Lutemax® 2020 Free Lutein Zeaxanthin Vegetarian Beadlets 5%, 10%, 20%, 25%
- Lutemax® Free Lutein Oil Suspension 20% - 5
- Lutemax® 2020 Free Lutein/Zeaxanthin Oil Suspension 20% - 4
- Lutemax® 2020 Ultra Oil Suspension 6.67%
- Lutemax 2020 Free L/Z Oil Suspension 20%/NG
USP Dietary Supplement Verification

USP Verified
#1 recommended program by Pharmacists in recent survey from Pharmacy Times.

Pharmacy Times

#1 PHARMACIST RECOMMENDED
Communication Channels

Print Ads

Digital Ads

Influencer Campaign

National Commercial

Social Media

Conference Communications

USP rigorously tests and verifies your supplements meet high-quality standards.

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USP Verified. Trust in Quality.

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National TV Commercial
Why Have Your Products USP Verified?  Provides Peace of Mind!

- USP provides trusted independent quality oversight
- USP product quality verification programs are best-in-class
- USP’s verification programs help manufacturers prepare to meet regulatory quality requirements in-country and globally
- USP verified products meet quality standards that differentiate them from competitors’ products which can mean increased success in the marketplace
- Manufacturers, healthcare practitioners and consumers value quality and are increasingly looking for quality products

USP Verified Mark makes quality visible!
USP Verification Website

http://www.usp.org/verification-services

Items found on the USP website:

- Program Manual for Participants
- List of verified products
- List of participating companies
Discussion