

WAY 16

bioCERTIFIED™ Products From Spectrum Pharmacy Deliver Quality Assurance for Regulatory Compliance

bioCERTIFIED chemicals are 100% tested and backed by scientific documentation to help you meet compliance requirements. Each product also undergoes additional testing for endotoxin, bioburden, and elemental impurities.

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Founded: 1971

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Company Background

Celebrating 50 years, Spectrum Pharmacy Products is a leading global supplier of quality chemicals, laboratory equipment, and supplies. The company's products include more than 45,000 chemicals and 3,000 bulk items with an emphasis on USP, NF, FCC, BP, EP, JP, and ACS grade products including active pharmaceutical ingredients, controlled substances, excipients, dietary supplements, cosmetic, and personal care ingredients. These products are available in laboratory, scale-up and production quantities. The company's U.S. facilities are ISO 9001:2015 certified, FDA-registered, and operate under current Good Manufacturing Practices (cGMP).

Product Overview

Backed by Spectrum Pharmacy's "100% Tested and 100% Transparent" guarantee, bioCERTIFIED products deliver quality assurance and help compounding pharmacies meet compliance requirements. Raw materials and finished goods undergo in-house testing to ensure all chemicals and ingredients meet stringent quality standards. Each lot is fully compendial-tested and includes extensive scientific documentation and certifications, as well as additional tests for endotoxin, bioburden, elemental impurities, and more. This ensures that all chemicals meet safety, purity, and efficacy requirements.

With a diverse team of in-house chemists, Spectrum analytical testing laboratories are fully equipped with state-of-the-art technology supported by best practices, current Good Laboratory Practices (cGLP) and current Good Manufacturing Practice (cGMP). This includes proficiency in a wide range of laboratory techniques including instrumental analysis, wet analysis, and microbial testing.

In addition, the company's industry-leading scientific documentation, validation, and qualification systems support the change control expected by all quality-driven organizations.

All Spectrum pharmacy products, including active pharmaceutical ingredients, are manufactured, packaged, and held under cGMP per 21 CFR parts 210 and 211 and meet USP 232/233 requirements.

Knowledge & Expertise

- Change Control Processes
- Electronic NDC Submissions
- Lot Sequestration
- Pedigree and Supply Chain Verification
- Batch Traceability
- Technical Product Support
- Regulatory Compliance Support
- Consulting Services
- EDI/Web Ordering

Testimonials

"Quick response, fair pricing, and great attention to detail on all orders. Customer service is personalized and they go out of their way to work with us! I order from Spectrum whenever I can!"

— Cindy F.

"Spectrum is impeccable and should be the industry standard!"

— Ken C.

Additional Product Lines

- 1,200+ Monograph Chemical Items
- 500+ In-depth Scientific Dossiers on Monograph Chemicals
- 400+ APIs Covering More Than 40 Therapeutic Areas
- 250+ Top Chemical Excipients
- DEA Controlled Substances (Schedules I-V)
- 200,000 Lab Equipment and Supplies

Markets Served

- 503A Pharmacies
- 503B Outsourcing Facilities