

bioCERTIFIED™ Products for Biopharmaceutical Manufacturing

The Right Materials from the Start

Spectrum Chemical Mfg. Corp has been in the chemical business for nearly five decades. We have earned the trust of quality-driven product manufacturers and laboratories by continuously reinvesting in quality systems to provide the finest ingredients and raw materials. Working with biopharma customers to improve our products and services and meet growing quality, safety and regulatory needs, Spectrum has expanded our laboratory testing with our new bioCERTIFIED™ quality program.

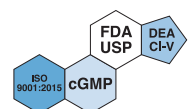
- Full testing for every lot: including bioburden, endotoxin and elemental impurities
- Comprehensive regulatory & scientific documentation
- Change control & batch traceability
- 4 Analytical Testing Labs
- US Locations ISO 9001:2015
- China Laboratory ISO 17025
- Biopharm industry standard CFR 210/211 cGMP packaging facilities



The bioCERTIFIED™ quality program covers an expanded menu of analytical tests and certifications required by biopharmaceutical manufacturers. For parenteral applications where a biological drug enters directly into the bloodstream, even more stringency is required to ensure a product is endotoxin-free with minimal bioburden. New USP 232/233 requirements for elemental impurities put even more demand on the certifications for raw materials. The new Spectrum bioCERTIFIED™ product label identifies products that have undergone additional testing for bioburden, endotoxin and elemental impurities.



800.772.8786 · SpectrumChemical.com



Built for Quality-Driven Industries

The quality of the chemical ingredients, APIs and excipients that make up a pharmaceutical or biological product is of primary importance to its safety and efficacy. Spectrum continues to invest in the facilities, instrumentation and regulatory compliance needed to support the needs of biomanufacturers.

bioCERTIFIED™ products

Catalog No.	Product Description	Brand	Size Range	Grade
T9700	TRIS Base (Tromethamine)	Spectrum	500 g – 20 Kg	USP, EP
A9600	L-Arginine	Spectrum	500 g – 20 Kg	USP, JP
L9800	L-Lysine Monochloride Monohydrate	Spectrum	500 g - 45 Kg	USP, EP, JP
H9400	L-Histidine	Spectrum	500 g – 20 Kg	USP, JP
S9400	L-Serine	Spectrum	500 g – 20 Kg	USP, JP
T9400	L-Threonine	Spectrum	500 g – 20 Kg	USP, JP
V9100	L-Valine	Spectrum	500 g – 20 Kg	USP, JP
B8200	Benzyl Alcohol	Spectrum	500 g – 20 Kg	NF, EP, BP, JP
E9200	Ethanol 20%	Spectrum	1, 5, 55 Gallons	cGMP Manufactured
G9300	Glycerin	Spectrum	4, 20, 200 Liters	USP, EP, BP, JP, FCC

Spectrum Chemical Mfg. Corp.

USA / Canada: 1.800.772.8786

Latin America / Europe: 1.310.516.8000

Asia Pacific: +86-21-67601398

New Jersey

Corporate Headquarters

ISO 9001:2015 • cGMP • FDA Registered

Manufacturing, Distribution & QC Labs

769 Jersey Avenue

New Brunswick, NJ 08901-3605

California

ISO 9001:2015 • cGMP • FDA Registered

Manufacturing, Distribution & QC Labs

14422 S. San Pedro Street

Gardena, CA 90248-2027

China

ISO 17025 • FDA Registered

Manufacturing, Distribution & QC Labs

3802 Shen Gang Road, Bldg A20,

Song Jiang District, Shanghai, China 201611



Professional Scientific Documentation

As part of Spectrum's expanded bioCERTIFIED™ program, the company offers hundreds of professionally prepared dossiers. Providing such documentation on pilot, scale-up and production chemicals mitigates downstream financial risks for biomanufacturers by avoiding costly down time.