BIOSPECTRA
Premium Pharmaceutical Ingredients

API DEVELOPMENT & MANUFACTURING

Exclusively Manufactured in the USA

Qualified - State-of-the-art equipment & facilities
Quality - Highest Purity Drug Ingredients
Value - Consistent, respected, reliable
Validated - FDA registered and inspected
Trusted - Most stringent quality system
Support - DMF submission
Security - Made in the USA

API Focus & Expertise

- Small Volume Support
- Small Molecule Synthesis
- Orphan Drug Substance Quantities
- Chlorinations / Chloride Compounds
- Salts of Complex Organic Compounds
- Inorganic & Boutique Organic Synthesis
- Full Compliance vs. Atypical Standards
- Low Bioburden, Low Endotoxin Demands
- Parenteral / Oral / Transdermal Applications

www.biospectra.us
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API Support Package

Process Development – Manufacture of Registration Batches – Ongoing Support

Analytical Support

- Analytical Method Validation
- Transfer of Analytical Methods
- Custom Analytical Methods and Specifications
- Bioburden and Endotoxin Testing
- Complete Impurity Profile
- Elemental Impurities
- Residual Solvents

Development Support

- Stability Study
- Custom GMP Services as needed
- Custom Labeling and Packaging
- Manufacture of API Registration Batches
- Drug Master File submission
- Letter of Authorization
- Efficient Development Timeline
- High-touch management of your project

Ongoing Support - Post FDA Approval

- Commercial Manufacturing of your API
- On Site Audits
- Annual Product Review
- Management of Change
- Post Submission Change Notification
- Full support through the life of your product