BIOSPECTRA

US Manufactured Premium Pharmaceutical Ingredients

Corporate Overview

Premium Pharmaceutical Ingredients, Manufactured by People who Care for People who Care

Commercial

01/01/19 rev 5.0

Corporate

People Matter

Vision

A world with safe & effective drugs that deliver consistent, reliable therapeutic effect with every dose

Mission

To manufacture the **highest quality** Pharmaceutical ingredients under the supervision of the **most rigorous** quality system while upholding the **most stringent** compliance standards

Values

Quality / Integrity / Respect

BioSpectra rigorously upholds uncompromised standards because… **“people matter”**

Premium Pharmaceutical Ingredients

Exclusively Manufactured in the USA

Commercial GMP Products:

- **Active** Substances
- **Excipients** & Critical **Process Chemicals**
- Bulk GMP **Biological Buffers** & **Denaturants**
- Unique **Compounded Solvents & Solutions**

Custom GMP Manufacturing Categories:

- **Synthesis** of APIs & Excipients
- **Purification** of Critical Ingredients
- **Compounding** of Solvents & Solutions

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Corporate Commitment to True GMP Products

- Authentic, Secure Supply Chain – 100% Traceable Raw Materials from Qualified Sources
- Reliable, Consistent, Uniform, Quality-Based Manufacturing of Premium Ingredients
- Fully Validated GMP Manufacturing Systems & Qualified Equipment
- True GMP Product Claim – Always Synthesized and/or Purified
- Manufactured Exclusively in the USA

TRUE GMP

BSI **does not** simply test and package under a "GMP system"; rather, **we always increase the quality and compliance levels** through multiple steps of synthetic **manufacturing and/or purification for all** BioSpectra labeled products.

Comprehensive Quality & Regulatory Program

Operating a Stringent Quality & Regulatory Program

- Upholding Global Regulatory Requirements
- Testing to the Highest Quality Standards
- Applying Rigorous Oversight & Controls

- **Global GMP Standards** Meeting US-FDA, ICH Q7 & IPEC Guidelines
- **Comprehensive Internal Auditing** of all Manufacturing Processes
- **Regulatory Services** including Drug Master File Submissions
- **FDA Process Validation** for all GMP Manufacturing Systems
- **Complete Testing** of all Finished Manufactured Lots
- **On-site Quality Control Labs** Operating 24/7
- **Robust Preventive Maintenance Program**
- **State-of-the-art Instrumentation**
- **FDA Registered & Inspected**
- **Raw Materials:**
  - Qualified and Inspected Sources
  - 100% Authentic Traceability
  - Complete Testing

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Comprehensive Quality & Regulatory Program

Quality Assurance

- Validation of all GMP Manufacturing Systems
- Rigorous Preventive Maintenance Program
- Qualification of all Equipment
- Stringent Cleaning Protocols
- Environmental Monitoring
- Change Control Process
- Equipment IQ-OQ-PQ
- Document Control

Regulatory Control & Support

- Creation and Submission of Drug Master Files for APIs and Excipients
- Creation and Control of all Critical Documentation
- Management of all External Audits and Certifications

Quality Control

- Fully staffed, on-site Quality Control Laboratories
- Validation and Verification of all Test Methods
- Qualification of all Instrumentation including ICP-MS, GC-MS, HPLC, UV/Vis, TOC, Ion Chromatographer, Conductivity Meter, Microcount UATR, Polarimeter, Karl-Fisher Titrator & more

GMP Facilities – Bangor and Stroudsburg PA, USA

US Manufactured Premium, Bulk, GMP Fine Chemicals

Key Features

- 175,000 square feet of GMP manufacturing & storage
- FDA Registered & Inspected
- True US GMP Manufacturing
- Total Quality Program
- Rigorous Quality Assurance and Process Controls
- Manufacturing Systems designed according to FDA Guidance on Process Validation
- Exemplary Preventive Maintenance Program
- Dedicated USP Water Systems

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Key Equipment & Manufacturing Scale

US Manufactured Premium, Bulk, GMP Fine Chemicals

- **More than 20 GMP Manufacturing Suites**
- **More than 30 Glass, 316-Stainless Steel and Composite Reactors**
- **Environmentally controlled Packaging Rooms**
- **Quality Control Labs** with industry leading instrumentation

- **Manufacturing Capabilities**: Synthesis / Purification / Compounding
- **Drying Systems**: Spray / Fluid Bed / Rotary / Tray
- **Particle Manipulation**: Jet Milling / Air Sieve / Rotary & Ribbon Blender

Scale & Capacity

- **Reactors:** Solvent & Alcohol / Corrosive Resistant Glass Lined / Stainless Steel
- **Reactor Scale:** 30 L to 20,000 L
- **Solutions Batch Scale:** 10 L to 20,000 L
- **Dry Batch Scale:** 1 kg to 24,000 kg
- **Overall Operational Capacity:** Thousands of Metric Tons per year

Our Focus

US Manufactured Premium, Bulk, GMP Fine Chemicals

1. Solving Key Ingredient Issues

Synthesis, Purity, Compliance & more…

2. Upgrading Your Supply Chain

Facilitating the move to higher compliance

3. Full GMP Product Development

APIs, Excipients & Key Ingredients

CRITICAL INGREDIENT ISSUES?

Purity?

Security?

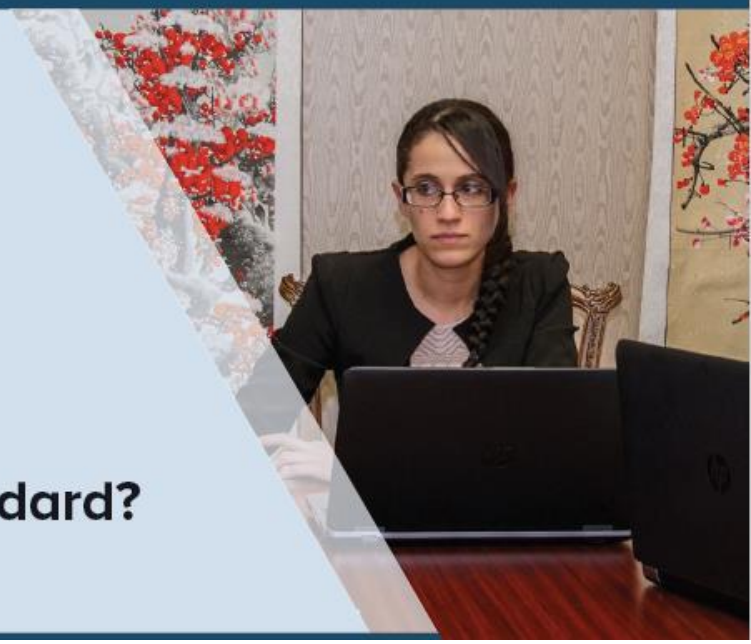
Source?

Scale?

Synthesis?

Specifications?

Compliance Standard?



Critical Manufacturing & Ingredient Issues:

Inconsistencies from lot to lot / Insufficient purity levels / Contamination / Need for "real" GMP mfg. / Non-dedicated facilities / Incomplete testing & Documentation deficiencies / Absence of true traceability / High Microbial & Endotoxin levels / Recalled or scrap product / Need for custom specifications / Need for higher levels of quality and compliance

Supply Chain Security Issues:

Availability / Reliability & trustworthiness / Distance / Safety stock / Manufacturing interruptions / Authentic chain of custody

Regulatory Issues:

IPEC, ICH, GMP, FDA, EMA Compliance issues / Need for global specifications / Need for true validated manufacturing processes / Requirement for a higher compliant raw material

Mitigation Experts

Exclusively Manufactured in the USA - Premium, Bulk, GMP Fine Chemicals

SOLUTION

- True GMP Process
- Actual Purification
- Dedicated Facilities
- Base Synthesis of raw materials
- US Manufactured GMP Products
- True Quality-Based Manufacturing
- Total Quality Program: QC / QA / Regulatory
- 100% Reliable Traceability of all raw materials
- Proven record of adherence to GMP, IPEC, ICH Guidelines

BioSpectra represents consistent high quality, uniformly manufactured pharmaceutical ingredients.

Exclusively made in the USA and always synthesized, purified or compounded under true GMP standards.

Always manufactured at the appropriate specifications and compliance levels for the intended use in the final drug product.

Product Grades & Compliance Levels

US Manufactured Premium, Bulk, GMP Fine Chemicals

- **Bio Active & LBLE* Active**
- **Bio Excipient & LBLE* Excipient**
- **Bio Pharma** (Intended use: GMP Process)

***Note: LBLE** = Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

- **cGMP (US-GMP)**
- **IPEC (International GMP)**
- **FDA Registration / Inspection**
- **Internal Controls and Systems**
- **ICH Q7 & other applicable USP & ICH standards**

Current Focus Products

US Manufactured Premium, Bulk, GMP Fine Chemicals

Commercial Products	Bio Pharma	Bio Excipient	Bio Active	LBLE* Active/Excipient
Galactose				X
Guanidine HCl (also 6M Solution)	X	X		X
Guanidine Thiocyanate	X	X		X
HEPES Free Acid	X	X		
L-Cystine Dihydrochloride		X		
MES Monohydrate	X	X		
MOPS Free Acid	X	X		
Potassium Bromide (KBr)			X	
Sodium Hydroxide 10N <5 ppm Cl	X			
Sucrose				X
Trehalose				X
TRIS HCl	X	X		X
TRIS/Tromethamine	X	X	X	X
Uracil	X			
Urea	X	X	X	X

LBLE* = Low Bioburden Low Endotoxin, non-sterile products for further use in parenteral manufacturing

Parenteral Drug Ingredients

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LOW BIOBURDEN – LOW ENDOTOXIN – HIGH PURITY

- Stringent Environmental Controls
- Rigorous Quality System
- Validated GMP Process
- State-of-the-art facility
- MADE IN THE USA

- BUFFERS
- CARBOHYDRATES
- EXCIPIENTS & ACTIVE INGREDIENTS
- FULL GMP PRODUCT DEVELOPMENT
- CONTRACT SYNTHESIS & PURIFICATION

API Contract Development & Manufacturing

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Exclusively Manufactured in the USA

- Parenteral | Transdermal | Oral Applications
- Full Development & Compliance Support
- Orphan Drug Substance Quantities
- FDA Registered & Inspected
- MADE IN THE USA

- Small Molecule
- Small Volume Support
- Chlorinations | Chloride Compounds
- Inorganic & Boutique Organic Synthesis
- Low Endotoxin – Low Bioburden Demands

API Support Package

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Analytical Support

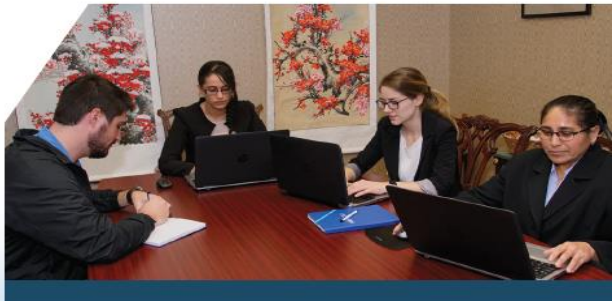
- Analytical Method Validation
- Transfer of Analytical Methods
- Custom Analytical Methods and Specifications
- Bioburden and Endotoxin Testing
- Complete Impurity Profile
- Elemental Impurities
- Residual Solvents

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



Custom GMP Manufacturing

ACTIVES | EXCIPIENTS | PROCESS CHEMICALS

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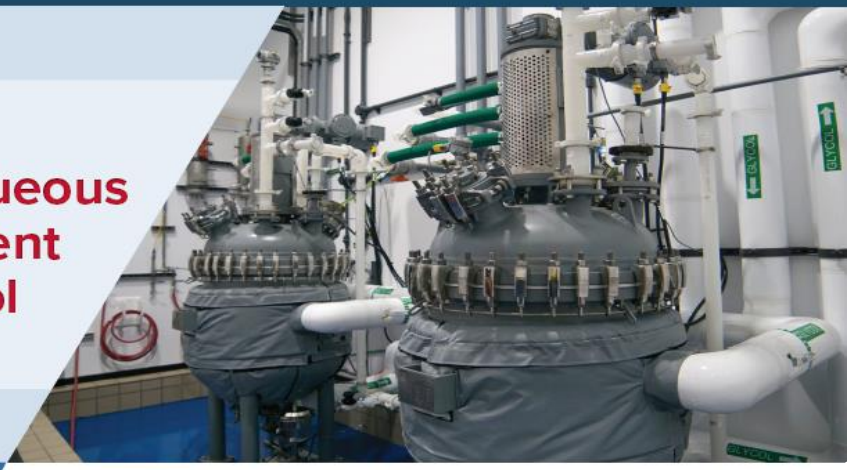
Synthesis
Compounding
Purification

Aqueous
Solvent
Alcohol



- PURIFICATION
- API DEVELOPMENT
- SMALL MOLECULE SYNTHESIS
- SCALE-UP FROM BENCH TO BULK
- FULL GMP PRODUCT DEVELOPMENT
- CUSTOM TESTING, LABELING & PACKAGING
- UNIQUE COMPOUNDED SOLVENTS & SOLUTIONS

Custom GMP Manufacturing (In-House)

- **SYNTHESIS:** APIs & other Key Ingredients / Organic and Inorganic molecules and salts / Corrosive molecules / Chlorides Chlorinations / Ionic Substitution / Small volume support with Scale 1-1000 kg lots / Solvent, Alcohol & Aqueous based

- **LIQUID CHEMISTRY: UNIQUE GMP COMPOUNDED SOLVENTS & SOLUTIONS:** Acid-Base/ Solvent & Alcohol Based/ pH, Zwitterionic Buffers / Hazardous Blends and Compounds / Various Concentration Ranges / 10 liter to 24,000 liter batch volumes

- **PURIFICATION:** Crystallization / Low Micron Filtration / Ion Removal / Trace Metal Reduction / Low Bioburden Low Endotoxin demands / Alcohol, Aqueous & Solvent base

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- **CUSTOM TESTING, LABELING & PACKAGING:** Per Customer Request

- **SCALE-UP:** Bench to Bulk – We offer turnkey services for product and process development with the ability to scale-up from lab to pilot batches to bulk production all in one facility under one Quality & Regulatory system

- **PARTICLE CHARACTERISTICS:** Various milling and particle manipulation techniques to achieve consistent and defined crystal size according to customer requirements – Jet Milling / Blending / Rotary, Fluid Bed, Spray and Tray drying

- **GMP COMPLIANCE SUPPORT:** Up to and including DMF Type II and Type IV submissions

Final Word

We Seek To Service Customers Who

- Are struggling to solve their critical ingredient issues that falls within our scope of chemistry & capabilities
- Realize the need for higher-purity, higher-compliance Pharmaceutical Ingredients
- Understand the value of US manufactured, true-GMP APIs, Excipients and Key Ingredients

BioSpectra: Your Partner for Purity, Regulatory Compliance and GMP Product Development

US Manufactured Premium, Bulk, GMP Fine Chemicals

For more information, please contact:

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