BIOSPECTRA
Premium Pharmaceutical Ingredients

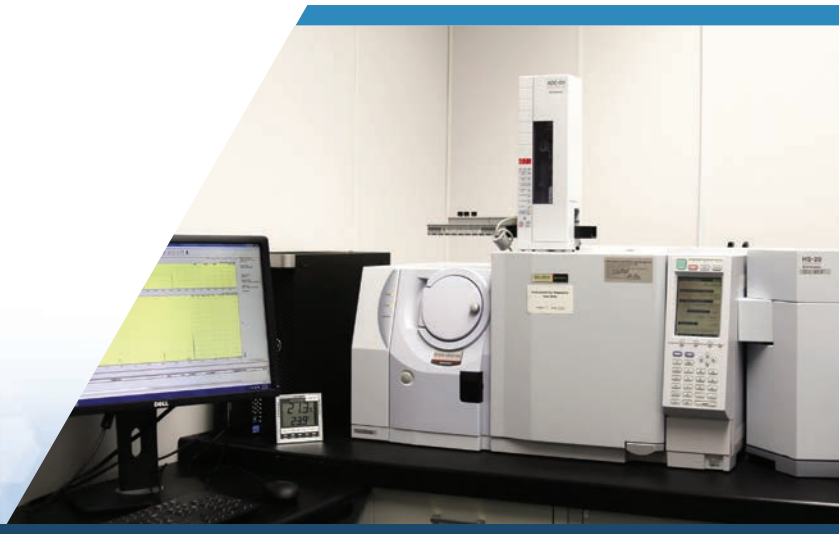
TOTAL QUALITY & REGULATORY PROGRAMS

Operating a Stringent Quality & Regulatory Program

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

Highlights Include:

- **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



www.biospectra.us

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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