


GMP PRODUCT GRADE SELECTION GUIDE

 Key Compliance Attributes of BioSpectra Grades	Bio Pharma Grade IPEC GMP Compliant Manufactured	Bio Excipient Grade ICH Q7 Compliant Manufactured	Bio Active Grade ICH Q7 Compliant Manufactured
Suitable for Research and Diagnostic	Yes	Yes	Yes
Each Batch 100% Analyzed	Yes	Yes	Yes
Management of Change	Yes	Yes	Yes
Validated Analytical Methods	Yes	Yes	Yes
Compendial Testing	Yes	Yes	Yes
Trace Metals Analyzed	Yes	Yes	Yes
Stability Testing Program	Yes	Yes	Yes
BioSpectra Supply Chain Audit Trail	Yes	Yes	Yes
Product Origin Statement	Yes	Yes	Yes
Customer Quality Audits	Yes	Yes	Yes
Validated Manufacturing Process	Yes	Yes	Yes
US Manufactured at BioSpectra	Yes	Yes	Yes
IPEC cGMP Compliant Manufactured	Yes	Yes	N/A
Customized Additional Specifications	Yes	Yes	Yes
Multi-Compendial Testing	Available	Available	Available
Enzyme Tested	Available	Available	Available
Suitable for use as Excipient	Available	Yes	Yes
Microbial / Endotoxin Tested	Available	Yes	Yes
Manufactured in FDA Registered Facility	Yes	Yes	Yes
Customized Manufacturing Schedule	Available	Available	Yes
Custom Regulatory Packet	Available	Yes	Yes
Accelerated Stability	Available	Available	Yes
Type IV Drug Master File	No	Available	N/A
Video Conference access to BioSpectra Sites	No	Available	Yes
Complete access to Product Traceability	No	Available	Yes
Access to Supply Chain Information	No	Yes	Yes
ICH Q7 Qualified Utilities	No	Yes	Yes
ICH Q7 Compliant Manufactured	No	Yes	Yes
Suitable for use as Active Ingredient	No	No	Yes
Type II Drug Master File	No	No	Available
Available indicates an attribute or level of compliance which is granted based on mutual contractual understanding. N/A indicates an attribute or level of compliance which does not apply to that particular grade.			
Bio Pharma Grade	Intended for use as IPEC cGMP Compliant Chemical.		
Bio Excipient Grade	Intended for use as ICH Q7 Compliant Excipient.		
Bio Active Grade	Intended for use as ICH Q7 Compliant Active Pharmaceutical Ingredient.		
LBLE	Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.		