


# PRODUCT GRADE SELECTION GUIDE

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