PRODUCT GRADE SELECTION GUIDE

BIOSPECTRA **Key Compliance Attributes of BioSpectra Grades**	**Bio Ultra Grade** Quality System Manufactured	**Bio Pharma Grade** IPEC GMP Compliant Manufactured	**Bio Excipient Grade** ICH Q7 Compliant Manufactured	**Bio Active Grade** ICH Q7 Compliant Manufactured	**Bio FUISA Grade** ICH Q7 Compliant Manufactured
Suitable for Research and Diagnostic	Yes	Yes	Yes	Yes	Yes
Each Batch 100% Analyzed	Yes	Yes	Yes	Yes	Yes
Management of Change	Available	Yes	Yes	Yes	Yes
Validated Analytical Methods	Available	Yes	Yes	Yes	Yes
Compendial Testing	Available	Yes	Yes	Yes	Yes
Trace Metals Analyzed	Available	Yes	Yes	Yes	Yes
Two Year Stability	Available	Yes	Yes	Yes	Yes
BioSpectra Supply Chain Audit Trail	Available	Yes	Yes	Yes	Yes
Product Origin Statement	Available	Yes	Yes	Yes	Yes
Customer Quality Audits	Available	Yes	Yes	Yes	Yes
Customized Additional Specifications	Available	Yes	Yes	Yes	Yes
Multi-Compendial Testing	Available	Yes	Yes	Yes	Yes
Enzyme Tested	Available	Yes	Yes	Yes	Yes
Validated Manufacturing Process	No	Yes	Yes	Yes	Yes
US Manufactured at BioSpectra	No	Yes	Yes	Yes	Yes
IPEC cGMP Compliant Manufactured	No	Yes	Yes	Yes	Yes
Suitable for use as Excipient	No	Available	Yes	Yes	Yes
Microbial / Endotoxin Tested	No	Available	Yes	Yes	Yes
Manufactured in FDA Registered Facility	No	Available	Available	Yes	Yes
Customized Manufacturing Schedule	No	Available	Available	Yes	Yes
Custom Regulatory Packet	No	Available	Available	Yes	Yes
Accelerated Stability	No	Available	Available	Yes	Yes
Type IV Drug Master File	No	No	Available	N/A	N/A
Video Conference access to BioSpectra Sites	No	No	Available	Yes	Yes
Complete access to Product Traceability	No	No	Available	Yes	Yes
Access to Supply Chain Information	No	No	Yes	Yes	Yes
ICH Q7 Qualified Utilities	No	No	Yes	Yes	Yes
ICH Q7 Compliant Manufactured	No	No	Yes	Yes	Yes
Suitable for use as Active Ingredient	No	No	No	Yes	Yes
Suitable for use in a Sterile Application	No	No	No	No	Yes
Type II Drug Master File	No	No	No	Available	Available

Attributes above are contingent on customer standing and minimum purchase volume.
Available indicates an attribute or level of compliance which is granted based on mutual contractual understanding and typically requires special pricing.
N/A indicates an attribute or level of compliance which does not apply to that particular grade.

Bio Ultra Grade	Intended for bulk chemical manufacturing
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
Bio FUISA Grade	Intended for use as ICH Q7 Compliant Non-Sterile Active Pharmaceutical Ingredient for use in a sterile application