

ELEMENTAL IMPURITY STATEMENT

MES, Monohydrate GMP

BioSpectra's MES, Monohydrate, Bio Excipient Grade, and Bio Pharma Grade material was profiled for elemental impurities via ICP-MS utilizing USP <232> and <233> in accordance with ICH Q3D with reference to parenteral application and associated limits. The results comply with the limits as per USP <232>, USP <233>, and ICH Q3D.

Current Product Number	Historic Product Number
MESM-3220	ME3220
MESM-3221	ME3221
MESM-3222	ME3222
MESM-3223	ME3223
MESM-3250	N/A
MESM-4220	ME4220

For further information, please contact info@biospectra.us


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