

July 10th, 2020 Revision 1

ELEMENTAL IMPURITY STATEMENT

MOPS Bio Excipient Bio Pharma MP3201 MP3220 MP4220

BioSpectra does not routinely analyze MOPS, Bio Excipient grade, and Bio Pharma Grade product codes MP3201, MP3220, MP4220 for elemental impurities. BioSpectra does not intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the product or the manufacturing process. BioSpectra has analyzed for Arsenic (As), Copper (Cu), Iron (Fe), and Lead (Pb) and results met the 5-ppm maximum specification.

For further information, please contact info@biospectra.us

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Crystal Hamelburg Compliance Manager

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