

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

May 3rd, 2024 Revision 1

DIETHYLENE GLYCOL AND ETHYLENE GLYCOL STATEMENT

L-Histidine Monochloride Monohydrate

BioSpectra has evaluated the material supply through the Supplier Qualification Program, and can state that L-Histidine Monochloride Monohydrate, Bio Pharma Grade for BioBuffer Solutions Product line is Diethylene Glycol and Ethylene Glycol free based on this evaluation. BioSpectra does not analyze L-Histidine Monochloride Monohydrate, Bio Pharma Grade for BioBuffer Solutions Product line for Diethylene Glycol and Ethylene Glycol. L-Histidine Monochloride Monohydrate, Bio Pharma Grade for BioBuffer Solutions Product line is manufactured in accordance with the approved Supplier's ISO 9001:2015 certified quality management system, and is not considered high-risk per the US FDA Guidance for Industry: Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol.

Current Product Number LHMM-4250

For further information, please contact info@biospectra.us

Cassie Baun

Senior Compliance Specialist