

April 29th, 2025 Revision 5

RESIDUAL SOLVENTS STATEMENT

Guanidine Hydrochloride GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Guanidine Hydrochloride, Bio Excipient Grade manufactured by BioSpectra complies with the requirements and specifications of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents. There are no Class 1, 2, 3, or other solvents used in the manufacturing process of Guanidine Hydrochloride, Bio Excipient Grade or its raw materials.

Current Product Number
GHCL-3202
GHCL-3220
GHCL-3221
GHCL-3224
GHCL-3225
GHCL-3250
GHCL-3251
GHCL-3253

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