



RE: Elemental Impurities - Guanidine Hydrochloride, Bio-Excipient Grade (Cat# G9800)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP <232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.2 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 0.3 ppm
Cobalt	Co	2A	< 0.5 ppm
Vanadium	V	2A	< 1 ppm
Nickel	Ni	2A	< 2 ppm
Thallium	Tl	2B	< 0.8 ppm
Gold	Au	2B	< 10 ppm
Palladium	Pd	2B	< 1 ppm
Iridium	Ir	2B	< 1 ppm
Osmium	Os	2B	< 1 ppm
Rhodium	Rh	2B	< 1 ppm
Ruthenium	Ru	2B	< 1 ppm
Selenium	Se	2B	< 1 ppm
Silver	Ag	2B	< 1 ppm
Platinum	Pt	2B	< 1 ppm
Lithium	Li	3	< 25 ppm
Antimony	Sb	3	< 9 ppm
Barium	Ba	3	< 70 ppm
Molybdenum	Mo	3	< 30 ppm
Copper	Cu	3	< 30 ppm
Tin	Sn	3	< 60 ppm
Chromium	Cr	3	< 110 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These

CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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