



RE: Elemental Impurities - Nortriptyline Hydrochloride, USP (Cat# N1054)

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
Lead	Pb	1	< 0.25 ppm
Arsenic	As	1	< 0.75 ppm
Cobalt	Co	2A	< 2.5 ppm
Vanadium	V	2A	< 5 ppm
Nickel	Ni	2A	< 10 ppm
Thallium	Tl	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	Ir	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	Not tested
Barium	Ba	3	Not tested
Molybdenum	Mo	3	Not tested
Copper	Cu	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

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

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



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.

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14422 South San Pedro Street
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