

RE: Elemental Impurities- Tranexamic Acid, USP (Cat# T4046)

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. Per the current supply chain, the following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	<0.5 ppm
Lead	Pb	1	<0.5 ppm
Arsenic	As	1	<1.5 ppm
Mercury	Hg	1	<3.0 ppm
Cobalt	Со	2A	<5.0 ppm
Vanadium	V	2A	<10.0 ppm
Nickel	Ni	2A	<20.0 ppm
Platinum	Pt	2B	<10.0 ppm
Lithium	Li	3	<55.0 ppm
Antimony	Sb	3	<120 ppm
Barium	Ва	3	<140 ppm
Copper	Cu	3	<300 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 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. 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.

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Sincerely,

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