



Citric Acid Anhydrous Elemental Impurities Statement

As part of our continued effort to provide customers with assurance of compliance to USP-NF monograph specifications, we have tested representative samples of ADM Citric Acid Anhydrous for the Elemental Impurities listed in USP <232>, following AOAC 2013.06 methodology. Results are presented in the table below, including elements that may be present in our product and the average concentration observed. None of the listed elemental impurities are intentionally added during the production of Citric Acid Anhydrous. ADM will conduct testing on a periodic basis in support of compliance with USP <232> and ICH Q3D.

Elemental Impurity	Sym	Class	Likely to be Present			Permitted Inhalation Concentrations USP <232> Table 3*	Expected Concentration /Units (or Range)*	Limit Of Detection
			Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>			
Arsenic (inorganic)	As	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.2 µg/g	3.5 µg/kg	2 µg/kg
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.2 µg/g	ND	2 µg/kg
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.5 µg/g	ND	2 µg/kg
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.3 µg/g	ND	2 µg/kg
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.5 µg/g	15 µg/kg	12 µg/kg
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.7 µg/g	ND	2 µg/kg
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 µg/g	ND	2 µg/kg
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	13 µg/g	ND	60 µg/kg
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.8 µg/g	ND	2 µg/kg
Barium	Ba	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	30 µg/g	1000 µg/kg	3 µg/kg
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.3 µg/g	20 µg/kg	6 µg/kg
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	3.0 µg/g	15 µg/kg	6 µg/kg
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	2.5 µg/g	ND	60 µg/kg
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1.0 µg/g	ND	2 µg/kg
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	2.0 µg/g	ND	2 µg/kg
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	6.0 µg/g	ND	2 µg/kg

*Please note that the Permitted Inhalation concentrations are given in parts per million (µg/g) values and the known/expected concentrations are given in parts per billion (µg/kg) values. Table 3 in USP 41 lists the permitted concentrations in oral, parenteral and inhalation applications. The lowest permitted concentration given in USP <232> Table 3 is in the Inhalation category.