

Edetate Disodium  
USP - GenAR®  
Suitable for Use in Biotechnology  
(EDTA, disodium salt, dihydrate)



Material No.: 7727-04  
Revision No.: 0

## Product Specification

Meets U.S.P Requirements, Meets E.P. Chemical Specifications, Meets B.P. Chemical Specifications, Meets F.C.C. Requirements, GMP Manufactured Product

Test	Specification
USP - Assay (dried basis)	99.0 - 101.0 %
USP - Identification A	Passes Test
USP - Identification B	Passes Test
USP - Identification C	Passes Test
USP - pH (1 in 20)	4.0 - 5.5
USP - Loss on Drying (by wt)	8.7 - 11.4 %
USP - Calcium (Ca)	Passes Test
USP - Limit of Nitritotriacetic Acid (by wt)	≤ 0.1 %
EP/BP - Appearance of Solution	Passes Test
EP/BP - Identification A	Passes Test
EP/BP - Assay	98.5 - 101.0 %
EP/BP - Identification B	Passes Test
EP/BP - Identification D	Passes Test
EP/BP - Impurity A and Related Substances - Impurity A	≤ 0.1 %
EP/BP - Iron (Fe)	≤ 80 ppm
EP/BP - pH (1 in 20)	4.0 - 5.5
Endotoxin Concentration (EU/g)	≤ 5
FCC - Assay (anhydrous basis)	99.0 - 101.0 %
FCC - Identification A	Passes Test
FCC - Identification B	Passes Test
FCC - Identification C	Passes Test
FCC - Lead (Pb)	≤ 10 mg/kg
FCC - pH (1 in 100)	4.3 - 4.7
FCC - Calcium (Ca)	Passes Test
FCC - Limit of Nitritotriacetic Acid (by wt)	≤ 0.1 %

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700  
Avantor Performance Materials, LLC  
100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone 610.386.1700

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Test	Specification
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GMP Manufactured Product  
Food GMP Manufactured Product  
Bulk Food Chemical  
Bulk Pharmaceutical Chemical  
CAUTION: For Manufacturing, processing or repackaging  
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.  
Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Packaging Site: Paris Mfg Ctr & DC

  
Jamie Ethier  
Vice President Global Quality

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