

Edetate Disodium, U.S.P.
Multi-Compendial

(edta, disodium salt dihydrate crystal)



Material No.: 8995-20
Batch No.: 0000272555
Manufactured Date: 2020/01/15
Retest Date: 2025/01/13
Release Date: 2021/01/04
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Identification A	Passes Test	PT
USP – Identification B	Passes Test	PT
USP – Identification C	Passes Test	PT
USP – pH (1 in 20)	4.0 – 6.0	4.5
USP – Loss on Drying	8.7 – 11.4 %	9.4
USP – Calcium (Ca)	Passes Test	PT
USP – Nitrilotriacetic Acid	<= 0.1 %	< 0.1
USP – Assay (C ₁₀ H ₁₄ N ₂ Na ₂ O ₈) (dried basis)	99.0 – 101.0 %	99.5
Endotoxin Concentration (EU/g)	<= 5	< 3
EP/BP – Assay	98.5 – 101.0 %	99.5
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification D	Passes Test	PT
EP/BP – Impurity A	<= 0.1 %	< 0.1
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH (1 in 20)	4.0 – 5.5	4.5
EP/BP – Iron (Fe)	<= 80 ppm	< 80
JP – Assay	99.0 – 101.0 %	99.6
JP – Identification A	Passes Test	PT
JP – Identification B	Passes Test	PT
JP – Identification C	Passes Test	PT
JP – pH of 1% Solution at 25°C	4.3 – 4.7	4.6
JP – Clarity and Color of Solution	Passes Test	PT

For questions on this Certificate of Analysis 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

Test	Specification	Result
JP – Cyanide (CN)	Passes Test	PT
JP – Heavy Metals (as Pb)	≤ 10 ppm	< 10
JP – Arsenic (As)	≤ 2 ppm	< 2
JP – Residue after Ignition	37.0 – 39.0 %	37.9

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.

Country of Origin: US
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0028001
Manufacturer source batch: D232K1AN91


Jamie Ethier
Vice President Global Quality