

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

(edta, disodium salt dihydrate crystal)



Material No.: 8995-01  
Batch No.: 0000194997  
Manufactured Date: 2017/08/15  
Retest Date: 2022/08/14  
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 %	9.6
USP – Calcium (Ca)	Passes Test	PT
USP – Nitrilotriacetic Acid	<= 0.1 %	< 0.1
USP – Assay (C <sub>10</sub> H <sub>14</sub> N <sub>2</sub> Na <sub>2</sub> O <sub>8</sub> ) (dried basis)	99.0 – 101.0 %	99.5
Endotoxin Concentration (EU/g)	<= 5	< 3
EP/BP – Assay	98.5 – 101.0 %	100.0
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 %	99.8
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 +1.610.573.2600  
Avantor Performance Materials, LLC.

3477 Corporate Parkway, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

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 %	38.0

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: D232H8EN42



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000  
Paris, KY 9001:2008  
Mexico City, Mexico 9001:2008  
Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003  
Gliwice, Poland 9001:2008, 13485:2012  
Selangor, Malaysia 9001:2008  
Dehradun, India, 9001:2008, 14001:2004, 13485:2003  
Mumbai, India, 9001:2008  
Panoli, India 9001:2008



Jamie Ethier  
Vice President Global Quality

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