

Edetate Disodium
U.S.P.
(EDTA, disodium salt, dihydrate)



Material No.: 1395-20
:
Revision No.: 0

Product Specification

Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification
USP – Assay (C ₁₀ H ₁₄ N ₂ Na ₂ O ₈) (anhydrous 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 – 6.0
USP – Loss on Drying	8.7 – 11.4 %
USP – Calcium (Ca)	Passes Test
USP – Limit of Nitrilotriacetic Acid	≤ 0.1 %

GMP Manufactured Product
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.

Meets Reagent Specifications for testing USP/NF monographs

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

For questions on this Product Specification please contact Technical Services at 855.282.6867 or +1.610.386.1700

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