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Edetate Disodium Injection

» Edetate Disodium Injection is a sterile solution of Edetate Disodium in Water for Injection, which, as a result of pH adjustment, contains varying amounts of the disodium and trisodium salts. It contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{10}H_{14}N_2Na_2O_8$.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass.

USP REFERENCE STANDARDS (11)—
[USP Edetate Disodium RS](#)

Identification—Transfer a volume of Injection, equivalent to about 1 g of edetate disodium, to an evaporating dish, adjust with 3 N hydrochloric acid to a pH of 5.0, and evaporate on a steam bath to dryness: the residue responds to *Identification* tests A and C under [Edetate Disodium](#).

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.2 USP Endotoxin Unit per mg of edetate disodium.

pH (791): between 6.5 and 7.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay—

Assay preparation—Dilute an accurately measured volume of Injection, equivalent to about 2 g of edetate disodium, with water to volume in a 100-mL volumetric flask, and mix.

Procedure—Proceed as directed for *Procedure* in the Assay under [Edetate Disodium](#). Calculate the weight, in mg, of $C_{10}H_{14}N_2Na_2O_8$ in the volume of Injection taken by the formula:

$$(336.21/100.09)W(V_T/V)$$

in which 336.21 and 100.09 are the molecular weights of edetate disodium and calcium carbonate, respectively; *W* is the weight, in mg, of calcium carbonate; *V_T* is the volume, in mL, of the *Assay preparation*; and *V* is the volume, in mL, of the *Assay preparation* consumed in the titration.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
EDETATE DISODIUM INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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