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# Edetate Calcium Disodium Injection

» Edetate Calcium Disodium Injection is a sterile solution of Edetate Calcium Disodium in Water for Injection. It contains, in each mL, not less than 180 mg and not more than 220 mg of  $C_{10}H_{12}CaN_2Na_2O_8$ .

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

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

**Identification**—

- A:** Transfer a volume of Injection, equivalent to about 1 g of edetate calcium disodium, to an evaporating dish, and evaporate on a steam bath to dryness: the residue responds to *Identification* test A under [Edetate Calcium Disodium](#).
- B:** It responds to *Identification* test B under [Edetate Calcium Disodium](#).

**BACTERIAL ENDOTOXINS TEST (85)**—It contains not more than 0.01 USP Endotoxin Unit per mg of edetate calcium disodium.

**pH (791)**: between 6.5 and 8.0.

**PARTICULATE MATTER IN INJECTIONS (788)**: meets the requirements for small-volume injections.

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

**Assay**—Dilute an accurately measured volume of Injection, equivalent to about 1 g of edetate calcium disodium with water to about 75 mL. Add 25 mL of 1 N acetic acid and 1 mL of diphenylcarbazone TS, mix, and titrate slowly with 0.1 M mercuric nitrate VS to the appearance of the first purplish color. Perform a blank determination, and make any necessary correction. Each mL of 0.1 M mercuric nitrate is equivalent to 37.43 mg of  $C_{10}H_{12}CaN_2Na_2O_8$ .

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

Topic/Question	Contact	Expert Committee
EDETATE CALCIUM DISODIUM INJECTION	<a href="#">Documentary Standards Support</a>	SM32020 Small Molecules 3

**Chromatographic Database Information:** [Chromatographic Database](#)

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