Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jul-2024
Document Type: USP Monographs
DocId: GUID-6E506E49-9EAA-4663-933B-D40EC072742A_3_en-US
DOI: https://doi.org/10.31003/USPNF_M12136_03_01
DOI Ref: tqf8c

Edetate Disodium Compounded Ophthalmic Solution

Change to read:

DEFINITION

Edetate Disodium Compounded Ophthalmic Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of edetate disodium ($C_{10}H_{14}N_2Na_2O_8$).

Prepare Edetate Disodium Compounded Ophthalmic Solution 10 mg/mL (1%) to 40 mg/mL (4%) as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Ophthalmic Solution 10 mg/mL (1%)	
Edetate Disodium (as Edetate Disodium Dihydrate)	0.1 g (0.111 g)
Sodium Chloride	0.07 g
Sodium Hydroxide Solution (1 N)	To adjust pH to 6.1–7.1
Water for Injection, a sufficient quantity to make	10 mL

Add *Edetate Disodium Dihydrate* and *Sodium Chloride* to 8 mL of *Water for Injection* and mix until dissolved. Adjust with *Sodium Hydroxide Solution* (1 N) to a pH between ▲6.1 and 7.1.▲ (ERR 1-Jul-2024) Add sufficient *Water for Injection* to bring to final volume, and mix well. Pass through a sterilizing filter of 0.22-µm pore size into a sterile single-dose ophthalmic dropper container. [NOTE—*Sodium Chloride* is added to the formulation to render it isotonic.]

Ophthalmic Solution 40 mg/mL (4%)	
Edetate Disodium (as Edetate Disodium Dihydrate)	0.4 g (0.444 g)
Sodium Hydroxide Solution (1 N)	To adjust pH to 6.1–7.1
Water for Injection, a sufficient quantity to make	10 mL

Add *Edetate Disodium Dihydrate* to 8 mL of *Water for Injection* and mix until dissolved. Adjust with *Sodium Hydroxide Solution* (1 N) to a pH between ▲6.1 and 7.1.▲ (ERR 1-Jul-2024) Add sufficient *Water for Injection* to bring to final volume, and mix well. Pass through a sterilizing filter of 0.22-µm pore size into a sterile single-dose ophthalmic dropper container.

ASSAY

• **PROCEDURE**

Solution A: Dissolve 10 mg of cupric sulfate in 1 L of water. Add 15 mL of tetrabutyl ammonium hydroxide and 20 mL of tetrahydrofuran. Adjust with phosphoric acid to a pH of 4.

Mobile phase: Methanol and *Solution A* (15:85)

Standard solution: 0.2 mg/mL of edetate disodium prepared from USP Edetate Disodium RS in water

Sample solution: Transfer a volume of Ophthalmic Solution equivalent to 20 mg of edetate disodium into a 100-mL volumetric flask, and dilute with water to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Column temperature: 40°

Flow rate: 2 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[NOTE—Edetate disodium may covalently bind the column packing material and may cause retention time to range between 15 and 20 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of edetate disodium ($C_{10}H_{14}N_2Na_2O_8$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Edetate Disodium RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of edetate disodium in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 6.1–7.1
- **STERILITY TESTS** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in a sterile plastic ophthalmic single-unit container for use in one patient only. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** In the absence of passing a sterility test, the beyond-use dates in *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩ apply. After successful completion of sterility testing, NMT 60 days after the day on which it was compounded when stored at controlled room temperature or in a refrigerator.
- **LABELING:** Label it to state the *Beyond-Use Date*. Label it to indicate that it is for ophthalmic use only.
- **USP REFERENCE STANDARDS** ⟨11⟩

  USP Edetate Disodium RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
EDETATE DISODIUM COMPOUNDED OPHTHALMIC SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 44(4)

Current DocID: GUID-6E506E49-9EAA-4663-933B-D40EC072742A_3_en-US

DOI: https://doi.org/10.31003/USPNF_M12136_03_01

DOI ref: tqf8c