



Edition: BP 2025 (Ph. Eur. 11.6 update)

Trisodium Edetate Infusion

[General Notices](#)

Trisodium Edetate Injection; Trisodium Edetate Intravenous Infusion

DEFINITION

Trisodium Edetate Infusion is a sterile solution containing trisodium edetate. It is prepared immediately by diluting Trisodium Edetate Sterile Concentrate with a suitable diluent in accordance with the manufacturer's instructions.

The infusion complies with the requirements stated under Parenteral Preparations and with the following requirements.

LABELLING

The strength is stated as the amount of trisodium edetate in a suitable dose-volume.

TRISODIUM EDETATE STERILE CONCENTRATE

DEFINITION

Trisodium Edetate Sterile Concentrate is a sterile solution in Water for Injections containing 20% w/v of trisodium edetate prepared by the interaction of Disodium Edetate and Sodium Hydroxide.

The concentrate complies with the requirements for Concentrates for Injections or Infusions stated under Parenteral Preparations and with the following requirements.

Content of trisodium edetate, $C_{10}H_{13}N_2Na_3O_8$

19.0 to 21.0% w/v.

CHARACTERISTICS

A colourless solution.

IDENTIFICATION

- Dilute 2.5 mL with 7.5 mL of [water](#) and add 0.5 mL of a 10% w/v solution of [calcium chloride](#); make alkaline to [litmus paper](#) with 5M [ammonia](#) and add 5 mL of a 2.5% w/v solution of [ammonium oxalate](#). No precipitate is produced.
- Dilute 10 mL with 15 mL of [water](#), add 2 mL of a 10% w/v solution of [lead\(II\) nitrate](#), shake and add 5 mL of [dilute potassium iodide solution](#); no yellow precipitate is produced. Make alkaline to [litmus paper](#) with 5M [ammonia](#) and add 5 mL of a 2.5% w/v solution of [ammonium oxalate](#); no precipitate is produced.
- Evaporate to dryness and ignite. The residue yields the reactions characteristic of [sodium salts](#), [Appendix VI](#).

TESTS

Acidity or alkalinity

pH, 7.0 to 8.0, [Appendix V L](#).

Bacterial endotoxins

Carry out the [test for bacterial endotoxins, Appendix XIV C](#). If necessary dilute the infusion with [water BET](#) to give a solution containing 10 mg per mL (solution A). The endotoxin limit concentration of solution A is less than 1.4 IU per mL.

ASSAY

Dilute 10 mL to 100 mL with [water](#) and use this solution to titrate a mixture of 25 mL of [0.05M magnesium sulfate VS](#) and 10 mL of [ammonia buffer pH 10.9](#) using [mordant black 11 mixed triturate](#) as indicator. Each mL of [0.05M magnesium sulfate VS](#) is equivalent to 17.91 mg of trisodium edetate, $C_{10}H_{13}N_2Na_3O_8$.

STORAGE

Trisodium Edetate Sterile Concentrate should be kept in containers made from lead-free glass.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of trisodium edetate.