## **Quality standards**

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

# Sodium Calcium Edetate Intravenous Infusion for Veterinary Use

**General Notices** 

Action and use

Chelating agent.

#### DEFINITION

Sodium Calcium Edetate Intravenous Infusion for Veterinary Use is a sterile solution of Sodium Calcium Edetate. It is prepared immediately before use by diluting Sodium Calcium Edetate Sterile Concentrate for Veterinary Use with a suitable diluent in accordance with the manufacturer's instructions.

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

#### **LABELLING**

The quantity of active ingredient is stated in terms of the equivalent amount of anhydrous sodium calcium edetate in a suitable dose-volume.

## SODIUM CALCIUM EDETATE STERILE CONCENTRATE FOR VETERINARY USE

### **DEFINITION**

Sodium Calcium Edetate Sterile Concentrate for Veterinary Use is a sterile solution of Sodium Calcium Edetate in Water for Injections containing the equivalent of 25.0% w/v of anhydrous sodium calcium edetate.

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

Content of anhydrous sodium calcium edetate,  $C_{10}H_{12}CaN_2Na_2O_8$ 

22.5 to 27.5% w/v.

## **CHARACTERISTICS**

A colourless solution.

## **IDENTIFICATION**

# https://nhathuocngocanh.com/bp

- A. Dilute 2.5 mL with 7.5 mL of <u>water</u>, make alkaline to <u>litmus paper</u> with 5M <u>ammonia</u> and add 5 mL of a 2.5% w/v solution of <u>ammonium oxalate</u>. Not more than a trace of precipitate is produced.
- B. To 10 mL add 2 mL of a 10% w/v solution of *lead(ii) nitrate*, shake and add 5 mL of <u>dilute potassium iodide solution</u>; no yellow precipitate is produced. Make alkaline to <u>litmus paper</u> with 5M <u>ammonia</u> and add 5 mL of a 2.5% w/v solution of <u>ammonium oxalate</u>; a white precipitate is produced.
- C. Evaporate to dryness and ignite. The residue yields the reactions characteristic of <u>sodium salts</u> and of <u>calcium salts</u>, <u>Appendix VI</u>.

#### **TESTS**

#### Acidity or alkalinity

pH, 6.5 to 8.0, Appendix V L.

#### **Bacterial endotoxins**

Carry out the <u>test for bacterial endotoxins</u>, <u>Appendix XIV C</u>. The endotoxin limit concentration is not more than 0.125 IU per mg of sodium calcium edetate.

#### **ASSAY**

To 2.5 mL add 90 mL of <u>water</u>, 7 g of <u>hexamine</u> and 5 mL of 2M <u>hydrochloric acid</u> and titrate with 0.05M <u>lead nitrate VS</u> using <u>xylenol orange solution</u> as indicator. Each mL of 0.05M <u>lead nitrate VS</u> is equivalent to 18.71 mg of  $C_{10}H_{12}CaN_2Na_2O_8$ .

## **STORAGE**

Sodium Calcium Edetate Sterile Concentrate for Veterinary Use should be kept in containers made from lead-free glass.