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Sodium Bromide Compounded Injection, Veterinary

DEFINITION

Sodium Bromide Compounded Injection, Veterinary contains NLT 27 mg and NMT 33 mg of Sodium Bromide (NaBr) per mL, equivalent to NLT 21.0 mg and NMT 25.6 mg of bromide (Br^-) per mL.

Prepare Sodium Bromide Compounded Injection, Veterinary as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Sodium Bromide	3.0 g
Sterile Water for Injection, *USP*, a sufficient quantity to make	100 mL

Dissolve the *Sodium Bromide* in *Sterile Water for Injection* with mixing. Sterilize by a suitable means such as sterile filtration or autoclaving.

ASSAY

• **Procedure**

TCA solution: 20% (w/v) trichloroacetic acid in water

Gold chloride solution: 5 mg/mL of gold chloride in water

Standard stock solution: Dissolve USP Sodium Bromide RS in water to obtain a solution with a nominal concentration of 20 mg/mL of bromide.

Standard solutions: Prepare four solutions of known concentrations of about 2.0, 1.0, 0.5, and 0.25 mg/mL of bromide from *Standard stock solution* and water.

Sample solution: Dilute Injection, Veterinary quantitatively with water (1:19).

Blank: Water

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: Vis

Analytical wavelength: 440 nm

System suitability

Samples: *Standard solutions* and *Blank*

Suitability requirements

Correlation coefficient: NLT 0.99, linear regression of the *Standard solutions*

Analysis

Samples: *Sample solution* and *Blank*

To 750-µL aliquots of each *Sample* add 500 µL of *TCA solution* and 250 µL of *Gold chloride solution*. Mix on a vortex mixer, and immediately read the absorbance of each *Sample*.

Calculate the concentration of bromide (Br^-), in mg/mL, in the portion of Injection, Veterinary taken:

$$\text{Result} = C \times D$$

C = concentration of the *Sample solution* (mg/mL) calculated from the standard curve

D = dilution factor of the *Sample solution* (20)

Acceptance criteria: 21.0–25.6 mg/mL of bromide (Br^-)

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.03 USP Endotoxin Units/mg of sodium bromide

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Other Requirements:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in single-dose containers, preferably of Type I glass, and store in a refrigerator.

Change to read:

• **Beyond-Use Date:** ▲In the absence of performing and completing a sterility and endotoxin test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations ⟨797⟩, 14.3 Establishing a BUD for a CSP* apply.▲ (CN 1-Nov-2023) After successful completion of sterility and endotoxin testing, NMT 180 days after the date on which it was compounded when stored in a refrigerator.

• **Labeling:** Label to state the *Beyond-Use Date*. Label to state that it is for infusion only at a rate not to exceed 150 mg of sodium bromide per kg of body weight per hour. Label to state that it is for veterinary use only.

• **USP Reference Standards ⟨11⟩**

USP Sodium Bromide RS

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

Topic/Question	Contact	Expert Committee
SODIUM BROMIDE COMPOUNDED INJECTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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