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Carboxymethylcellulose Sodium Compounded Intraperitoneal Solution, Veterinary

DEFINITION

Carboxymethylcellulose Sodium Compounded Intraperitoneal Solution, Veterinary contains NLT 80.0% and NMT 120.0% of the labeled amount of carboxymethylcellulose sodium ($C_8H_{15}NaO_8$). Prepare Carboxymethylcellulose Sodium Compounded Intraperitoneal Solution, Veterinary 10 mg/mL (1%) as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Carboxymethylcellulose Sodium[a]	5 g
Propylene Glycol	10 mL
Sterile Water for Injection, a sufficient quantity to make	500 mL

[a] High-viscosity carboxymethylcellulose sodium must be used.

Wet the *Carboxymethylcellulose Sodium* with the *Propylene Glycol* in a suitable container. Place 450 mL of *Sterile Water for Injection* in a calibrated container on a hot plate with a stir bar and heat to NMT 100° (do not allow to boil). Add the *Carboxymethylcellulose Sodium* and *Propylene Glycol* mixture to heated *Sterile Water for Injection* by pouring along the outer edge of the water level and not directly into the vortex created by the stir bar to avoid clumping. Continue heating and stirring to facilitate complete dissolution of the *Carboxymethylcellulose Sodium*. [Note—This may take 30–60 min to completely dissolve.] Once completely dissolved, bring to final volume with *Sterile Water for Injection*. Transfer to a 500-mL high-density polyethylene (HDPE) plastic single-dose container suitable for autoclaving and crimp seals tightly before autoclaving. Sterilize by autoclaving.

ASSAY

• **Procedure**

Mobile phase: 0.052% (v/v) methanesulfonic acid

Diluent: 0.52% (v/v) methanesulfonic acid

Standard solution: 0.03 mg/mL of sodium prepared by mixing USP Sodium Chloride RS and water

Sample solution: Transfer 1 mL of Intraperitoneal Solution, Veterinary into a 25-mL volumetric flask and dilute with *Diluent* to volume. [Note—The *Standard solution* and *Sample solution* are stable for only 24 h.]

Chromatographic system

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

Mode: LC

Detector: Conductivity

Column: 4.0-mm × 25-cm; packing L77

Column temperature: 15°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for sodium is about 3.3 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 sodium (Na) in the portion of Intraperitoneal Solution, Veterinary:

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

r_U = peak response of sodium from the *Sample solution*

r_S = peak response of sodium from the *Standard solution*

C_S = concentration of sodium in the *Standard solution* (mg/mL)

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

Acceptance criteria: 80.0%–120.0%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 6.7–7.7
- **Sterility Tests** ⟨71⟩*, Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium***:** Meets the requirements
- **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 1.75 USP Endotoxin Units/mL of carboxymethylcellulose sodium
- **Viscosity—Rotational Methods** ⟨912⟩

  Sample: 5 mL of Intraperitoneal Solution, Veterinary

  Analysis: Determine at 25° by using a rotational viscometer.

  Acceptance criteria: Between 600 and 1,200 centipoises

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in 500-mL autoclavable HDPE plastic containers. Store at controlled room temperature.
- **Labeling:** Label it to indicate to state the *Beyond-Use Date*.

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 60 days after the day on which it was compounded when stored at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

  USP Sodium Chloride RS

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

Topic/Question	Contact	Expert Committee
CARBOXYMETHYLCELLULOSE SODIUM COMPOUNDED INTRAPERITONEAL SOLUTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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