Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-558C6D8E-1C2E-4C7D-980B-13055DBA452A_2_en-US
DOI: https://doi.org/10.31003/USPNF_M19024_02_01
DOI Ref: fz1d7

Cloxacillin Sodium Intramammary Infusion

DEFINITION

Cloxacillin Sodium Intramammary Infusion is a suspension of Cloxacillin Sodium in a suitable natural or chemically modified vegetable oil vehicle with a suitable dispersing agent. It has a potency equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of cloxacillin ($C_{19}H_{18}ClN_3O_5S$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Transfer a quantity of Intramammary Infusion, equivalent to 500 mg of cloxacillin, to a 50-mL centrifuge tube. Add 15 mL of isooctane, mix, and centrifuge. Decant and discard the isooctane. Wash the residue with two 15-mL portions of isooctane and two 15-mL portions of ethyl ether, and discard the washings. Dry the residue in a current of air.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

(See *Antibiotics—Microbial Assays* ⟨81⟩.)

Sample solution: Expel the contents of 1 syringe of Intramammary Infusion into a high-speed glass blender jar containing 499.0 mL of *Buffer B.1* and 1.0 mL of polysorbate 80, and blend for 3–5 min. Allow to stand for 10 min, and dilute a measured volume of the aqueous phase with *Buffer B.1* to obtain a test dilution having a concentration assumed to be equal to the median dose level of the Standard.

Analysis: Proceed as directed in the chapter for Cloxacillin.

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

• **Sterility Tests ⟨71⟩:** Where the label states that it is sterile, it meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium*, except use Fluid Thioglycollate Medium containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the cloxacillin in each tube, use Soybean–Casein Digest Medium containing polysorbate 80 solution (1 in 200) and an amount of sterile penicillinase sufficient to inactivate the cloxacillin in each tube, and shake the tubes once daily.

• **Water Determination, *Method I*⟨921⟩**

Analysis: Use 20 mL of a mixture of toluene and methanol (7:3) in place of methanol in the titration vessel.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in disposable syringes that are well-closed containers, except that where the Intramammary Infusion is labeled as sterile, the individual syringes or cartons are sealed and tamper-proof so that sterility is assured at time of use.

• **Labeling:** Label it to indicate that it is for veterinary use only. Intramammary Infusion that is sterile may be so labeled.

• **USP Reference Standards ⟨11⟩**

USP Cloxacillin Sodium RS

Topic/Question	Contact	Expert Committee
CLOXACILLIN SODIUM INTRAMAMMARY INFUSION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-558C6D8E-1C2E-4C7D-980B-13055DBA452A_2_en-US
DOI: https://doi.org/10.31003/USPNF_M19024_02_01
DOI ref: fz1d7