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Heparin Lock Flush Solution

DEFINITION

Heparin Lock Flush Solution is a sterile preparation of Heparin Sodium Injection with sufficient Sodium Chloride to make it isotonic with blood. Heparin sodium used in the manufacture of Heparin Lock Flush Solution complies with the compendial requirements stated in the Heparin Sodium monograph. The potency of Heparin Lock Flush Solution is NLT 90.0% and NMT 120.0% of the potency stated on the label in terms of USP Heparin Units. It contains NMT 1.00% of sodium chloride (NaCl). It may contain a suitable preservative.

ASSAY

• **Anti-Factor IIa Potency**

(See *Anti-Factor Xa and Anti-Factor IIa Assays for Unfractionated and Low Molecular Weight Heparins ⟨208⟩*, *Anti-Factor Xa and Anti-Factor IIa Assays for Unfractionated Heparin*, *Anti-Factor IIa Activity for Unfractionated Heparin*.)

Acceptance criteria: 90.0%–120.0%

• **Sodium Chloride**

Sample solution: Pipet 10 mL of Solution into a suitable container, dilute with water to about 150 mL, and add 1.5 mL of potassium chromate TS.

Analysis: Titrate with 0.1 N silver nitrate. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of sodium chloride (NaCl).

Acceptance criteria: NMT 1.00%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.5 USP Endotoxin Units/mL

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **pH ⟨791⟩:** 5.0–7.5

• **Other Requirements:** It meets the requirements for *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose, prefilled syringes or containers; in multiple-dose containers, preferably of Type I glass; or in suitable plastic containers.

Change to read:

• **Labeling ⟨7⟩**, *Labels and Labeling for Injectable Products*, ▲*Quantity and Total Volume for Injectable Drug Products Packaged in Single- and Multiple-Dose Containers*▲ (CN-1-May-2019)**:** ▲For injectable drug products greater than 1 mL, whether packaged in single- or multiple-dose containers, the quantity per total volume should be the primary and prominent expression on the principal display panel of the label, followed in close proximity by quantity per milliliter enclosed by parentheses. For containers that hold a volume of less than 1 mL, the quantity per fraction of a milliliter should be the only expression of strength. For containers that hold a volume equal to 1 mL, the strength should be expressed as quantity/mL, not quantity/1 mL.▲ (USP 1-May-2019) For further information, see the entirety of *Injections and Implanted Drug Products ⟨1⟩*. Label it to indicate the organ and species from which the heparin sodium is derived. The label also states that the Solution is intended for maintenance of patency of intravenous injection devices only, and that it is not to be used for anticoagulant therapy. The label also states that in the case of the Solution having a concentration of 10 USP Heparin Units/mL it may alter, and that in the case of higher concentrations it will alter, the results of the blood coagulation tests.

Topic/Question	Contact	Expert Committee
HEPARIN LOCK FLUSH SOLUTION	Jennifer Tong Sun Senior Scientist II	BIO32020 Biologics Monographs 3 - Complex Biologics and Vaccines

Chromatographic Database Information: Chromatographic Database

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