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Heparin Sodium Injection

DEFINITION

Heparin Sodium Injection is a sterile solution of Heparin Sodium in Water for Injection. Heparin sodium used in the manufacture of Heparin Sodium Injection complies with the compendial requirements stated in the Heparin Sodium monograph. Heparin Sodium Injection exhibits NLT 90.0% and NMT 110.0% of the potency stated on the label in terms of USP Heparin Units per milliliter.

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%–110.0%

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST (85):** NMT 0.03 USP Endotoxin Units/USP Heparin Unit
- **PARTICULATE MATTER IN INJECTIONS (788):** Meets the requirements for small-volume injections
- **pH (791):** 5.0–7.5
- **OTHER REQUIREMENTS:** Meets the requirements for [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, and store between 20° and 25° at controlled room temperature.
- 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 tissue and the animal species from which it is derived.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

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