

Heparin Lock Flush Solution

» Heparin Lock Flush Solution is a sterile preparation of Heparin Sodium Injection with sufficient Sodium Chloride to make it isotonic with blood. Its potency is not less than 90.0 percent and not more than 120.0 percent of the potency stated on the label in terms of USP Heparin Units. It contains not more than 1.00 percent of sodium chloride (NaCl). It may contain a suitable preservative.

Packaging and storage—Preserve in single-dose prefilled syringes or containers, or in multiple-dose containers, preferably of Type I glass.

Labeling—Label it to indicate the volume of the total contents, and to indicate the potency in terms of USP Heparin Units only per mL, except that single unit-dose containers may be labeled additionally to indicate the single unit-dose volume and the total number of USP Heparin Units in the contents. Where it is labeled with total content, the label states clearly that the entire contents are to be used or, if not, any remaining portion is to be discarded. Label it to indicate the organ and species from which the heparin sodium is derived. The label states also 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 states also that in the case of Solution having a concentration of 10 USP Heparin Units per mL, it may alter, and that in the case of higher concentrations it will alter, the results of blood coagulation tests.

Change to read:

USP Reference standards <11>—*USP Endotoxin RS. USP Heparin Sodium for Assays* (RB 1-Oct-2009) *RS*.

Bacterial endotoxins <85>—It contains not more than 0.5 USP Endotoxin Unit per mL.

pH <791>: between 5.0 and 7.5.

Particulate matter <788>: meets the requirements for small-volume injections.

Other requirements—It meets the requirements under *Injections* <1>.

Assay for heparin sodium—Proceed as directed in the *Assay* under *Heparin Sodium Injection*, substituting Heparin Lock Flush Solution for the Injection.

Assay for sodium chloride—Pipet 10 mL of Solution into a suitable container, dilute with water to about 150 mL, add 1.5 mL of potassium chromate TS, and titrate with 0.1 N silver nitrate. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.