

Heparin Calcium Injection

Change to read:

» Heparin Calcium Injection is a sterile solution of Heparin Calcium in Water for Injection. It exhibits a potency not less than 90.0 percent and not more than 110.0 percent of the potency stated on the label in terms of USP Heparin Units per mL.

• (RB 1-Oct-2009)

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type 1 glass, and store at a temperature below 40°, preferably at room temperature.

Labeling—Label it to indicate the volume of the total contents and the potency in terms of USP Heparin Units only per mL, except that single-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 also that the entire contents are to be used

or, if not, any remaining portion is to be discarded. Label it to indicate also the tissue and the animal species from which it is derived.

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 0.03 USP Endotoxin Unit per USP Heparin Unit.

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>.

Change to read:

Assay—Proceed as directed in the *Assay* under *Heparin Sodium*, substituting Heparin Calcium Injection for the solution of heparin sodium prepared as directed for *Sample solutions*• (RB 1-Oct-2009)