Anticoagulant Heparin Solution

» Anticoagulant Heparin Solution is a sterile solution of Heparin Sodium in Sodium Chloride Injection. Its potency is 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. It contains not less than 0.85 percent and not more than 0.95 percent of sodium chloride (NaCl). It may be buffered. It contains no antimicrobial agents.

Heparin Sodium	<u>75,000 Units</u>
Sodium Chloride Injection, a	
sufficient quantity to make	1000 mL

Add the Heparin Sodium, in solid form or in solution, to the Sodium Chloride Injection, mix, filter if necessary, and sterilize.

Packaging and storage-Preserve in single-dose containers, of colorless, transparent, Type I or Type II glass, or of a suitable

plastic material (see Transfusion and Infusion Assemblies and Simi*lar Medical Devices* (161)).

Labeling—Label it in terms of USP Heparin Units, and to indicate the number of mL of Solution required per 100 mL of whole blood.

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 2.5 USP Endotoxin Units per mL.

pH $\langle 791 \rangle$: between 5.0 and 7.5.

Other requirements—It meets the requirements under Injections

Assay for heparin sodium-Proceed as directed in the Assay under Heparin Sodium Injection, substituting Anticoagulant Heparin Solution for the Injection.

Assay for sodium chloride-Pipet 10 mL of Solution into a suitable container, add 2 mL of potassium chromate TS, and titrate with 0.1 N silver nitrate VS. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of NaCl.