Edition: BP 2025 (Ph. Eur. 11.6 update)

Heparin Flush Solution

General Notices

Action and use

Maintenance of patency of intravenous devices.

DEFINITION

Heparin Flush is a sterile solution of Heparin Injection, containing the sodium salt only, with sufficient Sodium Chloride to make it isotonic with blood.

PRODUCTION

The final product is produced from the drug substance where the methods of manufacturing are designed to ensure freedom from contamination by over-sulfated glycosaminoglycans.

The solution complies with the requirements stated under Parenteral Preparations and with the following requirements.

Potency

The estimated potency is not less than 90% and not more than 111% of the stated potency.

CHARACTERISTICS

A colourless or straw-coloured liquid, free from turbidity and from matter that deposits on standing.

IDENTIFICATION

A. It complies with the requirements described under Assay.
B. Carry out the assay of anti-factor Xa activity of heparin, Appendix XIV J B2. The ratio of anti-factor Xa activity to anti-factor IIa activity determined as described under Assay ranges between 0.9 and 1.1.

TESTS

Acidity or alkalinity

pH, 5.5 to 8.0, Appendix V L.

Sodium Chloride

Titrate a volume containing 6.7 % v/v of the solution with *0.1M silver nitrate VS* using *potassium chromate solution* as indicator. Each mL of *0.1M silver nitrate VS* is equivalent to 5.844 mg of NaCl. The amount of NaCl is not less than 0.85% and not more than 0.95%.

ASSAY

Carry out the assay of anti-factor IIa activity of heparin, Appendix XIV J B2. The fiducial limits of error are not less than 80% and not more than 125% of the stated potency.

STORAGE

Heparin Flush Solution should be kept in a sealed ampoule or a stoppered vial.

LABELLING

The strength is stated as the number of IU (Units) in a suitable dose-volume except that for multi-dose containers the strength is stated as the number of IU (Units) per mL.

The label states (1) when no antimicrobial preservative is present that the preparation contains no antimicrobial preservative and that any portion of the contents not used at once should be discarded; (2) that the preparation is intended for the maintenance of patency of intravenous injection devices only and is not to be used for anticoagulant therapy.