PREKALLIKREIN ACTIVATOR IN ALBUMIN BRP batch 5

Intended use

This leaflet supplements the currently valid European Pharmacopoeia monograph(s) and/or general chapter(s) describing the suitable use of this Reference Standard.

Further information about the Reference Standards is available in the on-line catalogue currently at http://crs.edqm.eu (such as, batch validity statement and safety data sheet).

Instruction

Prekallikrein activator in Albumin BRP batch 5 is intended for use as the reference preparation for the prekallikrein activator assay according to the Ph. Eur. General Method Chapter 2.6.15. It consists of a freeze-dried preparation of albumin in vials with a declared content of

38 IU / vial

Storage

Store vials unopened at -20°C ± 5°C. Do not store at lower temperature to avoid deterioration of the rubber stoppers.

USE

• Allow the vial and contents to reach room temperature.
• Tap gently to collect material at the bottom.
• Using an appropriate syringe, reconstitute the reference preparation by injecting a suitable volume of solvent (for example either water or phosphate albumin buffer).
• Complete dissolution of the plug can take up to 30 minutes.
• Mix gently to ensure complete dissolution. Transfer the solution to an appropriate volumetric flask and rinse the vials, adding the rinsing to the flask; dilute so as to obtain the required concentration.

• Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

Caution

Prekallikrein activator in albumin BRP batch 5 is not appropriate for administration to humans. This preparation must be handled according to the appropriate QA system for biological testing laboratories. Please refer to the corresponding safety data sheet, which can be downloaded from the Internet web site of the EDQM (http://www.edqm.eu) or is delivered upon request.

LITERATURE