Human coagulation factor IX BRP batch 2 consists of a freeze-dried preparation in ampoules. It is intended for use in the assay of human coagulation factor IX according to the Ph. Eur. General Chapter 2.7.11. The declared potency is 7.9 IU / ampoule.

The same material has been established as the WHO 4th International Standard (07/182) and US FDA/CBER standard for human coagulation factor IX concentrate.

**STORAGE**

Store ampoules unopened at -20°C ± 5°C.

**USE**

- Allow the ampoule and contents to reach room temperature.
- Tap gently to collect material at the bottom.
- Carefully open the ampoule.
- Using an appropriate syringe, reconstitute the reference preparation by injecting 1 mL of solvent (for example 1.0 mL of distilled water).
- Allow ampoule to stand for 10 minutes at room temperature. Swirl gently to ensure complete dissolution. The obtained solution has a potency of 7.9 IU/mL.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

**CAUTION**

Human coagulation factor IX concentrate BRP batch 2 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 website of the EDQM (http://www.edqm.eu) or is delivered upon request.

**LITERATURE**


Pharmeuropa Bio is an open-access publication that is freely available on the EDQM website (www.edqm.eu).

**SIGNATURE**

This document is electronically signed by:

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