1. **Identification**

   Catalogue code: H0920500  
   Unit Quantity *: ca 30 mg

   *The total amount of material (active substance and excipients, if any) which has been filled in each vial or ampoule, for customs purposes. Circa (“ca”) quantity is not to be considered accurate from an analytical point of view.

2. **Scientific Information**

   **2.1 Intended use**

   HUMAN COAGULATION FACTOR IX CONCENTRATE BRP batch 3 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

   10.5 IU / ampoule

   The same material has been established as the WHO 5th International Standard (14/148) for Blood Coagulation Factor IX, concentrate.

   **2.2 Instructions for 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 calibrated pipette, reconstitute the reference preparation with 1.0 mL of distilled or deionised water. The end-use should not use solvent other than water as other solvents may contain excipients that may impact the fitness for use of this reference preparation.
   - Allow ampoule to stand for 10 minutes at room temperature. Swirl gently to ensure complete dissolution. The obtained solution has a potency of 10.5 IU/mL.
   - Reconstituted material should be stored on melted ice and use within 4 hour. Do not freeze or store for subsequent use.

   **2.3 The Uncertainty of the assigned value**

   According to ISO Guide 34 and ISO Guide 35, for this Pharmacopoeial standard the uncertainty of the assigned value is not stated since it is considered to be negligible in relation to the defined limits of the method-specific assays for which the reference standard is used. Please also refer to Ph. Eur. chapter 5.12.

   **2.4 Validity**

   A statement on the validity of the batch (Batch Validity Statement) can be printed directly from the EDQM website (Reference Standards Database).

3. **Storage conditions**

   Store the original container at -20°C ± 5°C. Once opened, the vial/ampoule is for immediate use and the stability of the contents of opened vials or ampoules cannot be guaranteed.
4. **Safety**
Biological preparation for laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure.

5. **Shipping conditions**
Please check shipping conditions on the EDQM website (Reference Standards Database).

6. **Additional information**

Pharmeur Bio & Sci Notes is an open-access publication that is freely available on the EDQM website (www.edqm.eu).
EDQM website (Knowledge Database, Reference Standards Database, HelpDesk).

7. **Citation**
Users shall ensure that any reference made to an EDQM Reference Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the exact name, and catalogue code of the Reference Standard and the exact name and address of EDQM as given on the first page of this information leaflet.

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9. **Adoption**
The present reference standard has been officially adopted by the European Pharmacopoeia Commission.

10. **Signature**
This document is electronically signed by:

    **Dr Pierre Leveau**
    Head of the Quality, Safety and Environment Division