1. **Identification**

Catalogue code: H0185000

Unit Quantity *: ca 1 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**

**Low-Molecular-Mass Heparin for assay Biological Reference Preparation batch 9** is a freeze-dried preparation of heparin which has an assigned activity of:

- Anti-IIa activity: 34 IU per vial
- Anti-Xa activity: 102 IU per vial

It is intended for use for anti-Xa and anti-IIa assays as described in the Ph. Eur. monograph on Heparins, low-molecular-mass (0828).

2.2 **Instructions for use**

- Allow the vials and contents to reach room temperature.
- Reconstitute the vial contents with 1 mL distilled water at room temperature, ensuring full reconstitution by gentle stirring for about 15 minutes.
- Use as soon as possible after reconstitution.

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 +5°C ± 3°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**
   Pharmeuropa 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