1. **Identification**
   Catalogue code: H0190000

   *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**
   Heparin low-molecular-mass for calibration CRS is intended to be used for use in the calibration of the system used in the identification and molecular mass distribution procedure of Low-Molecular-Mass (LMM) heparins (0828). The CRS is presented in vials with a content of 23 mg and an assigned number average relative molecular mass (Mna) of

   3 800

   2.2 **Instructions for use**
   Allow the vial and contents to reach room temperature.
   Tap vial gently to collect material at the bottom.
   Open carefully the vial and weigh out the amount of substance. Dissolve it in the required volume of solvent and proceed as indicated in the appropriate test in the monograph.
   Mix gently to ensure complete dissolution.

   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.

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

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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.

8. Warranties, Liability and disputes
a) Warranties
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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