

## Information Leaflet Ph. Eur. Reference Standard

### HEPARIN SODIUM BRP batch 4

#### 1. **Identification**

Catalogue code: **H0200000**

#### 2. **Scientific Information**

##### **2.1 Intended use**

Heparin sodium BRP batch 4 consists of a liquid heparin sodium preparation in ampoules. It was established for use in the assay of unfractionated heparin according to the Ph. Eur. General text 2.7.5. with assigned contents of 985 IU/mL for anti-IIa and 995 IU/mL for anti-Xa activities.

When used in the test for heparin in human antithrombin III according to the Ph. Eur. Monograph 0878, Heparin sodium BRP has an assigned content of 1035 IU/mL for sheep plasma clotting assay.

Heparin sodium BRP batch 4 may also be used in the assay of protamine sulfate according to the prescriptions of the Ph. Eur. Monograph 0569.

##### **2.2 Instructions for use**

- Open the ampoule by mechanical action, taking care that no glass falls into the ampoule.
- Extract the desired volume of solution and use as soon as possible after opening.

##### **2.3 Uncertainty of the assigned value, when applicable**

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**

Ph. Eur. Reference Standards are periodically tested to ensure their continuous fitness for purpose. For each valid Ph. Eur. Reference Standards, a Batch Validity Statement at the time of use can be downloaded and printed from the EDQM website (Reference Standards Database).

#### 3. **Storage conditions**

Store the original container at  $+5^{\circ}\text{C} \pm 3^{\circ}\text{C}$ , protected from light upon receipt. 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**

V. Lièvre, D. Le Tallec, E. Terao. Collaborative study for the establishment of the Heparin sodium Biological Reference Preparation batch 4. *Pharmeur Bio Sci Notes* 2021:167-183.

Pharmeur Bio & Sci Notes is an open-access publication that is freely available on the EDQM website ([www.edqm.eu](http://www.edqm.eu)).

Further information available on 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, Liabilities and responsibility**

### *- Safety*

In the event of any safety concerns, please read carefully the safety data sheets or safety data statements available for each product. It is for Purchasers to determine independently the risks associated with the items and to take appropriate safety measures, including the provision of appropriate information, equipment and training of those persons coming into contact with the item.

### *- Warranties*

Except for the use of Reference Standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and by professionals with the necessary technical skills and at their own discretion and risk, the EDQM makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for any particular purpose except that as described above.

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### *- Limitation of Liability*

In no event shall the EDQM be liable for any damages due to the use of items, included, but not limited to loss of business, loss of profit, loss of use, loss of opportunity, costs of procurement of substitute goods, services or systems or for any indirect, special, incidental, punitive or consequential damages, however caused and, whether in contract, tort or under any other theory of liability, whether or not the Purchaser has been advised of the possibility of such damages or costs.

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## **9. Arbitration & Applicable Law**

The aim of the EDQM is to settle any disputes amicably in the framework of its Terms and Conditions. In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the EDQM and the Purchaser as regards the application of these General Terms shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.

This transaction shall be governed by the Council of Europe's relevant regulatory framework, complemented, where necessary, by French national substantive law.

## **10. Adoption**

The suitability for intended use has been officially adopted by the European Pharmacopoeia Commission.

## **11. Signature**

This document is approved by:

**Head of the Quality and Risk Management Section**

**Name: Caroline OFFERLE**

**Date: 17/01/2022**