BRP INFORMATION LEAFLET Ph. Eur. Reference Standard

Erythropoietin BRP batch 5

1. Identification
Catalogue code: E1515000  
Unit Quantity *: ca 6 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

Erythropoietin BRP batch 5 is intended for use as the reference preparation for the in vivo bioassays as prescribed in the Assay section of the European Pharmacopoeia monograph Erythropoietin concentrated solution (1316). It consists of a freeze-dried preparation of erythropoietin (EPO)-alpha and EPO-beta in equal amounts (W/W) in ampoules containing 2000 IU per ampoule.

Please note that the BRP contains human serum albumin as a carrier.

2.2 Instructions for use

- Allow the ampoule and contents to reach room temperature.
- Tap gently to collect material at the bottom.
- Reconstitute the reference preparation with an appropriate volume of sterile solvent (for example water R or phosphate albumin buffer). Make sure that the contents remain sterile.
- Use as soon as possible after reconstitution. 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 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