1. Identification
Catalogue code: Y0001725    Unit Quantity*: ca 0.1 mg

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

2. Scientific Information

2.1 Intended use
Erythropoietin for physicochemical tests CRS batch 1 consists of a freeze-dried preparation of erythropoietin-alpha and -beta in equal amounts (W/W) in vials with a content of about

100 µg of erythropoietin per vial.

It is intended for use as the reference preparation for the following tests as prescribed in the European Pharmacopoeia monograph Erythropoietin concentrated solution (1316):

- Capillary zone electrophoresis
- Polyacrylamide gel electrophoresis and immunoblotting
- Peptide mapping

2.2 Instructions for use

- Allow the vial and contents to reach room temperature.
- Tap gently to collect material at the bottom.
- Reconstitute the reference preparation with an appropriate volume of solvent (water R or as requested in the monograph)
- Mix gently until complete dissolution. Transfer the solution to an appropriate container and rinse the vial, adding the rinsing to the container. Dilute so as to obtain the required concentration, if applicable.
- Use as soon as possible after reconstitution. Do not freeze or store for subsequent use.

2.3 Analytical information related to intended use

Capillary zone electrophoresis: an example of an electropherogram obtained with Erythropoietin for physicochemical tests CRS batch 1 is shown in appendix.

Peptide mapping: an example of a chromatogram obtained with Erythropoietin for physicochemical tests CRS batch 1 is shown in appendix.
2.4 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.

2.5 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. Do not store at lower temperatures to avoid deterioration of the rubber stopper. 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.

8. Warranties, Liability and disputes
a) Warranties
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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.

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
APPENDIX

Capillary zone electrophoresis

Peptide mapping