1. **Identification**

   Catalogue code: H0900000  
   Unit Quantity*: ca 50 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**

   This leaflet supplements the currently valid European Pharmacopoeia monograph(s) and/or general chapter(s) describing the suitable use of this Reference Standard. Further information about the Reference Standards is available in the on-line catalogue currently at [http://crs.edqm.eu](http://crs.edqm.eu) (such as, batch validity statement and SDS).

   **2.2 Instructions for use**

   93.8% to 98.3% of the total protein is in the main band (albumin).

   This substance has been freeze-dried and is known to be hygroscopic. Tap the container gently to collect the material at the bottom. Reconstitute the contents by injecting 1 mL of purified water. Mix gently to ensure complete dissolution. When necessary transfer the solution to an appropriate volumetric flask and dilute to the required concentration.

   **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.

3. **Validity**

   A statement on the validity of the batch (Batch Validity Statement) can be printed directly from the EDQM website (Reference Standards Database).

4. **Storage conditions**

   Keep vials unopened at +5°C ± 3°C.  
   After reconstitution, the resulting solution can be kept for up to 14 days at +5°C ± 3°C.

5. **Safety**

   Biological preparation for laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure.

6. **Shipping conditions**

   Please check shipping conditions on the EDQM website (Reference Standards Database).
7. **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).

8. **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.

9. **Warranties, Liability and disputes**

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10. **Adoption**
The present reference standard has been officially adopted by the European Pharmacopoeia Commission.

11. **Signature**
This document is electronically signed by:

    **Dr Pierre Leveau**
    **Head of the Quality, Safety and Environment Division**