The 4th International standard for Streptomycin

1. **Identification**
   
   Catalogue code: ISA_55821  
   Unit Quantity: ca 100 mg

2. **Scientific Information**

   2.1 **Intended use**
   
   The 4th International Standard for Streptomycin is supplied exclusively for use as primary standard for the establishment of National/Regional secondary standards for microbiological assay of antibiotics and for no other purpose. As secondary standard, please use the Ph. Eur. reference standard (Streptomycin sulfate CRS S1400000) established against the ISA.

   2.2 **Analytical information related to intended use**
   
   The standard was calibrated in an international collaborative study against the 3rd ISA for Streptomycin. The assigned potency is 76 000 IU per vial for the 4th IS for Streptomycin.

   2.3 **Stability**
   
   Accelerated degradation studies have shown that the standard is stable when stored in unopened vials at -20°C, with no predictable loss of potency over a period of 36 months. It is therefore recommended that the unopened vials are stored at -20°C or below until immediately before use.

   2.4 **Instructions for use**
   
   Allow the closed container to equilibrate at ambient temperature before breaching to avoid uptake of moisture. 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 a suitable volume of the solvent. Mix gently to ensure complete dissolution. When necessary transfer the solution to an appropriate volumetric flask and dilute to the required concentration. Once the container has been breached, stability of the contents cannot be guaranteed. It is for immediate use.

3. **Safety**

   **CLP Hazard Classification**
   
   For laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure.

   **Danger**
   
   For substances subject to GHS classification, the corresponding safety data sheet can be accessed via the EDQM website (WHO International Standards for Antibiotics Database) or is available upon request from the EDQM (Helpdesk-FAQ section).
4. **Shipping conditions**

Please check shipping conditions on the EDQM website (WHO International Standards for Antibiotics Database).

5. **Liability and disputes**

   a) **Liability**

   The Council of Europe accordingly 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. The product must be handled by professional persons having technical skill and at their own discretion and risk. It is for the purchasers of any such item who are responsible for persons in a workplace to determine independently the risks associated with the item according to the conditions of use and to take appropriate safety measures, including provision of appropriate information to persons working with the substance. Any liability of the Council of Europe for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted by law; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

   b) **Disputes**

   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 Council of Europe (EDQM) and the customer as regards the application of this contract 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.

6. **Citation**

In all publications (or data sheets for kits) in which this preparation is used as an assay calibrant, it is important that the title of the preparation, code and the name and addresses of EDQM are cited correctly.

7. **Adoption**

The 4th IS for Streptomycin has been officially adopted by the Expert Committee on Biological Standardization of the World Health Organization in 2015.

8. **References**


9. **Signature**

This document is electronically signed by:

Dr Pierre Leveau

Head of the Quality, Safety and Environment Division