

The 2nd International Standard for Neomycin B

1. **The Standard**

The 2nd International Standard (IS) for Neomycin B (ISA_46104) consists of vials of freeze-dried neomycin B sulfate. This preparation was established as the 2nd IS for Neomycin B by the Expert Committee on Biological Standardization of the World Health Organization in 2012.

2. **Biological Activity**

The standard was calibrated in an international collaborative study involving 7 laboratories from different countries, against the 1st IS for Neomycin B.

The assigned potency is 17640 IU per vial for the 2nd IS for Neomycin B.

3. **Use of the Standard**

Dissolve the entire content of the vial with an exact amount of solvent using gentle shaking. Transfer the solution to a plastic tube and keep at room temperature during the assay. The solution should be used as soon as possible and should be kept at 25°C maximum during assays. Unused material must be discarded and not frozen for later use. Unopened vials should be stored at -20°C.

The product in the vial is freeze-dried. Do not weigh out portions of the product; dissolve it preferably by injecting solvent through the rubber stopper while avoiding the generation of pressure within the vial which might lead to a loss of material when retracting the needle. The cake should dissolve rapidly. Care should be taken to avoid any loss and rinsing steps are recommended to ensure quantitative transfer into the volumetric flask.

4. **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.

5. **References**

Collaborative Study for the Establishment of the Second International Standard for Neomycin B, WHO/BS/2012.2201.

S. Jorajuria, C. Raphalen, V. Dujardin, A. Daas, K.-H. Buchheit, Collaborative Study for the Establishment of the Second International Standard for Neomycin B, Pharmeuropa Bio & Scientific Notes, submitted.

6. **Caution**

For laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure. This material is not for administration to humans or animals. The corresponding safety data sheet, when applicable, can be accessed via the EDQM website (Reference Standards Database) or is available upon request from the EDQM (Helpdesk-FAQ section).

7. **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.



8. Product 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.

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10. Signature

This document is electronically signed by:

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