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# The 2nd International Standard for Gentamicin

NB: Since April 2006, the European Directorate for the Quality of Medicines & HealthCare (EDQM-Council of Europe) is in charge of the establishment and distribution of International Standards for Antibiotics instead of the National Institute for Biological Standards and Control (NIBSC-UK).

## 1. Introduction

This International Standard is the primary biological standard for Gentamicin.

## 2. 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).

## 3. Unitage

The assigned potency agreed on the basis of the WHO International Collaborative Study is **31020 International units of biological activity per ampoule**.

## 4. Contents

Each ampoule contains a freeze-dried residue comprising approximately 49 mg gentamicin sulphate, under an atmosphere of nitrogen. Unopened ampoules should be stored at -20°C.

## 5. Use of ampouled material

No attempt should be made to weigh out any of the freeze dried material.

Dissolve the total contents of the ampoule with 0.5 mL of sterile distilled water. Rinse the ampoule with about 0.4 mL of sterile distilled water and make up the total volume to 1.0 mL with the same solvent. This solution will contain gentamicin (as gentamicin sulphate) at a concentration of 31020 International Units/mL.

For economy of use, it is recommended that the solution be sub-divided into several small aliquot and stored at -20°C. Avoid repeated freezing/thawing.

## 6. Stability

It is the policy of WHO not to assign an expiry date to their International Standard. They remain valid with the assigned potency and status until withdrawn or amended.
Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

## 7. Citation

In all publications (or data sheets for kits) in which this Standard is used as an assay calibrant, it is more important that the title of the Standard, 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.

## 9. 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

## 10. References

WHO Technical Report Series, No. 800, 1990, Annex 4.

WHO Unpublished document BS/95.1811.

## 11. Signature

This document is electronically signed by:

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