European Directorate for the Quality of Medicines & HealthCare
7, Allée Kastner CS 30026, F-67081 Strasbourg (France)
Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any questions: www.edqm.eu (HelpDesk)

The 1st International Standard for Netilmicin

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

The 1st International Standard for Netilmicin was established by the National Institute for Biological Standards and Control in accordance with the authorisation given by the WHO Expert Committee on Biological Standardisation at its 35th meeting in 1984[1].

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 activity of the contents of each ampoule has been defined as 4810 International Units.

4. Further Information

Biological Activity

The 1st International Standard for Netilmicin (code-labelled 83_577) was calibrated in 5 laboratories against the United States Pharmacopeial Netilmicin Sulphate Reference Standard in an international collaborative study[2]. A total of 40 individual assays were carried out in 7 laboratories by plate diffusion methods. Three different test organisms were used in the study (*B. pumilus, B.subtilis* and *S. epidermidis*). The potency agreed by the participants was **4810 International Units per ampoule**[2].

Preparation of the Standard

The bulk material consisted of approximately 35 gm of a netilmicin sulphate (Batch no. 070178) which had been stored in a sealed container at -20°C in the dark until required for filling. In December 1983 the material was dissolved in double glass distilled water so that there was 7.60 mg of the anhydrous material per 1.100 g of solution. This was distributed into non-actinic neutral glass ampoules which were then processed as described by Campbell (1974)[3], tested for leaks and finally placed on storage at -20°C in the dark.

The ampouled material

The batch consisted of about 3700 ampoules, the mean liquid filling weight being 1.1039 gm +/- 0.12% [2]. The residual moisture content of the material in the sealed ampoules was determined as being less than 0.05% w/w[2]. Because of the extremely hygroscopic nature of the ampoule contents no attempt should be made to weigh out any portion of the freeze-dried material.

Stability and Storage

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. Accelerated degradation studies carried out at elevated temperatures for seventeen months showed the ampoules material to be stable when stored unopened in the dark at -20°C or below.

Acknowledgements are made to:
Schering Plough, New Jersey, USA for generously supplying the material and to the participants in the collaborative study for calibrating the 1st International Standard.

References

1) World Health Organisation, Expert Committee on Biological Standardisation, WHO Technical Report Series, 1985, 725, 14.

2) Thomas, A.H., Mussett, M.V., and Broadbridge, R. A., (1986), Journal of Biological Standardisation, (submitted).

3) Campbell, P.J., (1974) Journal of Biological Standardisation, 2, 259-267.

5. 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.

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This document is electronically signed by:

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