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The 1st International Standard for Sisomicin

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 Sisomicin was established by the WHO Expert Committee on Biological Standardisation at its 35th meeting in 1984[1]. The activity of the contents of each ampoule has been defined as 35200 International Units.

2. Biological Activity

The 1st International Standard for Sisomicin (code-labelled 80_543) was calibrated in 7 laboratories against the United States Reference Standard for Sisomicin in an international collaborative study[2]. A total of 61 individual assays were carried out in 7 laboratories by plate diffusion methods and in addition, one laboratory used a respirometric assay twice and a turbidometric assay on six occasions. Five different test organisms were used in the study (*B. pumilus, B. subtilis, S. epidermis* and *S. aureus* two different strains). The potency agreed by the participants was **35200 International Units per ampoule**[2].

3. 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).

4. Further Information

Preparation of the standard

The bulk material consisted of approximately 300 gm of a single batch sisomicin sulphate, which had been stored in a sealed container at -20°C in the dark until required for filling. In June 1980 the material was dissolved in double glass-distilled water so that there was 62.90 mg of the 'as is' material per 1.100 gm of solution. This was distributed into non-actinic 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 4000 ampoules, the mean liquid filling weight being 1.101 gm +/- 0.15% [2]. The residual moisture content of the material in the sealed ampoules was determined as being less than 0.1% w/w. 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 eight months showed the stability of the 1st International Standard for Sisomicin was not significantly different from that of the trial fill[2], indicating the 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) Lightbown, J. W., Mussett, M.V., and Broadbridge, R.A (1986) Journal of Biological Standardisation, **14**, 377-385.

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:

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