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The 1st International Standard for Kanamycin

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 Kanamycin was established by the WHO Expert Committee on Biological Standardisation at its 37th meeting in 1986[1]. It consists of containing the residue after freeze drying of a solution of kanamycin sulphate, 10345 International Units per ampoule[2].

2. Biological Activity

The 1st International Standard for Kanamycin (code-labelled 83_521) was calibrated by 10 laboratories against the 1st International Reference Preparation for Kanamycin in an international collaborative study[3]. A total of 59 individual assays were carried out in 9 laboratories by plate diffusion methods and another laboratory employed a turbidimetric method. Three different test organisms were used in the study (*B. subtilis, B. pumilus and S. aureus*). The potency agreed by the participants was **10345 International Units per ampoule**[3].

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 reference standard

The bulk material consisted of 50 gm of a single batch of crystalline kanamycin monosulphate monohydrate which had been stored in a sealed container at -20°C in the dark until required for filling. In March 1983 the material was dissolved in double glass distilled water so that there was 12.66 mg of hydrated kanamycin sulphate per 1.10 gm of solution. After fine filtration to ensure homogeneity, the filling solution maintained at 4°C and protected from light was distributed into non-actinic neutral glass ampoules which were then processed as described by Campbell (1974)[4], 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 1.10582 gm +/- 0.16% w/w[3]. The residual moisture content of the material in the sealed ampoules was determined as being less than 0.2% w/w. The ampoule contents were found to be extremely hygroscopic, even at an atmosphere with a relative humidity of 20%[3]. No attempt should therefore be made to weigh out any 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 were carried out on sealed ampoules of the 1st International Standard for Kanamycin and showed no loss in potency after

storage at 56°C for 20 months[3], indicating the material to be stable when stored in unopened ampoules in the dark at -20°C or below.

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References

1) World Health Organisation, Expert Committee on Biological Standardisation, WHO Technical Report Series, 1987, 760, 17.

2) World Health Organisation, Expert Committee on Biological Standardisation, WHO Technical Report Series, 1979, 638, 8.

3) Thomas, A.H., Mussett, M.V., and Broadbridge, R. A., (1986), Journal of Biological Standardisation, 14, 35-44.

4) 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.

6. Product liability

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This document is electronically signed by:

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