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The 1st International Standard for Teicoplanin

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 International Standard for Teicoplanin was established by the WHO Expert Committee on Biological Standardisation at its 41st meeting in 1990[1].

2. Unitage

The activity of the contents of each ampoule has been defined as **51550 International Units**.

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 can be accessed via the EDQM website (Reference Standards Database) or is available upon request from the EDQM (Helpdesk-FAQ section).

4. Use of ampouled material

Dissolve the total contents by washing out both parts of the ampoule with a 1% v/v aqueous solution of methanol and adjust the solution so obtained to a known volume. This solution will contain 51550 International Units. The contents of the ampoule are extremely hygroscopic and no attempt should be made to weigh out any of the freeze dried material.

5. Further Information

Biological Activity

The International Standard for Teicoplanin (code-labelled 90_704) was examined in 5 laboratories. A total of 27 individual assays were done by plate diffusion methods using *B. subtilis* as the test organism. The potency agreed by the participants based on the data provided by the manufacturer was 51550 International Units per ampoule[2].

Preparation of the standard

The bulk material consisted of approximately 1.5 kg of teicoplanin (Batch no. 0029-MFD July 1986). In March 1987 the material was dissolved in water for injection so that there was 50 mg of teicoplanin per 1.0 mL. This was distributed into non-actinic neutral glass ampoules following the procedures 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 20000 ampoules and 1000 ampoules have been offered to WHO. The mean ampoule content is 54.09 mg, s.d. 0.567%, the residual moisture content of the material in the sealed ampoules was determined as being 0.99% corresponding to 0.54 mg per ampoule. Because of the extremely hygroscopic nature of the ampoule contents no attempt should be made to weigh 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 30 months showed the ampouled material to be stable when stored unopened in the dark at -20°C or below.

Acknowledgements are made to:
Merrell Dow Pharmaceuticals, Staines, UK. generously supplying the material and to the participants in the collaborative study for examining the International Standard.

References

1) World Health Organisation, Expert Committee on Biological Standardisation, WHO Technical Report Series (in press).

2) Thomas, A.H. and Wong, M.Y. Biologicals (submitted).

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

6. 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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