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The 2nd International Standard for Polymyxin B

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. 1. Introduction

The 2nd International Standard for Polymyxin B was established by the WHO Expert Committee on Biological Standardisation at its 22nd meeting in 1970[1]. It consists of ampoules containing the residue after freeze-drying, of a solution of polymyxin B sulphate, 8403 International Units per mg.

2. 2. Biological Activity

The 2nd International Standard for Polymyxin B (code-labelled 67_301) was calibrated by 5 laboratories against the 1st International Standard for Polymyxin B in an international collaborative study[2]. A total of 121 individual assays were carried out by plate diffusion methods. One test organism was used in the study (*B. bronchiseptica*). The potency agreed by the participants was **8403 International Units per mg.**

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 preparation

The bulk material consisted of approximately 400 gm of a single batch of polymyxin B sulphate, which had been stored in sealed containers at -20°C in the dark until required for filling. In December 1967 the material was dissolved in double glass-distilled water so that there was 75 mg of polymyxin B sulphate per 1.00 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 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 filling weight being 1.013 gm +/- 2.2% w/w. The residual moisture content of the material in the sealed ampoules was indetectable. The contents of the ampoule are hygroscopic. When exposed to an atmosphere of 36% relative humidity, samples increased in weight by approximately 0.5% w/w in 5 minutes. Care should therefore be exercised in weighing out material from the ampoule to avoid error due to uptake of moisture.

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. The 2nd International Standard for Polymyxin B is a stable preparation when stored in unopened ampoules in the dark at -20°C or below.

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Burroughs, Wellcome and Co., Dartford, Kent, UK for generously supplying the material and to the participants in the collaborative study for calibrating the 2nd International Standard.

References

1) World Health Organisation, Expert Committee on Biological Standardisation, WHO Technical Report Series, 1970, **444**, 8.

2) Lightbown, J. W., Thomas, A.H., Grab, B. and Outschoorn, A.S. (1973) Bulletin of the World Health Organisation **48**, 85-90.

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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