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The 1st International Standard for Spiramycin

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

A suitable sample (100 g) of spiramycin base (reference no. JM42) was obtained in 1962 by the generosity of May and Baker Ltd., Dagenham, England, and through the good offices of Mr F. J. Pazon of that company. The following analytical data were supplied by the manufacturer.

Appearance	granular powder
Colour	faintly yellow
Odour	slight
[α] 20 D	-83°
10% solution in H_2SO_4	slightly dim
Colour of solution	N/12 000 iodine
Nitrogen (in dry material)	3.25%
Water (Karl Fischer method)	<1.0%
Sulphated ash	<0.10%
Chlorides	<0.01%
Biological Assay	3200 units/mg
Composition:	
Spiramycin 1	65%
Spiramycin 2	20%
Spiramycin 3	15%

The French and the Canadian national standards for spiramycin have been prepared from part of the identical batch of spiramycin that was used for the International Reference Preparation of Spiramycin.

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 material was established in 1962 as the International Reference Preparation of Spiramycin and the International Unit was defined in 1964 as the activity contained in 0.0003125 mg of the International Reference Preparation, corresponding to a potency of **3200 IU/mg**.

4. The ampouled material

After distribution into ampoules, the moisture content of the material, measured as loss in weight at over 56°C over phosphorous (V) oxide at a pressure of 0.02mm Hg, was found to be 0.38% w/w (mean of 12 ampoules). The material in the ampoules increased in weight by approximately 1% w/w when exposed to the atmosphere for 30 min at a relative humidity of 45%.

5. Stability

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 They remain valid with the assigned potency and status until withdrawn or amended. Samples of the International Standard of Spiramycin lost 6% activity after storage at 56°C for 4 years.

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.

7. Product Liability

The Council of Europe accordingly makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for any particular purpose. The product must be handled by professional persons having technical skill and at their own discretion and risk. It is for the purchasers of any such item who are responsible for persons in a workplace to determine independently the risks associated with the item according to the conditions of use and to take appropriate safety measures, including provision of appropriate information to persons working with the substance. Any liability of the Council of Europe for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted by law; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

8. Disputes

In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the Council of Europe (EDQM) and the customer as regards the application of this contract shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.

9. References

1) (1961) WHO Technical Report Series, No. 222.

2) (1963) WHO Technical Report Series, No. 259.

3) (1964b) WHO Technical Report Series, No. 293.

Abstracted from Bull. WHO 1972, 47, 343-356. For outline of the procedure for preparing ampoules of material, see this paper.

10. Signature

This document is electronically signed by:

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