European Directorate for the Quality of Medicines & HealthCare
7, Allée Kastner CS 30026, F-67081 Strasbourg (France)
Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any questions: www.edqm.eu (HelpDesk)

3rd International Standard for Erythromycin

1. Identification

Catalogue code : ISA_65774

2. Scientific information

2.1 Intended use

The 3rd International Standard for Erythromycin is supplied exclusively for use as primary standard for the establishment of National/Regional secondary standards for microbiological assay of antibiotics and for no other purpose.

For routine use, please use the corresponding Ph. Eur. reference standard, if available.

2.2 Analytical information related to intended use

The standard was calibrated in an international collaborative study against the 2nd ISA for Erythromycin.

The assigned potency is 925 IU per mg for the 3rd ISA for Erythromycin.

2.3 Stability

Accelerated degradation studies have shown that the standard is stable when stored in unopened vials at -20°C, with no predictable loss of potency over a period of 6 months. It is therefore recommended that the unopened vials are stored at -20°C or below until immediately before use.

2.4 Instructions for use

Before use, allow the closed container to equilibrate at ambient temperature to avoid uptake of moisture. Use "as is". Do not dry/desiccate before use. ISA are for immediate use. Once the container has been breached, its entire content must be used immediately. Any further storage and re-use are not warranted.

Special instructions for freeze-dried materials: this substance has been freeze-dried and is known to be hygroscopic. Tap the container gently to collect the material at the bottom. Reconstitute the contents by injecting a suitable volume of the solvent. Mix gently to ensure complete dissolution. When necessary transfer the solution to an appropriate volumetric flask and dilute to the required concentration.

3. Safety

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. Shiping conditions

Please check shipping conditions on the EDQM website (WHO International Standards for Antibiotics Database).

5. Reference

Pharmeur Bio Sci Notes. 2020;2020:1-24.
"Collaborative study for the establishment of the 3rd international standard for erythromycin."
Jorajuria S, Raphalen C, Cozic G, Dujardin V, Regourd E

6. Adoption

The 3rd International Standard for Erythromycin has been officially adopted by the Expert Committee on Biological Standardization of the World Health Organization in 2018.

7. Citation

The user has an obligation to ensure that any reference made to the present Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the correct name, and code of the Standard and the correct name and address of EDQM as given in the present leaflet.

8. Product liability

The Council of Europe 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.

9. 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.

10. Signature

This document is approved by:

Head of the Quality and Risk Management Section

Name: Caroline OFFERLE

Date: 29/04/2020