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AMPICILLIN SODIUM International Chemical Reference Substance Control No 388002

1. Intended use

The International Chemical Reference Substance for ampicillin sodium is intended to be used in the infrared absorption spectrophotometric test for identity according to the monograph in *The International Pharmacopoeia*.

Note: According to the monograph the International Chemical Reference Substance for ampicillin (anhydrous) is used as reference substance in the assay of ampicillin sodium.

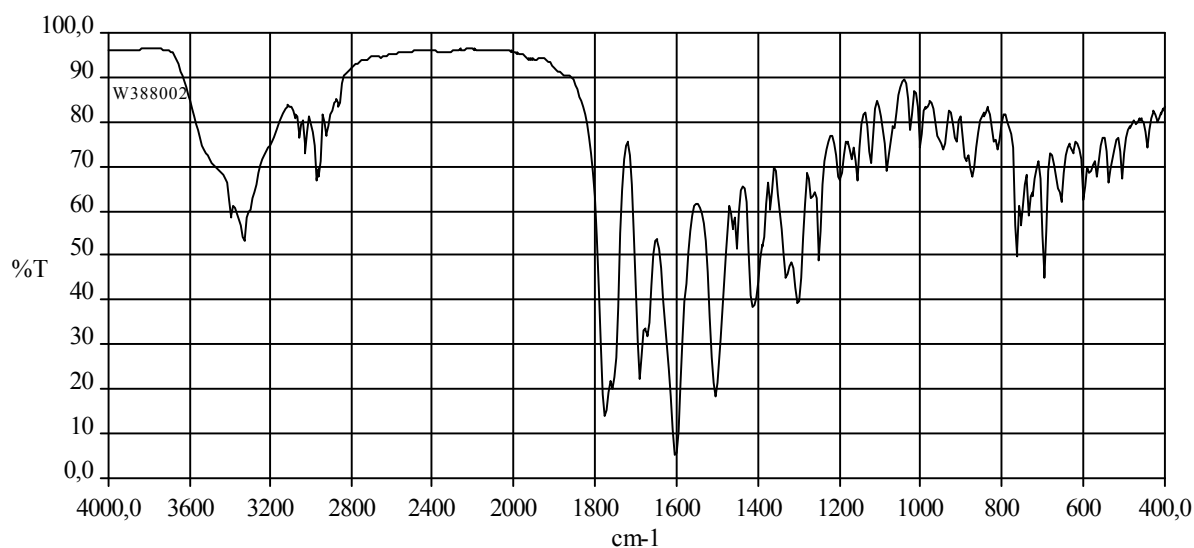
2. Caution

This material is not for administration to humans or animals. The corresponding Safety Data Sheet can be downloaded from the EDQM website (www.edqm.eu) or can be obtained from EDQM upon request.

Care should be exercised in opening the container to avoid cuts.

3. Analytical data

Infrared absorption spectrophotometry (IR): A spectrum, 0.9 mg of ampicillin sodium in 300 mg of potassium bromide, is given in figure W388002.



High performance liquid chromatography (HPLC): The purity was estimated by peak area normalization to 97.9% at 225 nm.

Thermogravimetric analysis (TG): When heated to 150 °C a loss of 0.6% (w/w) was observed.

4. Storage

Ampicillin sodium is hygroscopic and is deliquescent in air with a relative humidity of 60% or more. It should be kept in a tightly closed container, protected from light.

5. Reference

This certificate is extracted from the report, which is the basis for the adoption of this International Chemical Reference Substance by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-second Report, WHO Technical Report Series, 823.

6. 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.

7. Product liability

The present Standard has been established by Apoteket SA, Sweden on behalf of the WHO. The Council of Europe, EDQM is responsible for storage and distribution.

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.

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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.