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## CRS INFORMATION LEAFLET Ph. Eur. Reference Standard

### SPIRAMYCIN CRS batch 5

#### 1. Identification

Catalogue code: S1100000

Unit Quantity: ca 200 mg

#### 2. Scientific Information

##### 2.1 Intended use

Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only.

Established for use with the monograph(s): 20702, 0179, 1982, 0293.

##### 2.2 Analytical information related to intended use

Chromatogram(s)/spectrum : See attachment

The "as is" content is

: **4500 IU per mg (for 0293 and 20702)**

**Spiramycin I: 87.3%, Spiramycin II: 0.2%, Spiramycin III:  
4.4% (for 0293)**

##### 2.3 Uncertainty of the assigned value, when applicable

According to ISO Guide 34 and ISO Guide 35, for this Pharmacopoeial standard the uncertainty of the assigned value is not stated since it is considered to be negligible in relation to the defined limits of the method-specific assays for which the reference standard is used. Please also refer to Ph. Eur. chapter 5.12.

##### 2.4 Validity

A statement on the validity of the batch (Batch Validity Statement) can be printed directly from the EDQM website (Reference Standards Database).

##### 2.5 Instructions for use

Allow the closed container to equilibrate at ambient temperature before breaching to avoid uptake of moisture. Use "as is". Do not dry/desiccate before use. Once the container has been breached, stability of the contents cannot be guaranteed. It is for immediate use.

#### 3. Storage conditions

Store the original container at  $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ , protected from light. The container should not be opened until required for use.

#### 4. Safety

##### CLP Hazard Classification

For laboratory use only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure.



## Warning



For substances subject to GHS classification, 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).

## 5. Shipping conditions

Please check shipping conditions on the EDQM website (Reference Standards Database).

## 6. Warranties, Liability and disputes

### *a) Warranties*

The Council of Europe does not offer any warranty concerning the quality or safety of any item supplied, the absence of any defects, or its fitness for any particular purpose except that of use as a Ph. Eur. CRS, BRP or RS for use as reference standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia (Ph. Eur.) by professionals with the necessary technical skills. In particular, the Council of Europe (EDQM) does not guarantee that the items will meet the customer's specific expectations. The Council of Europe also does not guarantee that the purchase or use of the items will not infringe any intellectual property rights, in particular patents.

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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.

## 7. Citation

Users shall ensure that any reference made to an EDQM Reference Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the exact name, and catalogue code of the Reference Standard and the exact name and address of EDQM as given on the first page of this information leaflet.

## 8. Adoption

The present reference standard has been officially adopted by the European Pharmacopoeia Commission.

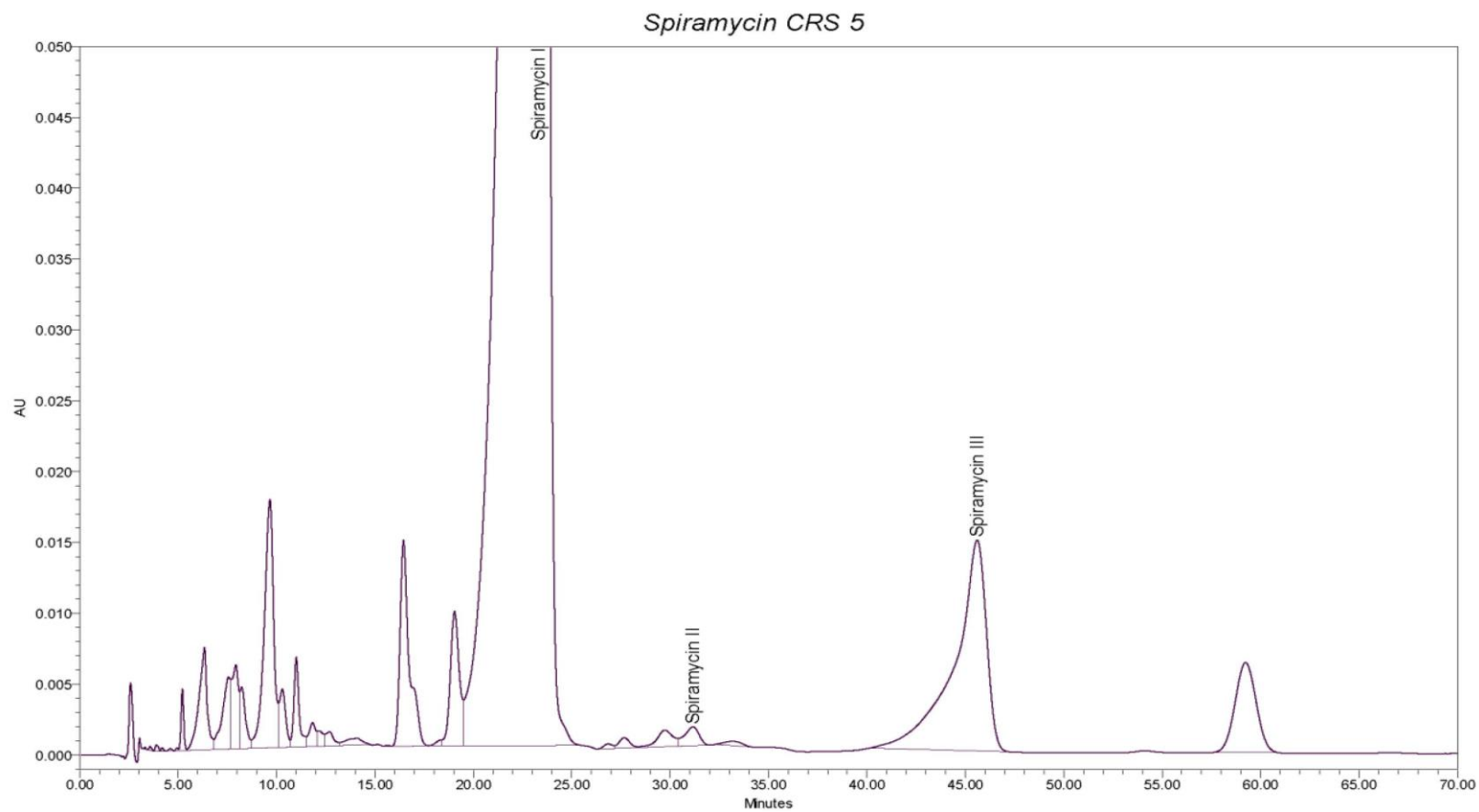
## 9. Signature

This document is electronically signed by:

**Dr Pierre Leveau**  
**Head of the Quality, Safety and Environment Division**

Annex 1:

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES



Project Name: LC05541Spiramycin

Result Id 1287