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INFORMATION LEAFLET Ph. Eur. Reference Standard

Levocarnitine impurity A CRS batch 4

1. Identification

Catalogue code: L0399905 Unit Quantity: ca 50 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): 1339.

2.2 Analytical information related to intended use, when applicable

Levocarnitine impurity A CRS 4 is supplied as a hydrochloride salt.
For the calculation of the amount of impurity A in the monograph for levocarnitine, multiply the peak area of impurity A obtained with reference solution (b) by a stoichiometric conversion factor of Mr 179.7 / Mr 143.2 = 1.3
Note: Molecular masses used for the calculation of the stoichiometric conversion factor in this leaflet:
Levocarnitine impurity A: C7H13NO2 – 143.2 g/mol
Levocarnitine impurity A [hydrochloride salt]: C7H14ClNO2 – 179.7 g/mol

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 +5°C ± 3°C, protected from light. The container should not be opened until required for use.

4. Safety

Hazard Classification

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

For substances subject to GHS/CLP 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.

The Council of Europe (EDQM) only guarantees that the items meet the above conditions in the moment they are handed over to the carrier being responsible for the delivery of the item to the purchaser and that the carrier and the purchaser have received clear and accurate instructions for the item's delivery and reception.

No other warranty, either express or implied, is given by the Council of Europe (EDQM).

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The Council of Europe (EDQM) shall not be liable for the failure to meet the requirements of the legislation of the country where the items are delivered. It is the purchaser's responsibility to check with the local, regional or national authorities and to make sure that the goods or services that they intend to order may be imported or used in that country. The purchaser is solely responsible for the choice of items, their storage from the time of delivery and their use.

In no event shall the Council of Europe (EDQM) be liable for any damages due to the use of items, including, but not limited to, lost profits, loss of use, costs of procurement of substitute goods, services or systems, or for any indirect, special, incidental, punitive, or consequential damages, however caused and, whether in contract, tort or under any other theory of liability, whether or not the Purchaser has been advised of the possibility of such damage.

c) 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.

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