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LUMEFANTRINE ICRS batch 2

1. Intended use

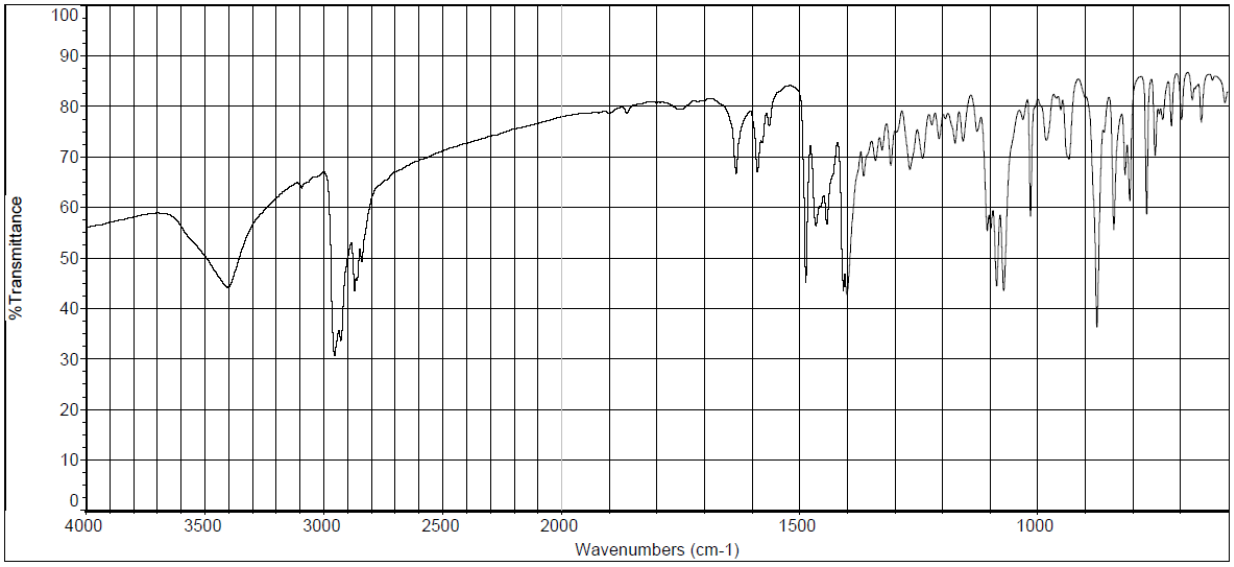
The International Chemical Reference Substance for LUMEFANTRINE ICRS is intended to be used for the following tests described in *The International Pharmacopoeia*:

- for identification by infrared absorption spectrophotometry and thin-layer chromatography according to the monograph for lumefantrine
- for identification by thin-layer chromatography and high-performance liquid chromatography according to the monographs for artemether and lumefantrine oral suspension and artemether and lumefantrine tablets
- for assay by high-performance liquid chromatography according to the monographs for artemether and lumefantrine oral suspension and artemether and lumefantrine tablets.

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. Analytical data



ADDITIONAL ANALYTICAL INFORMATION AT THE TIME OF ESTABLISHMENT

Liquid chromatography: total impurities 0.15 %.

Loss on drying: 0.1 %.

00ICRS2125

ASSIGNED CONTENT

99.7 % *m/m* of lumefantrine ($C_{30}H_{32}Cl_3NO$) (for use in assay by high-performance liquid chromatography according to the monographs for artemether and lumefantrine oral suspension and artemether and lumefantrine tablets).

4. 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.

5. Storage conditions

Store the original container at +5°C ± 3°C, protected from light. The container should not be opened until required for use. Let the container equilibrate at room temperature just before opening to avoid uptake of moisture during handling of the substance. Shipping conditions are on the EDQM website (Reference Standards Database).

6. 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.

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 electronically signed by:

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