

## Artemimol ICRS batch 2

### 1. **Intended use**

The above mentioned International Chemical Reference Substance is intended to be used for tests described in The International Pharmacopoeia.

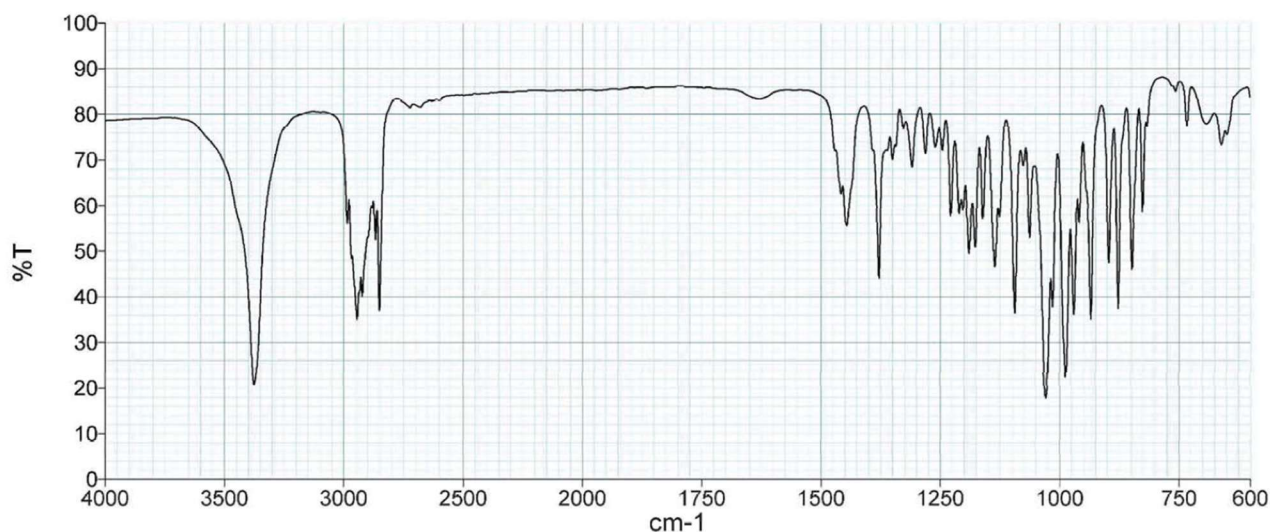
- for identification by infrared absorption spectrophotometry according to the monograph for artemimol;
- for identification by thin layer chromatography according to the monograph for artemimol;
- as external standard for the assay by high-performance liquid chromatography according to the monograph for artemimol;
- for the system suitability test in the assay and test for related substances by high-performance liquid chromatography according to the monographs for artemimol, for artesunate, for artesunate for injection and for artesunate tablets;
- as external standard in the test for related substances by thin layer chromatography according to the monographs for artemether and lumefantrine powder or oral suspension and for artemether and lumefantrine tablets.

### 2. **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).

### 3. **Analytical data**

Infrared absorption spectrophotometry (IR): A spectrum, 1.6 mg of artemimol in 300 mg of potassium bromide:



### **Additional analytical information at the time of establishment**

Liquid chromatography (LC): Total impurities 0.26% (determined using the LC method of the test for related substances in the monograph for artemimol).

Loss on drying <0.1%

Sulfated ash <0.1%

Residual solvents <0.1%

**Assigned content:** 99.7% m/m artemimol (C<sub>15</sub>H<sub>24</sub>O<sub>5</sub>)

#### **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. Special instructions apply to freeze-dried materials. ICRS 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.

#### **5. Storage conditions**

Store the original container at -20°C ± 5°C, protected from light. Re-instate promptly upon receipt.

#### **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 approved by:

**Head of the Quality and Risk Management Section**

**Name: Caroline Offerlé**

**Date: 27/03/2023**