

Certificate of Analysis

ASEAN Reference Substance (ARS)

Issued by ASEAN Reference Substances Working Group (ARSWG)

Coordinating Country

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Coordinator of the Project

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LUMEFANTRINE	Control No. I 223154
CI CH ₃ CH ₃ CH ₃	CAS No. : 82186-77-4 Molecular Formula : C ₃₀ H ₃₂ Cl ₃ NO Molecular Weight : 528.94

Description	: A White, crystalline powder
Identification	
Infrared absorption	: Concordant with the reference spectrum of Lumefantrine USPRS
HPLC	: The retention time of the lumefantrine peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.
Organic impurities	: (HPLC method)
- Desbutyl lumefantrine	: Not more than 0.05%
- Any other individual impurity	: Not more than 0.10%
- Total impurities	: Not more than 0.3%
Assay	: 99.37% of C ₃₀ H ₃₂ Cl ₃ NO, calculated on the as is basis, determined by HPLC method, compared with USPRS
Intended use	: For HPLC, chemical assay and identification
Direction for use	: Do not dry before use
Storage	: Keep container tightly closed and protected from light, preferably at the temperature 2-8°C

Date of Adoption : 31 March 2023 Next Retest Date : 31 March 2026