



## ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS  
supported by Japan Pharmaceutical Manufacturers Association



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**Certificate of Analysis**

**LUMEFANTRINE**

**Control No. V 113154**

Description : A white, crystalline powder

Infrared absorption : Concordant with the reference spectrum of Lumefantrine USPRS

Related compounds : (HPLC method)

- Related compound A : Not more than 0.1%
- Related compound B : Not more than 0.1%
- (stereoisomer A)
- Related compound B : Not more than 0.3%
- (stereoisomer B)
- Any individual impurity : Not more than 0.10%
- Total impurities : Not more than 0.3%

Assay : 99.50% of  $C_{30}H_{32}Cl_3NO$ , 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 : 16 August 2013

Retested Date : 31 July 2017

Next Retest Date : 31 July 2020