



ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS
supported by **Japan Pharmaceutical Manufacturers Association**



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Certificate of Analysis

AMODIAQUINE HYDROCHLORIDE

Control No. V 114155

Description : A yellow, crystalline powder

Identification

Infrared absorption : Concordant with the reference spectrum of
Amodiaquine Hydrochloride USPRS

UV-absorption : A 0.001 per cent solution in diluted hydrochloric acid (1 in 100)
exhibits a maximum at 223 nm with A (1%, 1 cm) about 845

Tests for chloride : Positive

HPLC : Correspond to the principle peak in the chromatogram obtained with
the standard solution of Amodiaquine Hydrochloride USPRS

Related substances : (HPLC method)

Any individual impurity : Less than 0.5%

Water : 8.35% (Karl Fischer method)

Assay : 100.50% of $C_{20}H_{22}ClN_3O \cdot 2HCl$, calculated on the anhydrous basis,
determined by HPLC method, compared with USPRS

Intended use : For HPLC 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 : 11 April 2014

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