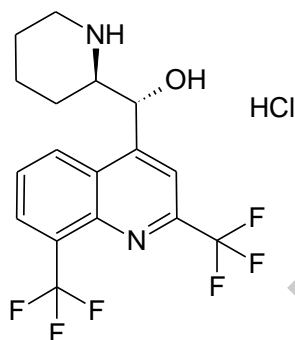


Reference Material Product Information Sheet

Epichem's Quality System conforms to ISO9001:2015 as certified by ECAAS Pty Ltd - Certification number 616061.



Name	(R*,R*)-(2,8-bis(trifluoromethyl)quinolin-4-yl)(piperidin-2-yl)methanol hydrochloride
USP Name	Mefloquine Related Compound A
BP Name	Mefloquine Impurity C hydrochloride
Epichem Item #	EPL-AA104 Batch 2
CAS #	58560-52-4
Molecular Formula	C ₁₇ H ₁₆ F ₆ N ₂ O.HCl
Molecular Weight	414.78 g/mol
Appearance	White powder
Melting Point	262.6-265.1°C (decomposition).
Combustion Analysis	Required (%): C:49.2; H:4.1; N:6.8. Found (%): C:49.4; H:4.0; N:6.7.
Purity*	99.2%
Date of Manufacture	30 April 2021
Storage Requirements	Protect from heat, light and moisture.
Special Precautions	This compound is for laboratory use only. Its toxicological properties may not have been fully established. It should be handled only by suitably qualified personnel.
Intended Use	This compound is suitable for the identification of impurities and degradants in pharmaceutical materials. The purity assay is considered as relative contribution.
Date of Shipment	TBA This certificate is valid for one year from the date of shipment provided the substance is stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

* NATA accreditation does not cover the performance of this service

EPL-AA104 Batch 2

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ABN 80 106 769 902

I. Identity

The identity of this product was established using the following analyses:

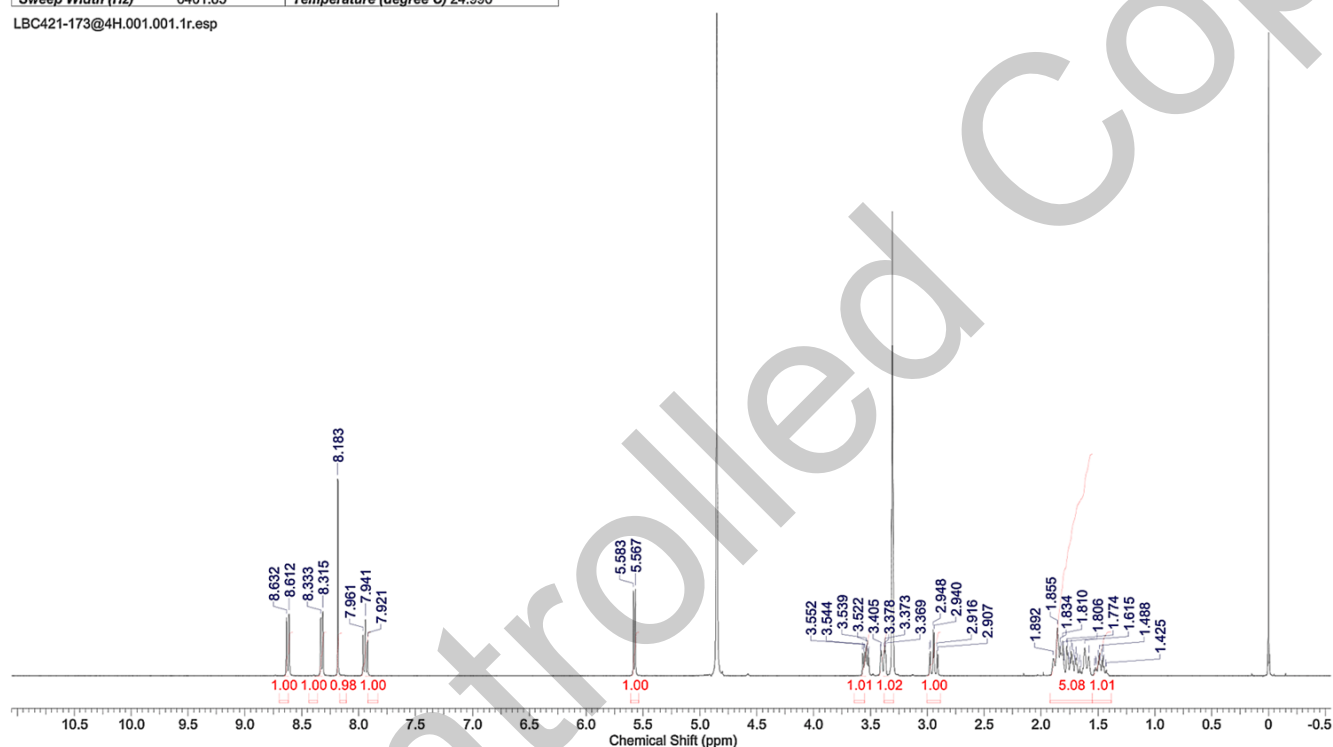
Ia. ¹H NMR Spectrum

Conditions: 400 MHz, MeOD

¹H NMR spectrum consistent with chemical structure.

Acquisition Time (sec)	3.7547	Comment	LBC421-173@4H 1H MeOD (E:\data\external\epichem) cygoh 11			
Date	04 May 2021 17:33:52	Date Stamp	04 May 2021 17:33:52			
File Name	\naphthalene\company\NMR files\LBC421-173@4H\1\data\1\1r		Frequency (MHz)	400.13		
Nucleus	1H	Number of Transients	8	Origin	spect	
Owner	nmr	Points Count	32768	Original Points Count	24038	
SW(cyclical) (Hz)	6402.05	Solvent	METHANOL-d4	Pulse Sequence	zg	
Sweep Width (Hz)	6401.85	Temperature (degree C)	24.996	Receiver Gain	161.00	
			Spectrum Offset (Hz)	2792.0068	Spectrum Type	STANDARD

LBC421-173@4H.001.001.1r.esp



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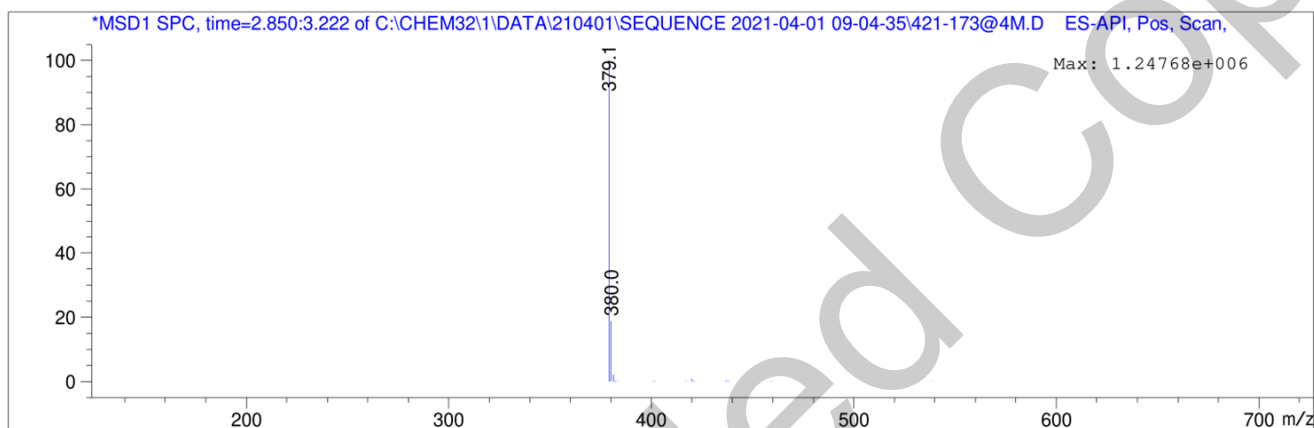
ABN 80 106 769 902

Ib. Mass Spectrum

The mass spectrum of this material was analysed by Liquid Chromatography Mass Spectroscopy (LCMS) using in-house EM005.WI08.

Method: ACN/water gradient (+ 0.1% formic acid).
ZORBAX SB-C18, 4.6 x 30 mm, 3.5 micron.

Retention Time (MS)	MS Area	Mol. Weight or Ion
2.918	40944520	380.05 379.10



Theoretical value: 379.1 [M+H]⁺.

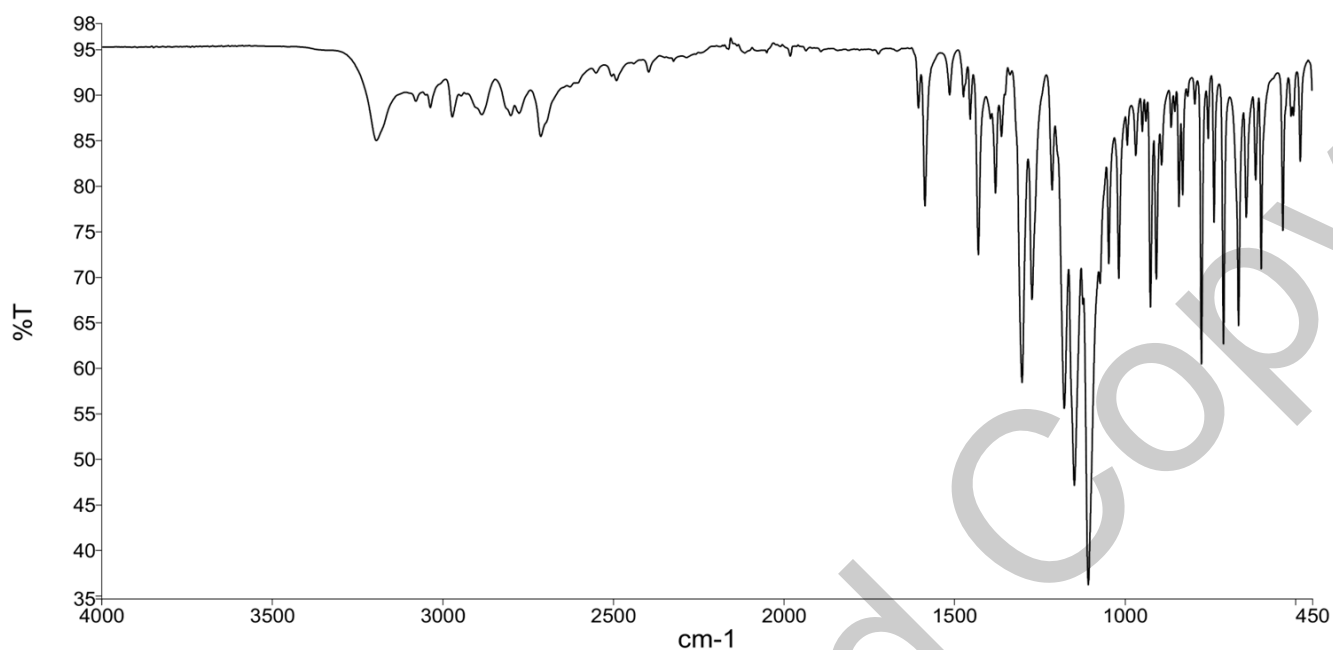
The signal of the Mass Spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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Ic. IR Spectrum

The infra-red spectrum of this material was analysed by Fourier-Transform Infra-red Spectroscopy (FTIR) using in-house EM005.WI09.



The interpretation of the signals of the Fourier Transform Infra-red Spectrum is consistent with the structural formula.

EPL-AA104 Batch 2

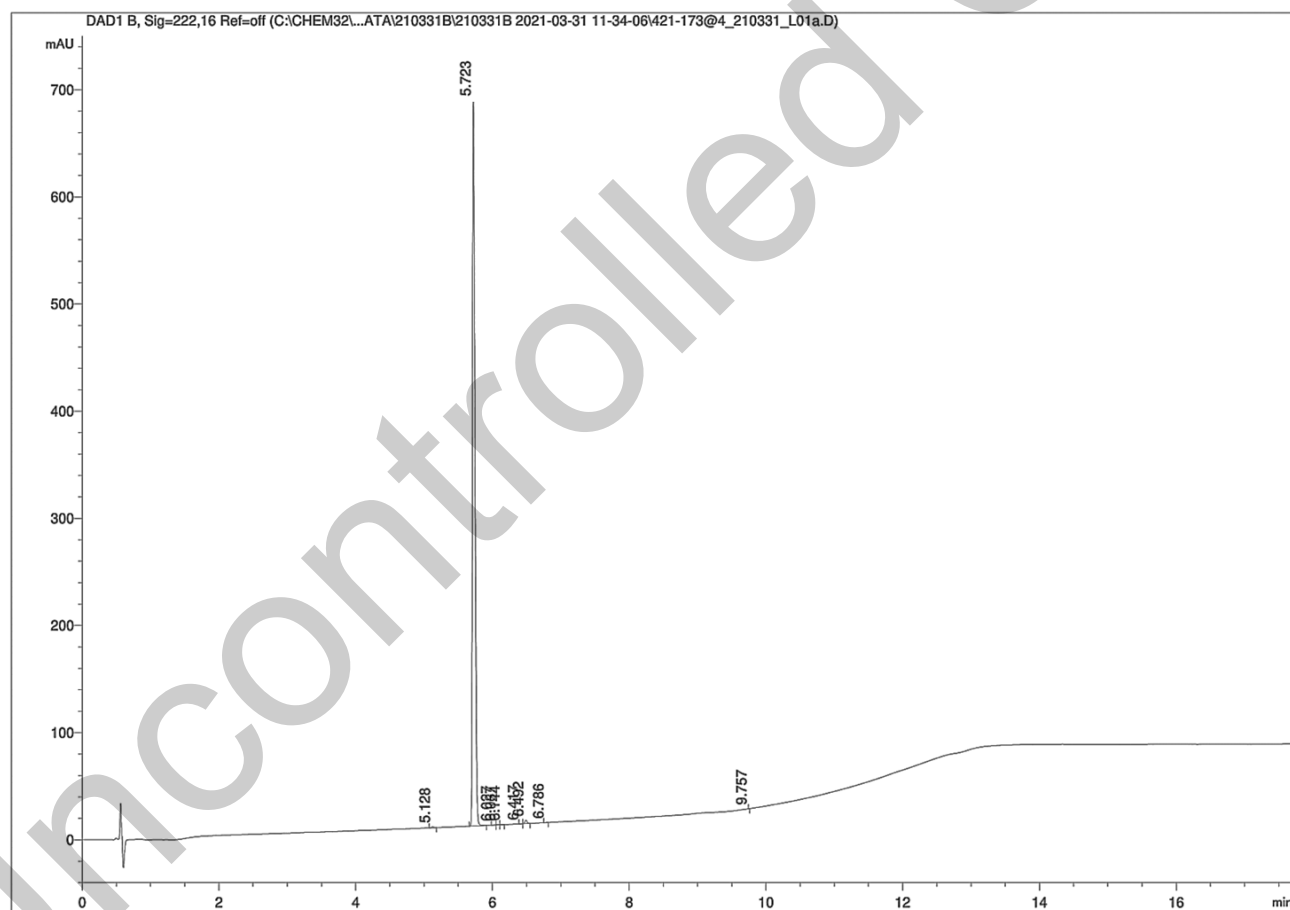
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II. Purity

The purity of this material was analysed by high performance liquid chromatography (HPLC) using in-house EM005.WI07.

HPLC Conditions:

Column	Conditions				Detector	Injector
Agilent Poroshell 120 EC-C18 4.6 x 50mm 2.7 micron	25°C				DAD 222nm	Auto 1.0 µL 0.35 mg/mL in 100% acetonitrile (NO MODIFIERS)
	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)		
	0.00	80	20	1.0		
	8.00	40	60	1.0		
	11.50	5	95	1.0		
	16.50	5	95	1.0		
	17.50	80	20	1.0		
	20.50	80	20	1.0		



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Area Percent Report – Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	5.13	2.11	0.13
2	5.72	1674.26	99.40
3	6.03	0.21	0.01
4	6.09	0.29	0.02
5	6.14	0.24	0.01
6	6.42	0.07	0.00
7	6.49	7.01	0.42
8	6.79	0.18	0.01
9	9.76	0.04	0.00
Total			100 (rounded)

For the calculation the system peaks were ignored. The content of the analyte was determined as a ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100%.

Results:

Average 99.4% (average of 10 duplicate runs)

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III. Water Content

Method: Karl-Fischer titration using in-house EM005.WI04.

Results:

Average 0.2%

IV. Ash Content

Method: BP2021 Appendix XI J Method II

Result:

Contains <0.1% ash.

V. Residual Solvents

Method: ¹HNMR

Result:

No significant impurities detected by ¹H NMR analysis.

VI. Final Result

Chromatographic purity (HPLC)	99.4%
Water content	0.2%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	99.2%

This purity is assessed to be 99.2%.

Product Reviewed By:

Product Released By:

James Rixson, PhD
Head of Production

Boon Tan
Quality Manager

Release Date: 6 May 2021

*NATA accreditation does not cover the performance of this service.

The calculation of the purity follows the formula:

$$\text{Purity(\%)} = \frac{((\text{Chromatographicpurity[HPLC]}) \times (100 - (\text{watercontent} + \text{ashcontent} + \text{volatilecontents})))}{100}$$

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