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epichem

The results of the tests, calibrations and/or measurements included in this document are traceable to Australia/national standards.

NATA is a signatory to the APLAC Mutual Recognition Arrangement for the mutual recognition of the equivalence of reference materials certificates.

Our Formula. Your Success.

Reference Material Product Information Sheet

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

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CI	

	Cl
Name	5-chloro-2-methylquinolin-8-ol
Synonym(s)	5-chloro-8-hydroxyquinaldine; 5-chloro-8-hydroxy-2-methylquinoline; 5-chlor-2-methyl-8-chinolinol; 5-chlor-8-hydroxy-chinaldin
Epichem Item #	EPL-AA121 Batch 2
CAS#	24263-93-2
Molecular Formula	C ₁₀ H ₈ ClNO
Molecular Weight	193.63 g/mol
Appearance	Beige crystalline powder
Melting Point	65.5-66.7°C
Combustion Analysis	Required (%): C:62.0; H:4.2; N:7.2. Found (%): C:62.0; H:4.1; N:7.2.
Purity*	99.7%
Date of Manufacture	17 August 2016
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 unopened and stored under the recommended conditions.
Retest Date	TBA (Proper Storage and Handling Required)

^{*} NATA accreditation does not cover the performance of this service

EPL-AA121 Batch 2

Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley WA 6102, Australia
Tel + 61 (0)8 6167 5200 Fax + 61 (0)8 6167 5201 www.epichem.com.au ABN 80 106 769 902

Form PC008.F07 Product Information Sheet Page 1 of 7

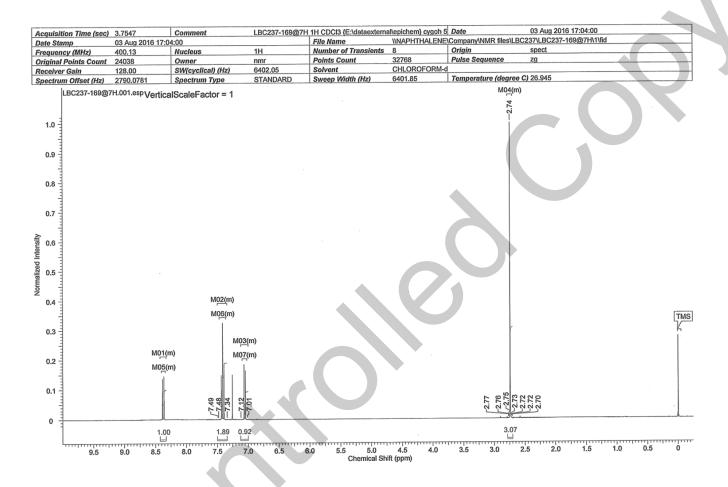
I. Identity

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

Ia. ¹HNMR Spectrum

Conditions: 400 MHz, CDCl₃

¹HNMR spectrum consistent with chemical structure.



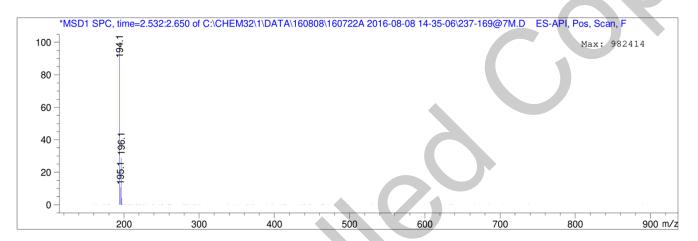
Ib. Mass Spectrum

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

Method: 5% to 100% ACN in water gradient (+0.1% formic acid)

Poroshell 120 EC-C18, 4.6 x 50 mm, 2.7 micron

Retention		Mol. Weight
Time (MS)	MS Area	or Ion
2.567	19289028	196.10 I
		195.10 I
		194.10 I



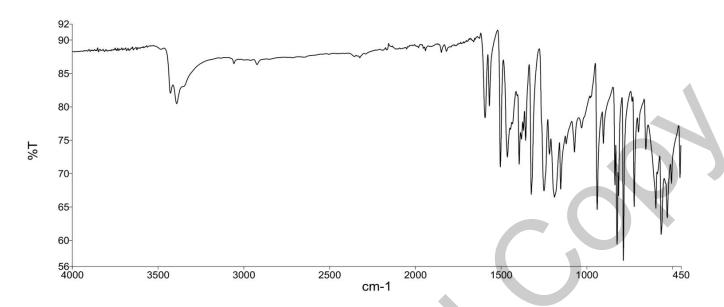
Theoretical value: 194.1 [M+H]⁺.

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

EPL-AA121 Batch 2

Ic. IR Spectrum

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



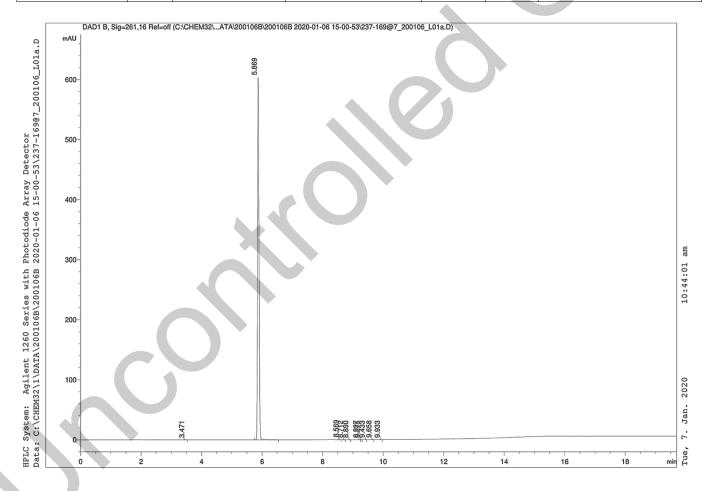
The interpretation of the signals of the Fourier-Transform Infrared Spectrum is consistent with the structural formula.

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	25°C				DAD	Auto
120 EC-C18 4.6 x 50mm	Time (min)	% Line A (Water + 0.1% (v/v) TFA)	% Line B (Acetonitrile + 0.1% (v/v) TFA)	Flow rate (mL/min)	261nm	1.0 µL 0.15 mg/mL in water (+0.1% TFA)
	0.00	95	5	1.0		water (+0.170 11A)
2.7 micron	6.00	80	20	1.0		
	13.50	5	95	1.0		
	18.50	5	95	1.0		
	19.50	95	5	1.0		
	22.50	95	5	1.0		



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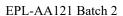
Area Percent Report - Sorted by Signal

Peak Number	Retention Time (rounded)	Area	Area % (rounded)
1	3.47	0.66	0.03
2	5.87	1971.09	99.84
3	8.57	1.86	0.09
4	8.71	0.08	0.00
5	8.89	0.05	0.00
6	9.23	0.10	0.00
7	9.27	0.10	0.01
8	9.43	0.03	0.00
9	9.66	0.23	0.01
10	9.93	0.05	0.00
Totals			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 99.8% (average of 10 duplicate analyses)



III. Water Content

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

Results:

Average 0.1%

IV. Ash Content

Method: BP 2016 Ash (Appendix XI J) as per WS001/C29155

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)	99.8%
Water content	0.1%
Ash content	<0.1%
Residual solvents	<0.1%
Purity*	99.7%

This purity is assessed to be 99.7%.

Product Reviewed By: Product Released By:

James Rixson, PhD

Boon Tan

Head of Fine Chemicals & Technical Services Quality Manager

Release Date: 7 January 2020

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

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^{*}NATA accreditation does not cover the performance of this service. The calculation of the purity follows the formula: