

CERTIFICATE OF ANALYSIS

0085 AMYLOCAINE HYDROCHLORIDE

Centipharm batch No: 0085-14-02/O

Analysis No: 14090/02

Quantity manufactured: 375 kg

Manufacturing date: 31/03/2014

Analytical method: MOP-LCA-P-0085 Edition E

Retest date: 30/03/2017

Specification code: 0085 Edition 001 application date January 31, 2008

DETERMINATIONS	SPECIFICATIONS	RESULTS
IDENTIFICATION		
✓ IDENTIFICATION	Tests A,B,C comply	tests comply
PHYSICAL-CHEMISTRY		
✓ APPEARANCE	fine to granular powder	granular powder
✓ COLOUR	white to almost white	almost white
✓ ODOUR	odourless to faint	odourless
✓ SOLUBILITY WATER 10 % (w/v)	NMT 3.0 ntu	0.4 ntu
✓ COLORATION IN WATER SOLUTION 10 % (w/v)	degree 7 max	degree 7
✓ MELTING POINT	between 175 °C and 179 °C	175 °C
✓ LOSS ON DRYING	NMT 0.5 %	0.1 %
✓ SULPHATED ASH	NMT 0.1 %	0.0 %
✓ HEAVY METALS	NMT 20 ppm	< 20 ppm
✓ CALCIUM	test complies	test complies
ASSAY		
✓ ACIDITY / ALKALINITY	NMT 0.05 ml (NaOH 0.1N or HCL 0.1N)	0.02 ml HCl 0.1N
✓ TITRATION BY HClO ₄	between 99.0 % and 101.0 %	100.7 %
✓ TITRATION BY AgNO ₃	between 99.0 % and 101.0 %	100.8 %
GC and Related Substances		
✓ NUMBER OF IMPURITIES >= 0.5 %	none	none
✓ NUMBER OF IMPURITIES BETWEEN 0.2 % AND 0.5 %	3 max	one
✓ TOTAL IMPURITIES	NMT 1.0 %	0.4 %
RESIDUAL SOLVENTS BY GC		
✓ ACETONE	NMT 1000 ppm	610 ppm

Conclusion: Complies with the specifications

On April 04, 2014, by Edouard NGUYEN
QC Manager

Decision: Accepted

On April 16, 2014, by Stéphane SUCHET
QA Manager