

Kalchem International

Chemicals & Compounding Supplies

Certificate of Analysis

Name of Product : Ketamine Hydrochloride, USP
Batch # : 5141-0182814P
Manufacture Date : July 10, 2014
Re-test Date : July 2019

<u>TESTING</u>	<u>REQUIREMENT</u>	<u>RESULTS</u>
Appearance :	White crystalline powder	Conforms
<u>Identification</u>		
A = IR :	identical versus reference spectrum	identical
B = UV		
a) acid solvent :	$\Delta a \leq 3.0\%$ at about 269 nm	0.2%
	$\Delta a \leq 3.0\%$ at about 276 nm	0.3%
b) basic solvent :	$\Delta a \leq 3.0\%$ at about 302 nm	1.0%
C = Chloride :	positive	positive
Optical rotation :	$0.0^\circ \pm 0.2^\circ$	0.0°
Assay (HPLC) :	98.0% - 102.0% (w/w)	100.9%
Assay (Titration, NaOH):	99.0% - 101.0% (w/w)	100.3%
Clarity/color of an Aqueous solution (20%):	clear and colorless	clear and colorless
Residue on Ignition :	nmf 0.10%	0.03%
Loss on Drying:	nmf 0.5%	0.0%
PH (solution, 10%) :	3.5 - 4.1	3.9
Heavy metals :	nmf 20 ppm	passed
Chromatographic purity		
Total impurities :	nmf 0.5% (area)	none
Individual knowns :	nmf 0.2% (area)	<0.05% (LOQ)
Individual unknowns:	nmf 0.10% (area)	<0.05% (LOQ)
Compound A :	nmf 0.1% (area)	<0.05% (LOQ)
Residual solvents :	complies with USP <467>	
	Nmf 300 ppm acetone	29 ppm
	Nmf 800 ppm ethyl acetate	149 ppm

Conclusion : Product is in conformity with the requirements of the Current USP and European Pharmacopoeia.

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