

Certificate of Analysis

Productname: Ketamini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-180623B
Batchnumber: 20A07-F01
Reference code / No.: 2060 / SLL/KH/1219061
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-0,2 - +0,2	Conform	°	Optical rotation
Identification B	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		Chloride
Appearance of solution	Clear / colourless	Conform		20% <i>m/V</i>
pH	3,5 - 4,1	3,9		10% <i>m/V</i>
Optical rotation	-0,2 - +0,2	0,0	°	2% <i>m/V</i>
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,2	n.d.	%	
Impurity C	<=0,2	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<=0,5	0,4	%	3U 105
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Ketamine hydrochloride	99,0 - 101,0	100,6	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/20/20

Expiration: 11-2024

Conclusion: APPROVED

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