

## Certificate of Analysis

**Productname:** Ketamini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-195064B  
**Batchnumber:** 21L13-F02-381850  
**Reference code / No.:** 4254 / SLL/KH/1121096  
**Analysed according to:** PH.EUR10.6

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	0,0	%	3U 105
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Ketamine hydrochloride	99,0 - 101,0	100,2	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:  
 Anthony Amoureux  
 Qualified Person

07/13/22

Expiration: 10-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.