

Certificate of Analysis

Product name: **Hydroxyzini hydrochloridum**

Batch number / Weight: **22C15-B08-216299 / 10 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear / $\leq Y7$	Conform		
Optical rotation	-0,10 - +0,10	0,00	°	
Related substances	Conform	Conform		
Any impurity	$\leq 0,1$	max.0,06	%	
Total impurities	$\leq 0,3$	0,11	%	
Loss on drying	$\leq 5,0$	1,07	%	
Sulphated ash	$\leq 0,1$	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Hydroxyzine hydrochloride	99,0 - 101,0	99,3	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Toluene		<25	ppm	
Methanol		<25	ppm	
Di-isopropyl ether	≤ 2000	131	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

07-07-2022

Expiration: 30-11-2026

Conclusion: APPROVED

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