

## Certificate of Analysis

**Product name:** **Hydroxyzini hydrochloridum**

**Batch number / Weight:** **22C15-B08-236044 / 10 G**

**Analysed according to:** **Ph.Eur.11**

**Number of analysis / Inspection Code** **22C15-B08 / INS-22-4939**

**Reference Code / No.:** **V01812 / 21006HDARII**

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	$\leq 890$	<25	ppm	
Methanol	$\leq 2000$	<25	ppm	
Di-isopropyl ether	$\leq 2000$	131	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

04-04-2024

Expiration: 30-11-2026

Conclusion: APPROVED

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