

Certificate of Analysis

Productname: Hydroxyzini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-184441B
Batchnumber: 18I26-B11-370894
Reference code / No.: 2194 / 110718014
Analysed according to: PH.EUR 9.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		Hygroscopic
Identification A	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chloride
Appearance of solution	Clear / $\leq Y7$	Conform		10% <i>m/V</i>
Optical rotation	-0,10 - +0,10	-0,06	°	10% <i>m/V</i>
Related substances	Conform	Conform		HPLC
Any impurity	$\leq 0,1$	$\leq 0,03$	%	
Total impurities	$\leq 0,3$	$\leq 0,3$	%	
Loss on drying	$\leq 5,0$	0,5	%	105°C
Sulphated ash	$\leq 0,1$	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Hydroxyzine hydrochloride	99,0 - 101,0	99,5	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

07/22/20

Expiration: 05-2023

Conclusion: APPROVED

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