

Certificate of Analysis

Productname: Histamini dihydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-187349B
Batchnumber: 20J15-F03-375120
Reference code / No.: 1279 / 2007051.0969
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		Hygroscopic
Identification A	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear / <= Y7	Conform		5% <i>m/V</i>
pH	2,85 - 3,60	3,26		5% <i>m/V</i>
Histidine	Conform	Conform	%	TLC
Sulphates	<= 0,1	Conform	%	
Loss on drying	<= 0,5	0,1	%	105 °C
Sulphated ash	<= 0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Histamine dihydrochloride	98,5 - 101,0	100,0	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/26/20

Expiration: 07-2023

Conclusion: APPROVED

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