

Certificate of Analysis

Productname: Pseudoephedrini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-180207B
Batchnumber: 18L27-B01-367095
Reference code / No.: 1982 / 214318
Analysed according to: PH.EUR 9.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+61,0 - +62,5	Conform		Optical rotation; dried
Identification B	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear / colourless	Conform		5% m/V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	+61,0 - +62,5	62,2		5% m/V; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	< 1,0	%	
Any other impurity	<=0,5	< 0,5	%	
Sum of impurities other than A	<=1,0	< 1,0	%	
Loss on drying	<=0,5	0,1	%	105°C
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 Pseudoephedrine hydrochloride	99,0 - 101,0	100,7	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/06/20

Expiration: 10-2023

Conclusion: APPROVED

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