

Certificate of Analysis

Productname: Ephedrini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-180706B
Batchnumber: 18J11-B02-367911
Reference code / No.: 1982 / 107718
Analysed according to: PH.EUR 9.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear / colourless	Conform		10% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-33,5 - -35,5	-34,1		5% <i>m/V</i> ; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=0,2	n.d.	%	
Unspecified impurities	<=0,1	n.d.	%	
Sum of impurities other than A	<=0,5	n.d.	%	
Sulphates	<=100	Conform	ppm	
Loss on drying	<=0,5	0,1	%	105 °C
Sulphated ash	<=0,1	0,07	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Ephedrine hydrochloride	99,0 - 101,0	100,4	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

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

02/25/20

Expiration: 08-2023

Conclusion: APPROVED

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