

Certificate of Analysis

Product name: Ephedrini hydrochloridum
Batch number / Weight: 19F27-B03-194401 / 10 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification B	Conform	Conform		
Identification E	White	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-33,5 - -35,5	-34,02	°	
Related substances	Conform	Conform		
Impurity A	<=0,2	0,0	%	
Unspecified impurities	<=0,1	<0,05	%	
Sum of impurities other than A	<=0,5	0,0	%	
Sulphates	<=100	Conform	ppm	
Loss on drying	<=0,5	0,06	%	
Sulphated ash	<=0,1	Conform	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Ephedrine hydrochloride	99,0 - 101,0	100,39	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dorota Sutkowska
 Qualified Person

25-10-2019

Expiration: 31-08-2023

Conclusion: APPROVED

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