

Certificate of Analysis

Product name: **Ephedrini hydrochloridum**

Batch number / Weight: **21K18-B08-213801 / 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		
Melting point	about 219	220,3	°C	
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-33,5 - -35,5	-34,9		
Related substances	Conform	Conform		
Impurity A	<=0,2	0,00	%	
Unspecified impurities	<=0,1	<0,05	%	
Sum of impurities other than A	<=0,5	0,00	%	
Sulphates	<=100	Conform	ppm	
Loss on drying	<=0,5	0,03	%	
Sulphated ash	<=0,1	0,03	%	
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	100,55	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

05-03-2022

Expiration: 30-06-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.