

Certificate of Analysis

Product name: **Ephedrini hydrochloridum**

Batch number / Weight: **21K18-B08-223005 / 10 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21K18-B08 / INS-22-0689**

Reference Code / No.: **V00884 / 109021**

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

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

05-10-2022

Expiration: 30-06-2026

Conclusion: APPROVED

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