

Certificate of Analysis

Product name: **Phenylephrini hydrochloridum**

Batch number / Weight: **22L02-B11-226291 / 5 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22L02-B11 / INS-23-0150**

Reference Code / No.: **V01714 / PEH-220508**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-43 - -47	Conform		
Identification C	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	Conform	0,2ml HCl 0,0		
Specific optical rotation	-43 - -47	-46,3		
Related substances	Conform	Conform		
Impurity C	<=0,1	0,00	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10 each	0,046	%	
Total impurities	<=0,2	0,05	%	
Sulphates	<=500	<500	ppm	
Loss on drying	<=1,0	0,01	%	
Sulphated ash	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Phenylephrine hydrochlori	98,5 - 101,0	100,59	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<= 3000	<3000	ppm	
Ethanol	<= 5000	<5000	ppm	
Isopropanol	<= 5000	<5000	ppm	

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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

Release:
Ewelina Gadzinowska
Qualified Person

25-01-2023

Expiration: 22-04-2025

Conclusion: APPROVED

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