

Certificate of Analysis

Product name: **Metformini hydrochloridum**

Batch number / Weight: **22C04-B02-216773 / 500 G**

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

Number of analysis / Inspection Code **22C04-B02 / INS-22-5136**

Reference Code / No.: **V01635 / A-22612111025**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or white crystals	Conform		
Identification B	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Impurity F	$\leq 0,05$	0,001	%	
Related substances	Conform	Conform		
Impurity A	$\leq 0,02$	0,001	%	
Unspecified impurities	$\leq 0,05$	0,03	%	
Total impurities	$\leq 0,2$	0,00	%	
Loss on drying	$\leq 0,5$	0,01	%	
Sulphated ash	$\leq 0,1$	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Metformine hydrochloride	98,5 - 101,0	99,46	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	≤ 3000	<3000	ppm	
Benzene	≤ 2	<2	ppm	
Toluene	≤ 890	<890	ppm	
Dimethylformamide	≤ 880	<880	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

26-08-2022

Expiration: 31-10-2026

Conclusion: APPROVED

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