

Certificate of Analysis

Product name: **Metoclopramidi hydrochloridum**

Batch number / Weight: **22A14-B04-218001 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification A	4,5 - 6,0	Conform		
Identification B	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Impurity E	<=0,5	<0,5		Data producer
Related substances	Conform	Conform		Data producer
Unspecified impurities	<= 0,10	<0,05	%	
Total impurities	<=0,2	0,00	%	
Water	4,5 - 5,5	5,08	%	
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
Metoclopramide hydrochloride	99,0 - 101,0	100,71	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
2-Propanol	<5000	<5000	ppm	
Methanol	<3000	0	ppm	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

15-04-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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