

Certificate of Analysis

Product name: **Domperidonum**
Batch number / Weight: **21B11-B08-215884 / 10 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification C	244 - 248	247	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear <=Y6	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,25	<0,05	%	
Impurity B	<=0,25	<0,05	%	
Impurity C	<=0,25	<0,05	%	
Impurity D	<=0,25	0,14	%	
Impurity E	<=0,25	<0,05	%	
Impurity F	<=0,25	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,5	%	
Loss on drying	<=0,5	0,1	%	
Sulphated ash	<=0,1	Conform	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

27-09-2021

Expiration: 30-06-2023

Conclusion: APPROVED

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