

## Certificate of Analysis

**Product name:** **Domperidonum**

**Batch number / Weight:** **21B17-B20-215885 / 10 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification C	244 - 248	244,77	°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	0,00	%	
Impurity C	≤0,25	0,00	%	
Impurity D	≤0,25	0,148	%	
Impurity E	≤0,25	0,00	%	
Impurity F	≤0,25	<0,05	%	
Unspecified impurities	≤0,10	0,052	%	
Total impurities	≤0,5	0,200	%	
Loss on drying	≤0,5	0,08	%	
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
Assay	99,0 - 101,0	99,27	%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: 30-11-2024

Conclusion: APPROVED

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