

## Certificate of Analysis

**Product name:** Domperidonum  
**Batch number / Weight:** 20H10-F02-217129 / 10 G  
**Analysed according to:** Ph.Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification C	244 - 248	245	°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	0,15	%	
Impurity E	<=0,25	0,00	%	
Impurity F	<=0,25	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,5	0,2	%	
Loss on drying	<=0,5	0,1	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
 Ewelina Gadzinowska  
 Qualified Person

10-12-2021

Expiration: 30-11-2024

Conclusion: APPROVED

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