

## Certificate of Analysis

**Productname:** Domperidonum  
**Number of analysis/Inspection Code:** 1 / KEUR-185580B  
**Batchnumber:** 20H10-F02-373110  
**Reference code / No.:** 4207 / 090DN19-20  
**Analysed according to:** PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	244 - 248	245	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear <=Y6	Conform		1% <i>m/V</i> in dimethylformamide
Related substances	Conform	Conform		HPLC
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	%	105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Domperidon	99,0 - 101,0	99,3	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

09/09/20

Expiration: 11-2024

Conclusion: APPROVED

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