

Certificate of Analysis

Product name: Domperidonum
Batch number / Weight: 24A11-B10-003259 / 10 g
Analyzed according to: Ph.Eur.11.5
Number of Analysis / Certificate no.: 24A11-B10 / QO0005972
Reference code / No.: V02332 / DMP-19223

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear <=Y6	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,2	0,12	%	
Sum of impurities D and E	<=0,25	0,14	%	
Unspecified impurities	for each <=0,10	0,068	%	
Total impurities	<=0,5	0,37	%	
Loss on drying	<=0,5	0,08	%	
Residue on ignition	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
Assay	99,0 - 101,0 (dried substance)	99,76	% m/m	

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:

22-10-2024
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-10-2028

Conclusion: APPROVED

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