

Certificate of Analysis

Product name: **Loperamidi hydrochloridum**

Batch number / Weight: **21E18-B06-213907 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
IR-spectrum	Conform	Conform		
Related substances	Conform	Conform		
Impurity B	$\leq 0,2$	$< 0,05$	%	
Impurity D	$\leq 0,2$	$< 0,05$	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 0,3$	$< 0,05$	%	
Loss on drying	$\leq 0,5$	0,04	%	
Sulphated ash	$\leq 0,1$	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Loperamide hydrochloride	99,0 - 101,0	99,1	%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

29-12-2021

Expiration: 30-11-2024

Conclusion: APPROVED

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