Certificate of Analysis

Product name: **Loperamidi hydrochloridum**

Batch number / Weight: **21K10-B07-223135 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21K10-B07 / INS-21-5921**

Reference Code / No.: **V01498 / LPD/1912018**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
IR-spectrum	Conform	Conform		
Related substances	Conform	Conform		
Impurity B	<=0,2	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	<0,05	%	
Loss on drying	<= 0,5	0,04	%	
Sulphated ash	<= 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

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, Eurofins

Release:
Ewelina Gadzinowska
Qualified Person

28-10-2022

Expiration: 30-11-2024

Conclusion: APPROVED

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