Certificate of Analysis

Product name: Naltrexoni hydrochloridum
Batch number / Weight: 24A19-B03-239978 / 25 g
Producer / Producer Batch Number: Saneca Pharmaceuticals a.s /
Analyzed according to: Ph. Eur.11
Number of Analysis / Certificate no.: 24A19-B03 / QO0005150

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder, very hygroscopic	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / <=Y6 or B6	Conform		
Acidity or alkalinity	<=0,2ml HCl or NaOH (0,02 mol/l)	0,05 NaOH	ml	
Specific optical rotation	-187 - -195	-191		
Related substances	Conform	Conform		
Impurity C	<=0,2	0,17	%	
Impurity D	<=0,2	<0,05	%	
Impurity E	<=0,2	<0,05	%	
Impurity F	<=0,2	<0,05	%	
Impurity G	<=0,2	0,06	%	
Impurity A	<=0,1	0,00	%	
Impurity B	<=0,1	0,07	%	
impurity H	<=0,1	0,00	%	
Impurity I	<=0,1	0,06	%	
Impurity J	<=0,1	<0,05	%	
Any impurity	<=0,1	0,05	%	
Total impurities	<=1,0	0,39	%	
Ethanol	<=3,0	0,93	%	
Water (Karl Fischer)	<=10,0	0,76	%	
Sulfated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	98,0 - 102,0	100,90	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

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 Own lab

Release:
9-10-2024

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Certificate of Analysis

	Requirement	Result	Unit	Standard remark

Agnieszka Pszczółka
Qualified Person

Expiration: 30-11-2026
Conclusion: APPROVED

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

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