Saneca Pharmaceuticals

KalChem INTERNATIONAL Compounding Chemicals You Can Trust

Certificate of Analysis

Product number	**12004744**		
Product	**NALTREXONE HYDROCHLORIDE**		
Batch number	**3141125**	*Batch LIMS HV*	819644
Manufacturing date	25.11.2025	*Released quantity*	2,401 kg
Retest date	31.10.2028	*Analysis date*	23.04.2026
Specification	PNA 12004744/17-04	*Pharmacopoeia*	USP
In-house appendix	ID-01	*CEP Number*	-

Test	*Limits*	*Results*
Appearance		
Appearance	white or almost white powder, very hygroscopic	complies
Identification		
IR spectrum	corresponds to IR spectrum of reference standard	positive
HPLC	concordant retention time	positive
Assay HPLC		
Assay (calculated on anhydrous and solvent free substance)	98.0 % to 102.0 %	100.5 %
Residue on ignition		
Residue on ignition	NMT 0.1 %	0.0 %
Total solvents	NMT 5.0 %	2.0 %
Related substances HPLC		
Noroxymorphone	NMT 0.5 %	ND
10-hydroxynaltrexone	NMT 0.5 %	ND
Related compound A	NMT 0.5 %	<0.05 %
2,2´-bisnaltrexone	NMT 0.5 %	<0.05 %
10-ketonaltrexone	NMT 0.5 %	ND
Unspecified impurities each	NMT 0.10 %	<0.05 %
RRT		N/A
Total impurities	NMT 1.5 %	<0.05 %
Content of chloride (calculated on anhydrous and solvent free substance)	9.20 % to 9.58 %	9.33 %
Specific rotation (calculated on anhydrous and solvent free substance)	-197 ° to -187 °	-189 °
Water content		
Water	NMT 5.0 %	0.39 %
Clarity of solution	NMT 3 NTU	0.58 NTU
Residual solvents		
Residual solvents		
Ethanol	NMT 30 000 ppm	16451 ppm
Cyclopentyl methyl ether	NMT 150 ppm	4 ppm
Cyclopropylmethyl bromide		

Saneca Pharmaceuticals

KalChem INTERNATIONAL Compounding Chemicals You Can Trust

Certificate of Analysis

Product number	**12004744**		
Product	**NALTREXONE HYDROCHLORIDE**		
Batch number	**3141125**	*Batch LIMS HV*	819644
Manufacturing date	25.11.2025	*Released quantity*	2,401 kg
Retest date	31.10.2028	*Analysis date*	23.04.2026
Specification	PNA 12004744/17-04	*Pharmacopoeia*	USP
In-house appendix	ID-01	*CEP Number*	-

Cyclopropylmethyl bromide	NMT 10 ppm	ND
Microbiological quality Ph.Eur. (5.1.4)		
Total aerobic microbial count (TAMC)	NMT 1 000 CFU/g	0 CFU/g
Total combined yeasts/moulds count (TYMC)	NMT 100 CFU/g	0 CFU/g

THE PRODUCT CONFORMS TO SPECIFICATION

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured including packaging and quality control at site fully operating in compliance with EU GMP requirements, the local Regulatory Authority and the marketing authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Released for sale

Manufacturing site:

Saneca Pharmaceuticals a.s, Nitrianska 100
920 27 Hlohovec, Slovak republic
Authorization number: SK/001A/2023
GMP Certificate No: SK/017V/2023

Quality control and release site:

Saneca Pharmaceuticals a.s, Nitrianska 100
920 27 Hlohovec, Slovak republic
Authorization number: SK/001A/2023
GMP Certificate No: SK/017V/2023

Certified by QP: Zavadil Vladimír

Certified on: 24.04.2026

Saneca Pharmaceuticals a.s.
Nitrianska 100
920 27 Hlohovec
Slovenská republika
IČO: 46 833 323
IČ DPH: SK2023599842