Certificate of Analysis

Product name: Naltrexoni hydrochloridum
Batch number / Weight: 25G28-B02-014614 / 25 g
Producer / Producer Batch Number: Temad Co. Active pharmaceutical Ingredients / NAH4030802
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25G28-B02 / QO0021214

	Requirement	Result	Unit	Standard remark
Appearance	White or almost white powder, very hygroscopic	Conform		
Identification	A, B	Conform		
Appearance of solution	Clear / <= Y6 or B6	Conform		
Acidity or alkalinity	<= 0,2 ml of NaOH (0,02M) or HCl (0,02M)	0,10 (NaOH)	ml	
Specific optical rotation	(-195) - (-187)	-190,6		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity C	<= 0,2	0,06	%	
Impurity D	<= 0,2	0,11	%	
Impurity E	<= 0,2	0,20	%	
Impurity F	<= 0,2		ppm	
Impurity G	<= 0,2	< 0,05	%	
Impurity A	<= 0,1	< 0,05	%	
Impurity B	<= 0,1	< 0,05	%	
Impurity H	<= 0,1	< 0,05	%	
Impurity I	<= 0,1	< 0,05	%	
Impurity J	<= 0,1	< 0,05	%	
Any other impurity	<= 0,1	< 0,05	%	
Total impurities	<= 1,0	0,36	%	
Ethanol	<= 3,0	0,26	%	
Water	<= 10,0	1,96	%	
Sulfated ash	<= 0,1	0,00	%	
Assay	98,0 - 102,0	100,20	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		

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 FSNE

Release:

3-9-2025

Ewelina Gadzinowska

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Certificate of Analysis

	Requirement	Result	Unit	Standard remark
Qualified Person				

Expiration: 26-5-2030
Conclusion: APPROVED

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

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