



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242139

Product:	Naltrexone hydrochloride
Lot:	242139
Expiry date:	01/02/2029
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C ₂₀ H ₂₄ ClNO ₄
Molecular weight:	377.9 g/mol

Assay	Result	Specification	
Unspecified Impurities	< 0,05 %	<= 0,1 %	
Impurity J	< 0,05 %	<= 0,1 %	
Impurity I	< 0,05 %	<= 0,1 %	
Impurity H	< 0,05 %	<= 0,1 %	
Sulphated ashes	0,02 %	<= 0,1 %	
Water	0,54 %	<= 10,0 %	
Total impurities	< 1,0 %	<= 1,0 %	
Impurity C	< 0,05 %	<= 0,2 %	
Impurity B	< 0,05 %	<= 0,1 %	
Impurity A	< 0,05 %	<= 0,1 %	
Related substances (HPLC)	Conform		
Impurity G	0,18 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,2 %	
Impurity D	< 0,05 %	<= 0,2 %	
Identification	Conform (A,B)		
Nitrosamine impurities	Conform		#
Elemental impurities	Conform		#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Specific rotation	-187	(-187) - (-195)	
Acidity or alkalinity	Conform		
Appearance of solution	Conform		
Organoleptic properties	Conform		
Assay	99,3 %	98,0 -102,0 %	

Organoleptic characteristics: White or almost white powder, very hygroscopic. Freely soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.

Conservation: In tightly closed containers. Protect from light and moisture.

Date of analysis: 29/01/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMIKALIEN MINDEN GmbH

Manufacturer batch: 24052125

Product	Name	Capacity	Batch
1126480	NALTREXONA CLORHIDRATO	5 g	242139-E-1
1126480	NALTREXONA CLORHIDRATO	5 g	242139-E-2
1126481	NALTREXONA CLORHIDRATO	10 g	242139-F-1
1126481	NALTREXONA CLORHIDRATO	10 g	242139-F-2
1126482	NALTREXONA CLORHIDRATO	50 g	242139-I-1
1126482	NALTREXONA CLORHIDRATO	50 g	242139-I-2

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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