



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 260594**

Product:	Naltrexone hydrochloride
Lot:	260594
Expiry date:	12/02/2031
Reference:	Cumple PhEur12.2
Synonyms:	
Formula:	C <sub>20</sub> H <sub>24</sub> ClNO <sub>4</sub>
Molecular weight:	377.9 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)		
Organoleptic properties	Conform		
Appearance of solution	Conform		
Acidity or alkalinity	Conform		
Specific rotation	-190	(-187) - (-195)	
Related substances (HPLC)	Conform		
Impurity A	< 0,05 %	<= 0,1 %	
Impurity B	< 0,05 %	<= 0,1 %	
Impurity C	< 0,05 %	<= 0,2 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity E	< 0,05 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,2 %	
Impurity G	< 0,05 %	<= 0,2 %	
Impurity H	< 0,05 %	<= 0,1 %	
Impurity I	< 0,05 %	<= 0,1 %	
Impurity J	< 0,05 %	<= 0,1 %	
Unspecified Impurities	< 0,05 %	<= 0,1 %	
Total impurities	< 1,0 %	<= 1,0 %	
Ethanol	2,6 %	<= 3,0 %	
Water	0,42 %	<= 10,0 %	
Sulphated ashes	0,03 %	<= 0,1 %	
Assay	100,3 %	98,0 -102,0 %	
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

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.

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Date of analysis: 13/05/2026

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMIKALIEN MINDEN GmbH

Manufacturer batch: 26072109

Product	Name	Capacity	Batch
1126480	NALTREXONA CLORHIDRATO	5 g	260594-E-1
1126481	NALTREXONA CLORHIDRATO	10 g	260594-F-1
1126482	NALTREXONA CLORHIDRATO	50 g	260594-I-1
1126483	NALTREXONA CLORHIDRATO	100 g	260594-J-1

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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C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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