METAPHARMACEUTICAL IND SL
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NALTREXONA HCL (EUR. PH.)

PRODUCT CODE: 002843	CAS Nº: 16676-29-2	ANALYSIS Nº: 265/25	
MANUFACTURER BATCH:	NAH4030802	CERTIFICATE ID:	47.905
SUPPLIER BATCH:	----	MANUFACTURING DATE:	26/05/2025
METAPH BATCH:	0060825	EXPIRY DATE:	26/05/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder, very hygroscopic	White powder, very hygroscopic
Solubility	Freeky soluble in water, slightly soluble in ethanol (96 %), practically insoluble in methylene chloride	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured the ref. sol. Y6 or BY6	Complies
Acidity or alkalinity	<= 0.2 mL of NaOH 0.02M or HCl 0.02M	0.05 mL of 0.02M NaOH
Specific optical rotation	-187 / -195	-194
Related substances		
Impurity C	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	0.1 %
Impurity E	=< 0.2 %	0.2 %
Impurity F	=< 0.2 %	< 0.05 %
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 %	0.3 %
Ethanol	=< 3.0 %	0.3 %
Water	=< 10.0 %	1.5 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.0 - 102.0 %	98.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Naltrexone Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the

Analysis date: 28/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001545
TEMAD CO.
Karaj Makhsous Road, 28th km
Tehran
(Irán)

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product before use.

STORAGE

Keep the containers hermetically closed, protected from light and heat.

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