METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

002843-TDS-ENG-2025

NALTREXONA HCL (EUR. PH.)		
DESCRIPTION DCI: NALTREXONE HYDROCHLORIDE	DESCRIPTION DOE: NALTREXONA HIDROCLORURO	
CAS Nº: 16676-29-2	EC Nº: 240-723-0	AEMPS CODE: 2458CH
MOL. WEIGHT: 377,9	MOL. FORMULA: C20H24ClNO4	ARTICLE CODE: 002843

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder, very hygroscopic
Solubility	Freeky soluble in water, slightly soluble in ethanol (96 %), practically insoluble in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured the ref. sol. Y6 or BY6
Acidity or alkalinity	<= 0.2 mL of NaOH 0.02M or HCl 0.02M
Specific optical rotation	-187 / -195
Related substances	
Impurity C	=< 0.2 %
Impurity D	=< 0.2 %
Impurity E	=< 0.2 %
Impurity F	=< 0.2 %
Impurity G	=< 0.2 %
Impurity A	=< 0.1 %
Impurity B	=< 0.1 %
Impurity H	=< 0.1 %
Impurity I	=< 0.1 %
Impurity J	=< 0.1 %
Any other impurity	=< 0.1 %
Total impurities	=< 1.0 %
Ethanol	=< 3.0 %
Water	=< 10.0 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.

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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 product before use.