



S.A.L.A.R.S. S.p.A.
(Società Azionaria Laboratori Alcaloidi Riformamenti Sanitari)
Via San Francesco n° 5 - 22100 COMO ITALY
Tel. 0039 031 520610 / 031 524095 Fax 0039 031 520751
Internet: <http://www.salars.it> E-mail: contact@salars.it

CERTIFICATE OF ANALYSIS

Product		NALTREXONE HYDROCHLORIDE		Date of manufacture			
Batch N.		F19080177		10/09/2019			
Retest date		10/09/2024					
Analysis record N.		23042		According to Current E.P. and Certificate of suitability R1-CEP 2006-117-Rev 02			
Tests		Results		Specification		Units	
1 Characters							
Appearance		Complies		White or almost white powder, very hygroscopic			
Solubility		Complies		Freely sol. in water, slightly sol. in ethanol 96 %, practically insol. in methylene chloride			
2 Identification							
A) IR Spectrum (2.2.24)		Complies		Complies with standard			
B) Reaction (a) of chloride (2.3.1)		Positive		Positive			
3 Appearance of solution S (2.2.1)		Clear Complies		Clear ≤ Y ₆ or B ₆		ml	
4 Acidity or alkalinity		0.05		≤ 0.2 (HCl or NaOH 0.02 M)		degrees	
5 Specific optical rotation (a.s., 2.2.7)		-193		Between -195 and -187			
6 Related substances (HPLC, 2.2.29)							
Impurity A		nd		≤ 0.1		percent	
Impurity B		<0.05		≤ 0.1		percent	
Impurity C		<0.05		≤ 0.2		percent	
Impurity D		<0.05		≤ 0.2		percent	
Impurity E		<0.05		≤ 0.2		percent	
Impurity F		<0.05		≤ 0.2		percent	
Impurity G		<0.05		≤ 0.2		percent	
Impurity H		<0.05		≤ 0.1		percent	
Impurity I		<0.05		≤ 0.1		percent	
Impurity J		<0.05		≤ 0.1		percent	
Any other impurity (unspecified)		nd		≤ 0.1 (each)		percent	
Unknown impurities		<0.05		≤ 0.10 (each)		percent	
Total		<0.05		≤ 1.0		percent	
7 Residual solvents							
Ethanol		12		≤ 5000		ppm	
8 Water (2.5.12)		7.6		≤ 10.0		percent	
9 Sulfated ash (2.4.14)		0.06		≤ 0.1		percent	
10 Assay (a.s., 2.2.20)		99.8		Between 98.0 and 102.0		percent	
Notes		Assay date 12/09/2019		The head of Q.C. department 			
a.s. = anhydrous substance nd = not detected (below detection limit) Disregard limit for HPLC impurities = 0.05 percent (LOQ) Storage: in an airtight container, protected from light							