

Salars

DAL 1932

Salars

S.A.L.A.R.S. S.p.A.

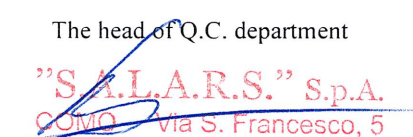
(Società Azionaria Laboratori Alcaloidi Rifornimenti Sanitari)

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	25/03/2019
Batch N.		F19030111		Retest date	25/03/2024
Analysis record N.		22890		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) (2.2.2, method II)	Clear Complies	Clear ≤ Y ₆ or B ₆		
4	Acidity or alkalinity	0.08	≤ 0.2 (HCl or NaOH 0.02 M)	ml	
5	Specific optical rotation (a.s., 2.2.7)	-189	Between -195 and -187	degrees	
6	Related substances (HPLC, 2.2.29)				
	Impurity A	<0.05	≤ 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	nd	≤ 0.1	percent	
	Impurity I	nd	≤ 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	9	≤ 5000	ppm	
8	Water (2.5.12)	5.6	≤ 10.0	percent	
9	Sulfated ash (2.4.14)	0.06	≤ 0.1	percent	
10	Assay (a.s., 2.2.20)	100.4	Between 98.0 and 102.0	percent	
Notes			The head of Q.C. department		
a.s. = anhydrous substance		Assay date			
nd = not detected (below detection limit)					
Disregard limit for HPLC impurities = 0.05 percent (LOQ)		27/03/2019			
Storage: in an airtight container, protected from light					