



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

(Società Azionaria Laboratori Alcaloidi Rifornimenti Sanitari)

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CERTIFICATE OF ANALYSIS

Product NALTREXONE HYDROCHLORIDE		Date of manufacture 11/2016		
Batch N.	NT 5/2016	Net weight		Retest date 10/2021
Analysis record N.	22377	N. of packages	According to Current E.P. and Certificate of suitability R1-CEP 2006-117-Rev 01	
	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	0.06	≤ 0.2 (HCl or NaOH 0.02 M)	ml
5	Specific optical rotation (a.s., 2.2.7)	-188	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	<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	16	≤ 5000	ppm
8	Water (2.5.12)	5.0	≤ 10.0	percent
9	Sulphated ash (2.4.14)	0.06	≤ 0.1	percent
10	Assay (a.s., 2.2.20)	99.7	Between 98.0 and 102.0	percent
Notes 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		Assay date 02/12/2016	The head of Q.C. department "S.A.L.A.R.S." S.p.A. COMO Via S. Francesco, 5	