

DAL 1932

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

Sede e luogo di produzione:

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CERTIFICATE OF ANALYSIS

Product NALTREXONE HYDROCHLORIDE		Date of manufacture 04/2011	
Batch N. NT 2/2011		Net weight	
Analysis record N. 21268		Retest date 03/2016	
N. of packages		According to Current E.P. and Certificate of suitability R0-CEP 2006-117-Rev 00	
1	Tests	Results	Specifications
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)	Complies Complies	Clear ≤ Y ₆ or B ₆
4	Acidity or alkalinity	0.08	≤ 0.2 (HCl or NaOH 0.02 M)
5	Specific optical rotation (a.s., 2.2.7)	-190	Between -195 and -187
6	Related substances (HPLC, 2.2.29)		
	Impurity A	<0.05	≤ 0.1
	Impurity B	0.09	≤ 0.1
	Impurity C	<0.05	≤ 0.2
	Impurity D	nd	≤ 0.2
	Impurity E	<0.05	≤ 0.2
	Impurity F	<0.05	≤ 0.2
	Impurity G	<0.05	≤ 0.2
	Impurity H	<0.05	≤ 0.1
	Impurity I	nd	≤ 0.1
	Impurity J	<0.05	≤ 0.1
	Any other impurity (unspecified)	nd	≤ 0.1 (each)
	Unknown impurities	0.09	≤ 0.10 (each)
	Total	0.24	≤ 1.0
7	Residual solvents		
	Ethanol	8	≤ 5000
8	Water (2.5.12)	7.2	≤ 10.0
9	Sulphated ash (2.4.14)	0.05	≤ 0.1
10	Assay (a.s., 2.2.20)	100.1	Between 98.0 and 102.0
Notes		The head of Q.C. department	
a.s. = anhydrous substance		S.A.L.A.R.S. S.p.A.	
nd = not detected (under detection limit)		QUALIFIED PERSON	
Disregard limit for HPLC impurities = 0.05 percent (LOQ)		(Dr. Claudio Caraffi)	
Storage: in an airtight container, protected from light		03/05/2011	