

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

Sede e luogo di produzione:

Via San Francesco n° 5 - 22100 COMO ITALY

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CERTIFICATE OF ANALYSIS

Product		NALTREXONE HYDROCHLORIDE	
Batch N.	NT 2/2011	Net weight	
Analysis record N.	21268	N. of packages	According to Current E.P. and Certificate of suitability R0-CFP 2006-117-Rev 00
Tests		Results	Specifications
1	Characters	Complies	White or almost white powder, very hygroscopic
2	Identification	Complies	Freely sol. in water, slightly sol. in ethanol 96 %, practically insol. in methylene chloride
3	Appearance of solution S	Complies	Clear
4	Acidity or alkalinity	Complies	≤ Y ₆ or B ₆
5	Specific optical rotation (a.s., 2.2.7)	-190	Between -195 and -187
6	Related substances (HPLC, 2.2.29)	<0.05	≤ 0.1
7	Residual solvents	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		Assay date	The head of Q.C. department
a.s. = anhydrous substance nd = not detected (under detection limit) Disregard limit for HPLC impurities = 0.05 percent (LOQ) Storage: in an airtight container, protected from light		03/05/2011	S.A.L.A.R.S. S.p.A. QUALIFIED PERSON (Dr. Claudio Caraffi)