

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	
Tests	Results	Specifications	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)	Complies 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)	-190	Between -195 and -187	degrees
6 Related substances (HPLC, 2.2.29)			
Impurity A	<0.05	≤ 0.1	percent
Impurity B	0.09	≤ 0.1	percent
Impurity C	<0.05	≤ 0.2	percent
Impurity D	nd	≤ 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	nd	≤ 0.1	percent
Impurity J	<0.05	≤ 0.1	percent
Any other impurity (unspecified)	nd	≤ 0.1 (each)	percent
Unknown impurities	0.09	≤ 0.10 (each)	percent
Total	0.24	≤ 1.0	percent
7 Residual solvents			
Ethanol	8	≤ 5000	ppm
8 Water (2.5.12)	7.2	≤ 10.0	percent
9 Sulphated ash (2.4.14)	0.05	≤ 0.1	percent
10 Assay (a.s., 2.2.20)	100.1	Between 98.0 and 102.0	percent
Notes 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	Assay date 03/05/2011	The head of Q.C. department S.A.L.A.R.S. S.p.A. QUALIFIED PERSON (Dr. Claudio Caraffi) 	