S.A.L.A.R.S. S.p.A.
Sede e luogo di produzione:
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 04/2011
Batch N. NT 2/2011	Net weight		Retest date 03/2016
Analysis record N. 21268	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)	Complies	Clear	
	(2.2.2, method II)	Complies	≤ 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)