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 03/2015
Batch N. NT 2/2015	Net weight g 2500		Retest date 02/2020
Analysis record N. 22101	N. of packages 5	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)	Complies	Clear	
	(2.2.2, method II)	Complies	≤ Y_6 or B_6	
4	Acidity or alkalinity	0.10	≤ 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	nd	≤ 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	0.09	≤ 0.2	percent
	Impurity F	<0.05	≤ 0.2	percent
	Impurity G	<0.05	≤ 0.2	percent
	Impurity H	nd	≤ 0.1	percent
	Impurity I	nd	≤ 0.1	percent
	Impurity J	nd	≤ 0.1	percent
	Any other impurity (unspecified)	nd	≤ 0.1 (each)	percent
	Unknown impurities	0.06	≤ 0.10 (each)	percent
	Total	0.15	≤ 1.0	percent
7	Residual solvents			
	Ethanol	6	≤ 5000	ppm
8	Water (2.5.12)	9.6	≤ 10.0	percent
9	Sulphated ash (2.4.14)	0.06	≤ 0.1	percent
10	Assay (a.s., 2.2.20)	99.8	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

28/03/2015

The head of Q.C. department

S.A.L.A.R.S. S.p.A.
QUALIFIED PERSON
(Dr. Claudio Gerelli)