



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

(Società Azionaria Laboratori Alcoloidi Riformimenti Sanitari)

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

Certificate 0000001253 Print date 16.02.2023 Page / Pages 1 / 2

Article 05NT00 **NALTREXONE HYDROCHLORIDE**

Lot F23010011
Production date 01/02/2023 Retest date 01/02/2028
Approval date 13/02/2023 09:57:53 Approval user Luca Braga

According to Current E.P. and Certificate of Suitability
R1-CEP-2006-117-Rev 02

Test Test method	Test results	Specification		Complies (C - NC)
		Lower limit / Unit	Upper limit / Unit	
APPEARANCE SLS0010_NN	Complies	White or almost white crystalline powder, very hygroscopic		C
SOLUBILITY SLS0020_NN	Complies	Freely soluble in water, slightly soluble in ethanol 96%, practically insoluble in methylene chloride		C
IR IDENTIFICATION EP 2.2.24	Complies	Complies		C
REACTION (A) CHLORIDES EP 2.3.1	Complies	Positive		C
APPEARANCE OF SOLUTION S EP 2.2.1	Complies	Clear		C
METHOD II EP 2.2.2	Complies	≤Y6 or BY6		C
ACIDITY/ALKALINITY SLS0050_ML1	0,1 ml	≤	0,2 ml	C
SPECIFIC OPTICAL ROTATION EP 2.2.7	-191 Degrees	≥ -195	Degrees ≤ -187 Degrees	C
IMPURITY A EP 2.2.29	ND	≤	0,1 %	C
IMPURITY B EP 2.2.29	ND	≤	0,1 %	C
IMPURITY C EP 2.2.29	ND	≤	0,2 %	C
IMPURITY D EP 2.2.29	ND	≤	0,2 %	C

The head of QC department
"S.A.L.A.R.S." S.p.A.
COMO - Via S. Francesco, 5



Certificate of analysis

Certificate 0000001253 Print date 16.02.2023 Page / Pages 2 / 2
Article 05NT00 **NALTREXONE HYDROCHLORIDE**

Lot F23010011
Production date 01/02/2023 Retest date 01/02/2028
Approval date 13/02/2023 09:57:53 Approval user Luca Braga

According to Current E.P. and Certificate of Suitability
R1-CEP-2006-117-Rev 02

Test Test method	Tests results	Specification		Complies (C - NC)
		Lower limit / Unit	Upper limit / Unit	
IMPURITY E EP 2.2.29	ND		≤ 0,2 %	C
IMPURITY F EP 2.2.29	ND		≤ 0,2 %	C
IMPURITY G EP 2.2.29	ND		≤ 0,2 %	C
IMPURITY H EP 2.2.29	ND		≤ 0,1 %	C
IMPURITY I EP 2.2.29	ND		≤ 0,1 %	C
IMPURITY J EP 2.2.29	ND		≤ 0,1 %	C
ANY OTHER KNOWN IMPURITIES EP 2.2.29	ND		≤ 0,1 %	C
UNKNOWN IMPURITIES EP 2.2.29	0,06 %		≤ 0,10 %	C
TOTAL IMPURITIES EP 2.2.29	0,1 %		≤ 1,0 %	C
RESIDUAL SOLVENTS ETHANOL SLS0040_PPM	31 ppm		≤ 5000 ppm	C
WATER EP 2.5.12	5,1 %		≤ 10,0 %	C
SULPHATED ASH EP 2.4.14	0,0 %		≤ 0,1 %	C
ASSAY A.S. EP 2.2.20	100,2 %	≥ 98,0 %	≤ 102,0 %	C

NOTES

A.S.: ANHYDROUS SUBSTANCE

ND: NOT DETECTED (BELOW DETECTION LIMIT)

DISREGARD LIMIT FOR HPLC IMPURITIES = 0.05 PERCENT (LOQ)

STORAGE: IN AN AIRTIGHT, PROTECT FROM LIGHT

The head of QC department

"S.A.L.A.R.S." S.p.A.
COMO - Via S. Francesco, 5