

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

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Certificate of analysis

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Article 05NT00 **NALTREXONE HYDROCHLORIDE**

Lot F21120103
Production date 20/12/2021 Retest date 20/12/2026
Approval date 23/12/2021 12:01:58 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 OR ALKALINITY (HCl OR NaOH 0.02 M) SLS0050_ML2	0,12		≤ 0,2 ml	C
SPECIFIC OPTICAL ROTATION EP 2.2.7	-190	≥ -195	Degrees ≤ -187 Degrees	C
IMPURITY A EP 2.2.29	ND		≤ 0,1 %	C
IMPURITY B EP 2.2.29	< 0,05		≤ 0,1 %	C
IMPURITY C EP 2.2.29	< 0,05		≤ 0,2 %	C
IMPURITY D EP 2.2.29	< 0,05		≤ 0,2 %	C

The head of QC department
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Test Test method	Tests results	Specification		Complies (C - NC)
		Lower limit / Unit	Upper limit / Unit	
IMPURITY E EP 2.2.29	< 0,05		≤ 0,2 %	C
IMPURITY F EP 2.2.29	< 0,05		≤ 0,2 %	C
IMPURITY G EP 2.2.29	< 0,05		≤ 0,2 %	C
IMPURITY H EP 2.2.29	< 0,05		≤ 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 UNSPECIFIED IMPURITIES EP 2.2.29	< 0,05		≤ 0,1 %	C
UNKNOWN IMPURITIES EP 2.2.29	< 0,05		≤ 0,10 %	C
TOTAL IMPURITIES EP 2.2.29	< 0,05		≤ 1,0 %	C
RESIDUAL SOLVENTS ETHANOL SLS0040_PPM	3		≤ 5000 ppm	C
WATER EP 2.5.12	4,5		≤ 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

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