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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 Lower limit / Unit			Upper limit / Unit		Complies (C - NC)
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%, pratically 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
"S.A.L.A.R.S." S.p.A.
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Test Test method	Tests results	Specification Lower limit / Unit		Upper limit / Unit		Complies (C - NC)
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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