



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

(Società Azionaria Laboratori Alcaloidi Rifornimenti Sanitari)  
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## CERTIFICATE OF ANALYSIS

Product		<b>NALTREXONE HYDROCHLORIDE DIHYDRATE</b> (# CAS: 850808-02-5; M <sub>w</sub> : 413,9 g/mol)		Date of manufacture	30/06/2020
Batch N.		F20060065		Retest date 30/06/2025	
Analysis record N.		23260		According to Current USP	
	<b>Tests</b>	<b>Results</b>	<b>Specification</b>	<b>Units</b>	
1	Appearance	Complies	White or almost white powder, very hygroscopic		
2	Solubility	Complies	Freely sol. in water, slightly sol. in ethanol 96 %, practically insol. in methylene chloride		
3	Completeness of solution <641>	Clear	Clear		
4	Identification IR spectrum <197K> Retention time	Complies Complies	Complies with IR of standard Complies with USP R.T.		
5	Specific rotation <781S>	-189	Between -197° and -187° (o.a.s.b.)	degrees	
6	Water Determination, method I <921>	7.4	Report the found value	percent	
7	Residue on ignition <281>	0.05	≤ 0.1	percent	
8	Heavy Metals, method II <231>	Complies	≤ 20	ppm	
9	Content of chloride	9.34	Between 9.20 and 9.58 (o.a.s.b.)	percent	
10	Related substances (HPLC) Each known * Unknown Total	0.07 <0.05 0.07	≤ 0.5 ≤ 0.1 (each) ≤ 1.5	percent percent percent	
11	Assay (HPLC)	100.1	Between 98.0 and 102.0 (o.a.s.b.)	percent	
12	Clarity of Solution	3	≤ 3	NTU	
13	Residual solvents (GLC) Ethanol	7	≤ 5000	ppm	
14	Limit of total solvents (Water + Ethanol)	7.4	≤ 11.0	percent	
Notes * The known impurities are: Noroxymorphone (Imp. B Ph. Eur.) Naltrexone related compound A (Imp. C Ph. Eur.) 2,2'-Bisnaltrexone (Imp. D Ph. Eur.) 10-Hydroxynaltrexone [Imp. F(10α) and G(10β) Ph. Eur.] 10-Ketonaltrexone (Imp. I Ph. Eur.) o.a.s.b. = on anhydrous, solvent-free basis nd = not detected (below detection limit)		Assay date  20/07/2020	The head of Q.C. department   <b>"S.A.L.A.R.S." S.p.A.</b> COMO - Via S. Francesco, 5		
Packaging and storage: preserve in tight containers					