

Certificate of Analysis

Product Name	Naltrexone HCl
Catalog No.	V3777
Batch No.	V377701

1. Physical and Chemical Properties

Appearance	White or almost white powder
Molecular Formula	C ₂₀ H ₂₃ NO ₄ ·HCl
Molecular Weight	377.86
Purity	= 99.9%
CAS No.	16676-29-2
Production Date	
Retest Date	2028-07-08

2. Analytical Data

Test Item	Specification	Result
Identification	Chloride positive	Conform
Identification	IR	Conform
Clarity	Should be clear	Conform
Color	Not more than Y6	Less than Y6
Specification Rotation	-195~-187(on anhydrous substance)	-191.0
Water(KF)	NMT 10.0%	0.7%
Acidity or alkalinity	NMT 0.2 ml 0.02M NaOH or 0.02M HCl	NaOH 0.10ml
Sulphated ash	NMT 0.1%	<0.05%
Impurity A	NMT 0.1%	0.05%
Impurity B	NMT 0.1%	0.05%
Impurity C	NMT 0.2%	0.05%
Impurity D	NMT 0.2%	0.05%
Impurity E	NMT 0.2%	0.05%
Impurity F	NMT 0.2%	0.05%
Impurity G	NMT 0.2%	0.05%
Impurity H	NMT 0.1%	0.05%
Impurity I	NMT 0.1%	0.05%
Impurity J	NMT 0.1%	0.05%
Any other impurity	NMT 0.1%	Conform
sum of all impurities	NMT1.0%	0.0%
Assay(By potentiometry)	98.0~102%(on anhydrous and solvent-free substance)	99.1%
Residual solvents	NMT 0.089% toluene	<20ppm
Dv(0.1)	As an indication	13.2μm
Dv(0.5)	As an indication	41.1μm
Dv(0.9)	As an indication	109.0μm

3. Structure
