



Certificate of analysis

Product name: Naltrexone HCl

Cas number: 16676-29-2

Molecular Formula: C₂₀H₂₄ClN₀₄

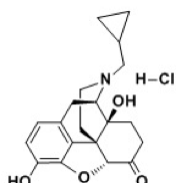
Molecular Weight: 377.86

Date of production: Feb. 16, 2019

Batch NO: 20190216

Exp Date: Feb. 15, 2021

Chemical structure:



Items	Specifications	Results
Appearance	White or almost white powder	Conforms
Solubility	Freely soluble in water, Practically insoluble in dichloromethane	Conforms
Specific optical rotation	-187.0° TO -197.0°	-191.7°
Identification By H NMR	The H NMR spectra of standard and sample is concordant	Conforms
Heavy metals	Not more than 20ppm	Conforms
Water	Not more than 10%	5.64%
Residue on ignition	Not more than 0.1%	0.04%
Limit of Total solvent	Methanol Not more than 2000 ppm Acetone Not more than 1000 ppm	Not detected 100PPM
Content of Chloride	Between 9.20% and 9.58%	9.4%
Retated Substance	Noroxymorphone <0.5% 10-Hydroxynaltrexone <0.5% Naltrexone related compound A <0.5% 2,2' Bisnaltrexone <0.5% 10-ketonaltrexone <0.5% Impurity H <0.5% Impurity J <0.5% Max unknown imp. <0.5% Total impurities <1.5%	Conforms Conforms Conforms Conforms Conforms Conforms 0.11% 0.40%
Assay(hplc)	Between 98.0% and 102% (on anhydrous and solvent free basis)	99.6%

Conclusion: It complies with the USP35 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang

