Mallinckrodt™

KalChem™ INTERNATIONAL Compounding Chemicals You Can Trust

Issued by the Manufacturer:
SpecGx LLC
3600 N. Second Street
St. Louis, MO 63147 USA
Print Date: 03/19/26 11:18:59 AM

CERTIFICATE OF ANALYSIS

Item: NALTREXONE HYDROCHLORIDE USP

Code: 1479
Lot#: 2602000080
Date of Manufacture: FEB 2026

Specification: 24-JAN-2025
Retest Date: JAN 2030
Released: 19-MAR-2026

MEETS UNITED STATES PHARMACOPEIA (USP) SPECIFICATIONS
MEETS EUROPEAN PHARMACOPEIA (EP) SPECIFICATIONS
FOR USP (<467>) RESIDUAL SOLVENTS - ONLY CLASS 2 SOLVENTS (METHANOL AND CHLOROFORM) AND CLASS 3 SOLVENTS (ETHANOL) ARE LIKELY TO BE PRESENT. THESE SOLVENTS ARE QUANTIFIED BELOW.

Tests	Limits	Results
APPEARANCE	WHITE TO SLIGHTLY OFF-WHITE POWDER	WHITE POWDER
IDENTIFICATION A (IR) (USP<197K> or <197A>)	MATCHES REFERENCE STANDARD	MATCHES REFERENCE STANDARD
SPECIFIC ROTATION (25 degrees C) (ANHYDROUS, SOLVENT-FREE BASIS) (USP<781S>)	-187 TO -197 degrees	-191 degrees
CLARITY OF SOLUTION (USP<855>)	NMT 3 NTU	1 NTU
IDENTIFICATION B (MAJOR PEAK)	MATCHES STANDARD	MATCHES STANDARD
WATER (USP)	3.0% MAX	0.7 %
RESIDUE ON IGNITION (USP<281>)	0.1% MAX	0.0 %
LIMIT OF TOTAL SOLVENTS	5.0% MAX	2.1 %
RESIDUAL SOLVENTS(GC)		
ETHANOL	3.0% MAX	1.4 %
METHANOL	0.10% MAX	<0.05 %
CHLOROFORM	60 ppm MAX	5 ppm
ASSAY (ANHYDROUS, SOLVENT FREE BASIS) (USP)	98.0 - 102.0% w/w	100.0 %w/w
RELATED COMPOUNDS (AS RECEIVED BASIS) (USP)		
N-FORMYL-NOROXYMORPHONE	0.15% w/w MAX	<0.05 %w/w
NOROXYMORPHONE	0.50% w/w MAX	<0.05 %w/w
10-ALPHA HYDROXYNALTREXONE	0.50% w/w MAX	<0.05 %w/w

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Tests	Limits	Results
N-(3-BUTENYL)NOROXYMORPHONE	0.50% w/w MAX	<0.05 %w/w
2,2'-BISNALTREXONE	0.50% w/w MAX	<0.04 %w/w
10-KETONALTREXONE	0.50% w/w MAX	<0.04 %w/w
3-CYCLOPROPYLMETHYLNALTREXONE	0.15% w/w MAX	0.06 %w/w
UNKNOWN RELATED SUBSTANCES (EACH)	0.10% w/w MAX	<0.05 %w/w
TOTAL RELATED SUBSTANCES	1.0% w/w MAX	0.1 %w/w
CONTENT OF CHLORIDE(Cl) (ANHYDROUS, SOLVENT-FREE BASIS) (USP)	9.20 - 9.58%	9.43 %
IDENTIFICATION (TLC)	MATCHES REFERENCE STANDARD	MATCHES REFERENCE STANDARD
IDENTIFICATION (UV)	A281 / A262 = 1.55 TO 1.95	1.74
IDENTIFICATION (FERRIC CHLORIDE)	CLEAR PURPLISH-BLUE COLOR	CLEAR PURPLISH-BLUE COLOR
DELTA-7 NALTREXONE HCL	50 ppm MAX.	<10 ppm
SIEVE TEST US STANDARD NO. 100	100% MIN THROUGH	100 %
IDENTIFICATION A (IR) (EP<2.2.24>)	MATCHES STANDARD	MATCHES STANDARD
IDENTIFICATION B (CHLORIDES) (EP)	MEETS EP REQUIREMENTS	MEETS EP REQUIREMENTS
APPEARANCE OF SOLUTION (EP<2.2.1 & 2.2.2>METHOD II)		
DEGREE OF CLARITY	CLEAR	CLEAR
DEGREE OF COLORATION	NOT MORE INTENSELY COLORED THAN REFERENCE SOLUTION Y6 OR B6	NOT MORE INTENSELY COLORED THAN REFERENCE SOLUTION Y6 OR B6
ACIDITY AND ALKALINITY (EP)	0.2 mL MAX	0.0 mL

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Tests	Limits	Results
SPECIFIC ROTATION (20 degrees C) (ANHYDROUS, SOLVENT-FREE BASIS) (EP<2.2.7>)	-187 degrees to -195 degrees	-192 degrees
RELATED SUBSTANCES (HPLC) (EP<2.2.2>)		
EP IMPURITY A	0.1% area MAX	<0.1 %area
EP IMPURITY B	0.1% area MAX	<0.1 %area
EP IMPURITY C	0.2% area MAX	<0.2 %area
EP IMPURITY D	0.2% area MAX	<0.2 %area
EP IMPURITY E	0.2% area MAX	<0.2 %area
EP IMPURITY F	0.2% area MAX	<0.2 %area
EP IMPURITY G	0.2% area MAX	<0.2 %area
EP IMPURITY H	0.1% area MAX	<0.1 %area
EP IMPURITY I	0.1% area MAX	<0.1 %area
EP IMPURITY J	0.1% area MAX	<0.1 %area
EP UNKNOWNS (EACH)	0.10% area MAX	<0.10 %area
EP TOTAL RELATED IMPURITIES	1.0% area MAX	<1.0 %area
ETHANOL (EP)	3.0% MAX	1.4 %
WATER (EP<2.5.12>)	10.0% MAX	0.7 %
SULPHATED ASH (EP<2.4.14>)	0.1% MAX	0.0 %
ASSAY (EP) (ANHYDROUS, SOLVENT FREE BASIS)	98.0 - 102.0%	100.0 %
PARTICLE SIZE (LASER DIFFRACTION)		
PARTICLE SIZE (D90)	REPORT	28 micrometers
PARTICLE SIZE (D50)	REPORT	6 micrometers
PARTICLE SIZE (D10)	REPORT	2 micrometers

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The information shown above is certified to be an accurate representation of the analytical results for this lot.

19-MAR-2026

Date

Jacqulyn Gleason / Quality Authority
SpecGx LLC