

Specification

Technical Data Sheet

CAS

16676-29-2

STORAGE

2 to 8 °C

MOLECULAR WEIGHT

377.86

PRODUCT

Naltrexone hydrochloride USP Grade

Product number 90034747

CAS number 16676-29-2

Molecular formula C₂₀H₂₃NO₄ · HCl

Molecular weight 377.86 g/mol

PARAMETER

SPECIFICATION

Appearance

White or almost white powder

Assay (HPLC)

98.0% - 102% w/w (on anhydrous and solvent free basis)

Acetone

≤ 1000 ppm

Heavy metals

≤ 0.001%

Identification

IR absorption spectrum of the sample in potassium bromide dispersion should be concordant with similarly recorded spectrum of 17-(Cyclopropylmethyl)-,4,5-Epoxy-3, 14-Dihydmorphinan-6-One hydrochlorided dihydrate working standard.

Water

5.0% - 11.0% w/w

Cyclohexane

≤ 1000 ppm

Acetic acid

≤ 1000 ppm

b) 10-Hydroxynaltrexone

≤ 0.50%

Benzene

≤ 2 ppm

c) Naltrexone related compound A

≤ 0.50%

Carbon tetrachloride

≤ 4 ppm

Chloride (Cl-)

9.20% - 9.58% w/w (on anhydrous and solvent free basis)

PARAMETER	SPECIFICATION
Colour	Absorbance of 1 cm layer of 6.5% w/v solution in water at 420 nm should less than 0,1 An
Completeness and colour of solution	Should obtain clear solution
Content of Didehydronaltrexone	≤ 10 ppm
d) 2,2' Bisnaltrexone	≤ 0.50%
Dichloromethane	≤ 250 ppm
e) 10-ketonaltrexone	≤ 0.50%
Ethyl acetate	≤ 1000 ppm
f) Impurity H	≤ 0.50%
g) Impurity J	≤ 0.50%
h) Impurity E	≤ 0.20%
i) Highest unknown impurity	≤ .10%
impurity Related compounds(by HPLC) a) Noroxymorphone	≤ 0.50%
j) Total impurities	≤ 1.50%
Methanol	≤ 2000 ppm
N,N-Dimethylformamide	≤ 200 ppm
Particle size (by Malvern)	99% Particles should below 250µm, 90% Particles should below 100µm, 50% Particles should below 50 µm
Residue on Ignition	≤ 0.1% w/w
Solubility	Freely soluble in water, Practically insoluble in
Specific optical rotation	-187.0o to -197.0 o (on anhydrous and solvent free basis)
Toluene	≤ 200 ppm
Total solvents	Sum of all solvents(from test no.: 10.1+ test no.
Chlorobenzene	≤ 360 ppm
Sulphates (SO4)(2-)	≤ 500 ppm

**SPECIFICATION
STATEMENT**

The values stated above represent the standard specification for this product, issued under **Molekula Ltd's** quality management system. Batch-specific results are provided on the Certificate of Analysis.

STORAGE	Store as indicated on the product label, away from light, moisture and incompatible materials.
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Molekula Ltd would like to thank you for your support of our products and service.

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