



## Certificate of Analysis

Product Name: Topotecan Hydrochloride  
Chemical Name: (S)-10-[(Dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-1H-pyrano[3',4':6,7]indolizino-[1,2-b]quinoline-3,14(4H,12H)-dione monohydrochloride

Batch Number: 70710AA039  
Molecular Weight: 457.91  
Molecular Formula: C<sub>23</sub>H<sub>23</sub>N<sub>3</sub>O<sub>5</sub> · HCl  
CAS Number: 119413-54-6

COA No.: 373393  
Issue Date: **NOV 08 2018**  
Specification No.: S1131C19

Test	Specification	Result
Appearance	Yellow to orange powder	Conforms
Identification: FT-IR (EP<2.2.24>)	Conforms to standard	Conforms
Identification: HPLC	Conforms to standard	Conforms
Assay and Purity: HPLC		
Topotecan Hydrochloride (Anhydrous basis)	NLT 98.0% and NMT 102.0%	100.4%
Camptothecin	NMT 0.05%	N.D.
10-Hydroxy-camptothecin	NMT 0.05%	LT 0.01%
Other max. individual impurity	NMT 0.10%	LT 0.05%
Total impurities	NMT 0.40%	LT 0.05%
Water Content: Karl Fischer	NLT 7% and NMT 11%	9%
Residual Solvents: GC Headspace		
Ethanol	NMT 1,000ppm	N.D.
Acetone	NMT 1,000ppm	N.D.
Isopropyl Alcohol	NMT 1,000ppm	N.D.
Dichloromethane	NMT 300ppm	N.D.
Acetonitrile	NMT 100ppm	N.D.
Ethyl Acetate	NMT 1,000ppm	53ppm
N,N-Dimethylformamide	NMT 100ppm	N.D.
Total solvents	NMT 3,000ppm	53ppm
Residual TEA: GC Headspace		
Triethylamine	NMT 15ppm	N.D.
Sulphated Ash: EP <2.4.14>	NMT 0.1%	LT 0.05%
Chloride Content : Titration (300 mg in 50 mL of 0.65% HNO <sub>3</sub> :ACN=1:1(v/v), Anhydrous basis)	NLT 8.5% and NMT 10.5%	9.7%
Specific Rotation (250 mg in 25 mL of H <sub>2</sub> O, cell: 100 mm, 25°C, Anhydrous basis)	NLT +96deg and NMT +103deg	+99deg
Bacterial Endotoxins	NMT 1.25EU/mg	LT 0.25EU/mg
Microcount		
Bacteria	NMT 25CFU/g	LT 1CFU/g
Fungi	NMT 25CFU/g	LT 1CFU/g
X-ray Powder Diffraction	Conforms to Form D	Conforms

Quality Control

Quality Assurance



台灣神隆股份有限公司  
ScinoPharm Taiwan, Ltd.

Page 2 of 2

## Certificate of Analysis

Product Name: Topotecan Hydrochloride  
Chemical Name: (S)-10-[[Dimethylamino)methyl]-4-ethyl-4,9-dihydroxy-1H-pyrano[3',4':6,7]indolizino-[1,2-b]quinoline-3,14(4H,12H)-dione monohydrochloride

Batch Number: 70710AA039  
Molecular Weight: 457.91  
Molecular Formula: C<sub>23</sub>H<sub>23</sub>N<sub>3</sub>O<sub>5</sub> · HCl  
CAS Number: 119413-54-6

COA No.: 373393  
Issue Date: NOV 08 2018  
Specification No.: S1131C19

Test	Specification	Result
------	---------------	--------

NMT:Not more than;NLT:Not less than;MT:More than;LT:Less than;deg:degree;N.D.:Not Detected

Manufacturing Date: 2018/10/13

Test Date: 2018/10/31

Next Retest Date: 2023/10/13

Manufacturing Site: No. 1st, Nan-Ke 8th Road, Shan-Hua, Tainan, Taiwan

Total impurities reported of HPLC testing is the sum of all impurities detected which are greater than or equal to 0.05%.

Any solvent at a level lower than the LOQ in the validation report will be reported as "LT LOQ value", and it won't be counted into the total solvents.

Complies with ICH Q3D based on risk assessment.

  
Quality Control

  
Quality Assurance