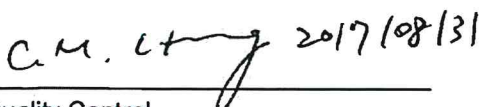



Certificate of Analysis

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: 70710AA035
 Molecular Weight: 457.91
 Molecular Formula: C₂₃H₂₃N₃O₅ · HCl
 CAS Number: 119413-54-6

COA No.: 339226
 Issue Date: SEP 01 2017
 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%	99.8%
Camptothecin	NMT 0.05%	N.D.
10-Hydroxy-camptothecin	NMT 0.05%	0.02%
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	55ppm
N,N-Dimethylformamide	NMT 100ppm	N.D.
Total solvents	NMT 3,000ppm	55ppm
Residual TEA: GC Headspace		
Triethylamine	NMT 15ppm	N.D.
Heavy Metals: EP <2.4.8> (Method C)	NMT 10ppm	Conforms
Sulphated Ash: EP <2.4.14>	NMT 0.1%	LT 0.05%
Chloride Content : Titration (300 mg in 50 mL of 0.65% HNO ₃ :ACN=1:1(v/v), Anhydrous basis)	NLT 8.5% and NMT 10.5%	9.6%
Specific Rotation (250 mg in 25 mL of H ₂ O, cell: 100 mm, 25°C, Anhydrous basis)	NLT +96deg and NMT +103deg	+98deg
Bacterial Endotoxins	NMT 1.25EU/mg	LT 0.25EU/mg


 Quality Control


 Quality Assurance

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: 70710AA035

Molecular Weight: 457.91

Molecular Formula: C₂₃H₂₃N₃O₅ · HCl

CAS Number: 119413-54-6

COA No.: 339226

Issue Date: SEP 01 2017

Specification No.: S1131C19

Test	Specification	Result
Microcount		
Bacteria	NMT 25CFU/g	LT 1CFU/g
Fungi	NMT 25CFU/g	LT 1CFU/g
X-ray Powder Diffraction	Conforms to Form D	Conforms

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

Manufacturing Date: 2017/04/12

Test Date: 2017/05/02


Next Retest Date: 2022/04/12

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%.

C.M.  2017/08/31

Quality Control

 2017/08/01

Quality Assurance