



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: 70710AA049
Molecular Weight: 457.91
Molecular Formula: C₂₃H₂₃N₃O₅ · HCl
CAS Number: 119413-54-6
COA No.: 441497
Issue Date: MAR 24 2022
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%	100.0%
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	LT 50ppm
N,N-Dimethylformamide	NMT 100ppm	N.D.
Total solvents	NMT 3,000ppm	LT LOQ
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 ₃ :ACN=1:1(v/v), Anhydrous basis)	NLT 8.5% and NMT 10.5%	9.4%
Specific Rotation (250 mg in 25 mL of H ₂ O, cell: 100 mm, 25°C, Anhydrous basis)	NLT +96deg and NMT +103deg	+100deg
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

TJL 2022/03/24

API Quality Control

Daniel Chen 2022/03/24

API Quality Assurance



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Test	Specification	Result
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: 2022/03/05

Test Date: 2022/03/17

Next Retest Date: 2027/03/05

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

Total impurities reported in HPLC testing is the sum of all impurities with a level greater than or equal to 0.05%.

Any solvent at a level lower than its LOQ described in the validation report is reported as "LT LOQ value".

Complies with ICH Q3D based on risk assessment.

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API Quality Control

David Chen 2022/03/17

API Quality Assurance