



Certificate of analysis

Productname: Amphotericin B

Cas number: 1397-89-3

Molecular Formula: C₄₇H₇₃NO₁₇

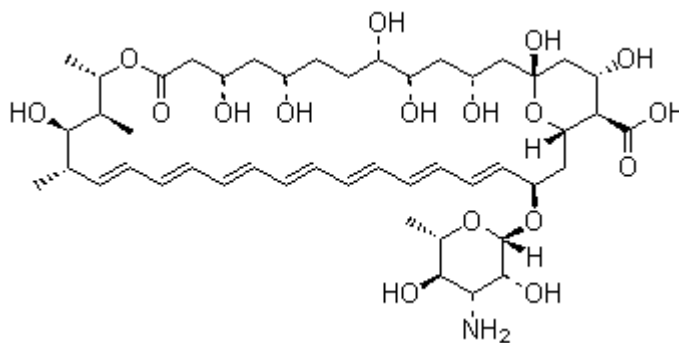
Molecular Weight: 924.08

Date of production: May. 15, 2019

Batch NO: 20190515

Exp Date: May. 14, 2017

Chemical structure:



Items	Specifications	Test results
Appearance	Yellow to orange powder	Yellow powder
Solubility	Insoluble in water and in ether, slightly soluble in methanol	Complies
Identification A: (UV)	Conforms to standard; absorbance in the range of 240nm to 320nm	Complies
Identification B: (UV/Vis)	Conforms to standard; absorbance in the range of 320nm to 400nm	Complies
Loss on drying	Not more than 5.0%	0.5%
Residue on Ignition	Not more than 0.5%	0.05%
Limit of amphotericin A	Not more than 5.0% calculated on the dried basis	Not detected
Assay (microbial)	Not less than 750 µg/mg calculated on the dried basis	1050µg/mg
Microbiological Examination	Total Aerobic Count :Not more than 100 CFU/gram	0 CFU/gram
	Salmonella Species: Negative	Complies
	Escherichia Coli: Negative	Complies
Bacterial Endotoxins	Less than 0.9 EU/mg	Complies
Residual Solvents	Ethanol Not more than 5000 ppm	2206 ppm
	Acetone Not more than 5000 ppm	1243 ppm
	DMF Not more than 5000 ppm	2736 ppm

Conclusion: It complies with the usp42 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F