



Certificate of analysis

Productname: Anidulafungin

Cas number: 166663-25-8

Molecular Formula: C₅₈H₇₃N₇O₁₇

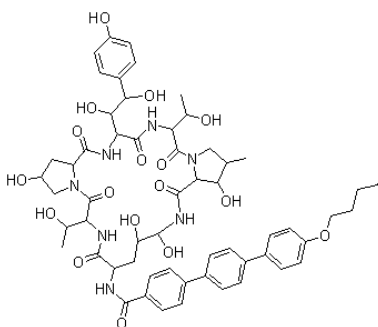
Molecular Weight: 1140.24

Date of production: Dec. 13, 2017

Batch NO: 20171213

Exr Date: Dec. 12, 2019

Chemical structure:



Items	Specifications	Results
Appearance	White or off-white powder	White powder
Identification	HPLC: The retention time of major peak of test solution should correspond to that of comparison solution.	Conform
	IR: Spectrum of the sample corresponds to that of reference standard.	Conform
	UV: In the 303nm wavelength place should have maximum absorption	Conform
Methanol Solution color and clarity	The Solution should be clear, If the solution is opalescent, the opalescence of the solution is not more intense than that of No 1 Turbidity Standard Solution; the solution should be tiny blue, In the wavelength range of 400-760 absorbance values are less than 0.02	Conform
Related substances	Impurity A NMT 0.25%	0.02%
	Impurity B NMT 0.15%	0.02%
	Specified unidentified impurity RRT 1.09 NMT 0.30%	0.12%
	Impurity D NMT 0.15%	0.09%
	Impurity E NMT 0.15%	0.07%
	Impurity F NMT 0.15%	0.06%
	Single maximum impurity NMT 1.0%	0.08%
Residual solvents	Total impurities NMT 1.0%	0.77%
	Methanol NMT 3000ppm	1157ppm
	Acetone NMT 5000ppm	N.D
	Acetonitrile NMT 410ppm	N.D
	Ethyl acetate NMT 5000ppm	N.D
	Tetrahydrofuran NMT 720ppm	N.D
Water	DMF NMT 720PPM	N.D
Bacterial Endotoxins	NMT 10.0%	6.6%
Microbial Limit	< 1.0EU/mg	Conform
	Total Aerobic ≤ 100cfu/g Total Yeasts and Molds ≤ 100cfu/g	Conform
Residue on ignition	NMT 0.10%	0.06
Heavy metals	NMT 10ppm	NMT 0
Assay	98.0% ~ 102.0% (Calculated on anhydrous, and solvents-free basis)	99.9%
	98.0% ~ 102.0% (Calculated on anhydrous)	99.8%

Conclusion: It complies with the Enterprise Standard.