

Certificate of Analysis

Product name	Micafungin FR-179642 impurity (acid)		
Batch No.	16RY0502	CAS No.	168110-44-9
Mfg. Date	27 th , June, 2016	Exp. Date	26 th , June, 2017

Tests	Specifications	Result
Appearance	White to off white powder	Off-white powder
Identity	IR:sample spectrum corresponds to that of standard spectrum	comforms
	HPLC:The retention time of major peak of test solution should correspond to that of reference solution	
Related substances	Impurity C \leq 0.6%	0.2%
	Impurity D \leq 0.5%	ND
	Impurity E \leq 2.0%	1.2%
	Any individual impurity \leq 0.15%	0.09%
	Total impurities \leq 3.0%	2.0%
Related solvents	Ethanol \leq 5000ppm	ND
	Methano \leq 3000ppm	ND
	Acetonitrile \leq 410ppm	ND
Water	\leq 8.0%	4.3%
PH	5.0~7.0	6.4
Specific optical rotation	-30.0° ~~36.0°	-30.2°
Assay	95.0%~102.0%	95.5%
Storage condition	Store in tight container and not exceeding -20°C, protected from light	
Conclusion : Conforms to In-house specification.		

Tested by: Alice

Checked by: Penny

Approved by: Michelle

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