

Certificate of Analysis

Product name	Micafungin sodium		
Batch No.	RY20200315	CAS No.	208538-73-2
Mfg. Date	2020.03.15	Exp. Date	2022.03.14
Standard	In-house	Quantity	6KG

Tests	Specifications	Result
Appearance	White to off-white powder	White powder
Specific optical rotation	-20°C ~ -25°C	-21.9°C
Identification	HPLC: the retention time of principle peak obtained from test solution should conform with that obtained from standard solution, as test in assay	Conforms
	Chemical identification: show the identification reaction of sodium salt	Conforms
Water	≤8.0%	3.4%
PH	5.5~7.0	6.4
Related substances I(on anhydrous and acetic acid free basis)	Impurity A≤0.50%	0.04%
	Impurity B≤0.15%	0.09%
	Impurity D≤0.15%	0.002%
	Impurity E≤0.20%	0.15%
	Impurity H≤0.15%	0.04%
	Single unknown impurity≤0.10%	0.07%
	Total impurities ≤0.80%	0.47%
Residual solvents	Methanol ≤3000ppm	ND
	Ethanol ≤5000ppm	ND
	Isopropanol ≤5000ppm	ND
	Acetonitrile≤410ppm	29ppm

	Ethyl acetate≤5000ppm	1ppm
	N,N-dimethyl formamide ≤880ppm	ND
	N,N-diisopropylethylamine ≤1000ppm	143ppm
Bacterial endotoxins	<0.5Eu/mg	Conforms
Microbial limit	Total aerobic bacteria≤100cfu/g	<10cfu/g
	Total number of moulds and yeasts ≤100cfu/g	<10cfu/g
Assay	98.0%~102.0%(on anhydrous free basis)	101.9%
	98.0%~102.0%(On anhydrous and solvent free basis)	101.9%
Conclusion : Conforms to In-house specification.		
Storage condition: Store in a tightly closed container and the Temp below -15°C		



Tested by: Alice

Checked by: Penny

Approved by: Michelle