

### Certificate of Analysis

Name of Product	DOTA	Batch No.	RY-20210301
Manufacture date	2021.03.06	Analysis date	2021.03.08
Quantity	55.62kg	CAS No.	60239-18-1
Standard	In-house	Retest date	2023.08

Item	Specification		Results
Description	White to off-white powder		Conforms
Identification	1) IR: The infrared spectrum of the sample should correspond to that of the reference standard		Conforms
	2) HPLC: The retention time of the major peak of the test solution should correspond to that of the standard solution, as obtained in the test item of Related substances 1		Conforms
Solubility	Soluble in water, insoluble in methanol and ethanol		Conforms
Water	≤10%		8.2%
Residue on ignition	≤0.1%		0.06%
Total halogen	≤200ppm		Conforms
Related substances	Related substances 1	339002P01≤0.05%	N.D
		339002P02≤0.05%	N.D
		339002P03≤0.05%	N.D
		339002P04≤0.05%	N.D
		312301≤0.05%	N.D
		Any other individual impurity≤0.05%	0.02%
	Related substances 2	339001M03≤0.05%	N.D
Total impurities	≤0.5%	0.05%	
Assay(on the anhydrous basis)	98.0%-102.0%		99.5%



Residual solvent	Ethanol≤5000ppm	<LOQ (LOQ=100ppm)
Microbiological tests	Total aerobic microbial count(TAMC)≤10 <sup>2</sup> CFU/g	<1 CFU/g
	Total combined yeasts and molds count(TYMC)≤10 <sup>2</sup> CFU/g	<1 CFU/g
Bacterial endotoxins	<25EU/g	Conforms
Conclusion	The test results conform to the standard of In-house	

Tested by: Meng Xiao

Checked by: Shen Junli

Approved by: He Youguang



**Storage condition:** Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

**Remarks:**

Impurity Name:

339002P01: 2, 2', 2''-(1, 4, 7, 10-tetraazacyclododecane-1, 4, 7-triyl)triacetic acid

339002P02: 2, 2' - (1, 4, 7, 10-tetraazacyclododecane-1, 7-diyl)diacetic acid

339002P03: 2, 2' - (1, 4, 7, 10-tetraazacyclododecane-1, 4-diyl)diacetic acid

339002P04: 2, 2' - (1, 4, 7, 10-tetraazacyclododecane-1, 4-diyl)diacetic acid

312301: CYCLEN; 1, 4, 7, 10-Tetraazacyclododecane

339001M03: Glycolic acid