

CERTIFICATE OF ANALYSIS – VERSION 2

Commercial name: DOTA-NHS Ester
Chemical name: 2,2',2''-(10-(2-(2,5-dioxopyrrolidin-1-yloxy)-2-oxoethyl)-1,4,7,10-tetraazacyclododecane-1,4,7-triyl)triethanoic acid
Formula: $C_{20}H_{31}N_5O_{10}$
Mw: 501,20 g.mol⁻¹
Sample from batch # 084 G 270126 F1
Storage temperature: - 20°C ± 5°C

SPECIFICATIONS		RESULTS
Appearance		
Appearance - Visual inspection	White powder	White powder
Identification		
Identification – ¹ H NMR	Conform to reference spectrum	Conform to reference spectrum
Identification - MS	501.20 ± 1 (m + 1) g/mol	501,20 g/mol
Chemical analysis		
Chemical purity – HPLC-UV	Total impurities ≤ 5% No single impurity ≥ 0,5%	Total impurities ≤ 5% No single impurity ≥ 0,5%
DOTA content – HPLC-UV	Report result	2,1%
NHS content – HPLC-UV	Report result	0,64%
Heavy metals content – ICP-MS	Sum of metals < 30 ppm Cu, Fe, Zn, Ni	Sum of metal < 15 ppm Cu < 0,5 ppm Fe: 12 ppm Ni < 0,5 ppm Zn < 2,0 ppm
Silicium content – ICP-MS	Report result	608,6 ppm
Aluminium content – ICP-MS	Report result	123,8 ppm
TFA content – IC	≤ 28%	26,9%
Ion content – IC	Report result	F ⁻ : 0,30% PF ₂ O ₂ ⁻ : 2,45% PFO ₃ ⁻ : 0,40% PO ₄ ³⁻ < 0,25% PF ₆ ⁻ : 9,30%

Activities to support these results were conducted in compliance with internal procedures, approved product specifications, and cGMP regulations.



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CERTIFICATE OF ANALYSIS – VERSION 2

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SPECIFICATIONS		RESULTS
Chemical analysis		
Residual solvents– GC-MS	Report result	Dichloromethane < 6,0 ppm Acetonitrile: 137 282 ppm Ethyl acetate < 20,0 ppm Diethyl ether < 6,0 ppm
Water content – KF	≤ 4%	0,6%
Biological analysis		
Bioburden – Eu. Ph. 2.6.12	TAMC < 1000 CFU/g TYMC < 1000 CFU/g	TAMC < 20 CFU/g TYMC < 20 CFU/g
Endotoxins – Eu. Ph. 2.6.14	Report result	< 0,1 EU/mg

Activities to support these results were conducted in compliance with internal procedures, approved product specifications, and cGMP regulations.

Manufacturing date: 12/03/2026

Retest date: N/A

Head of Quality Control / Quality Assurance <i>Mathieu BIANCO, 04/05/2026</i>	Stamp  CheMatech macrocycle design technologies 2, rue Pauline Kergomard - 21000 Dijon - France SAS au capital de 995 085 Euros RCS DIJON 917 877 094 SIRET 917 877 094 00016 - APE 7112 Z
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Version	Date	Modification
1	19/03/2026	Creation of the CoA.
2	04/05/2026	Addition of missing analysis.