CheMatech SAS
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CERTIFICATE OF ANALYSIS

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
Forumula: $C_{20}H_{31}N_5O_{10}$
Mw: 501,20 $g.mol^{-1}$
Sample from batch # 084 G 230924 F1
Storage temperature: - 20°C ± 5°C

	SPECIFICATIONS	RESULTS
Appearance		
Appearance - *Visual inspection*	Whitish powder	White powder
Identification		
Identification - *^1H NMR*	Conform to reference spectrum	Conform to reference spectrum
Identification - *MS*	501.20 ± 1 (m + 1) g/mol	501.20 g/mol
Identification - *HPLC*	Conform to reference (Retention time)	Conform to reference (Retention time)
Chemical analysis		
Chemical purity – *HPLC-UV*	Total impurities ≤ 5%	Total impurities ≤ 5%
Activation purtiy - *HPLC-UV* %DOTA-NHS Ester / %DOTA	Report result	98%
Metals content (Cu, Fe, Zn, Ni) *ICP-MS*	Sum of metals < 30 ppm Reported result for each metal	Sum of metals < 30 ppm Cu < 0,5 ppm Fe: 4,9 ppm Ni < 0.5 ppm Zn < 0,5 ppm
TFA content – *IC*	Report result	25,68%
HPF_6 content - *ICP*	Report result	17,16%
Report stoichiometry		$C_{20}H_{31}N_5O_{10}$ + 1,97 TFA + 1,03 HPF_6 Fw = 876,84 g/mol

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	SPECIFICATIONS	RESULTS
Chemical analysis		
Residual solvents – *GC-MS*	Acetonitrile ≤ 410 ppm Dichloromethane ≤ 600 ppm Ethyl acetate ≤ 5 000 ppm Diethyl ether ≤ 5000 ppm	Acetonitrile < 0,3 ppm Dichloromethane < 0.3 ppm Ethyl acetate : 5,7 ppm Diethyl ether: 224,6 ppm
Water content – *KF*	≤ 5%	3,3%
Biological analysis		
Bioburden – *Eu. Pharmacopoeia*	≤ 10^3 CFU/g	TAMC < 20 CFU/g TYMC < 20 CFU/g
Endotoxin – *Eu. Pharmacopoeia*	Report result	< 0.1 UI/mg

Manufacturing date: 01/10/2024
Retest date: N/A

Head of Quality Control / Quality Assurance	Stamp
Matthieu BIANCO, le 29/07/2025	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 B

Version	Date	Modification
1	29/11/2024	Creation of the CoA
2	29/07/2025	Report stoichiometry addition