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CERTIFICATE OF ANALYSIS

Commercial name: DOTA-tris(tBu)ester
Chemical name: 2-(4,7,10-tris(2-tert-butoxy-2-oxoethyl)-1,4,7,10-tetraazacyclododecan-1-yl)acetic acid
Mw: 572,73 $g.mol^{-1}$
Sample from batch # 060 231220 F1
Storage temperature: + 25°C ± 3°C

	SPECIFICATIONS	RESULTS
Appearance		
Appearance - *Visual inspection*	From white to pale yellow powder	Yellowish powder
Identification		
Identification - *^1H NMR*	Conform to reference spectrum	Conform to reference spectrum
Identification - *MS*	573,73 ± 1 g/mol	572,96 g/mol
Analysis		
Chemical purity - *HPLC - UV*	≥ 98% Each impurity < 1%	98% No impurity > 1%
Metal content – *ICP-MS*	Sum of Cu, Fe, Ni, Zn < 30 ppm	< 4 ppm
Residual solvents – *GC-MS*	Acetonitrile < 410 ppm Chloroform < 60 ppm Dichloromethane < 600 ppm Diethyl ether < 5000 ppm Dimethylacetamide < 1090 ppm Heptane < 5000 ppm	Acetonitrile: 5 ppm Chloroform: 3 ppm Dichloromethane: 28 ppm Diethyl ether: 27 ppm Dimethylacetamide: 108 ppm Heptane < 1 ppm
Water content – *Karl Fischer*	≤ 3%	2,3 %
Bromide content – *ICP-MS*	< 300 ppm	< 5 ppm
Sodium content - *ICP-MS*	< 300 ppm	55 ppm
Elemental analysis - *OEA*	Δ%C, Δ%N < 0,4	Conform with $C_{28}H_{52}N_4O_8 + 0,9\ H_2O$ Mw = 588,96 g/mol

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	SPECIFICATIONS	RESULTS
Biological Analysis		
Bioburden - *European Pharmacopoeia*	≤ 1 CFU/mg	< 0,07 CFU/mg
Endotoxin - *European Pharmacopoeia*	≤ 10 EU/mg	< 0,007 EU/mg

Manufacturing date: 20/01/2021
Re-analysis date: 13/11/2023
Retest date: 11/2024

Head of Quality Control / Quality Assurance	Stamp
Matthieu BIANCO, le 13/11/2023	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	17/02/2021	Creation of the CoA
2	25/05/2021	Batch retest: Appearance, identification and chemical purity
3	22/02/2022	Batch retest: Appearance, identification and chemical purity
4	28/10/2022	Batch retest: Appearance, identification, chemical purity and addition of biological analyses
5	08/02/2023	Batch retest: Water content.
6	13/11/2023	Batch retest: NMR, HPLC and MS.