

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 G 151124 F1
Storage temperature: + 25°C ± 3°C

SPECIFICATIONS		RESULTS
Appearance		
Appearance - <i>Visual inspection</i>	From white to pale yellow powder	White powder
Identification		
Identification - ¹ H NMR	Conform to reference spectrum	Conform to reference spectrum
Identification - MS	572,73 ± 1 g/mol	572,73 g/mol
Analysis		
Chemical purity - HPLC - UV	≥ 98% Each impurity < 1%	≥ 98% No impurity ≥ 1%
Metal content – ICP-MS	Sum of metals < 30 ppm (Cu, Fe, Ni and Zn)	Sum of metals ≤ 8,2 ppm Cu < 0,5 ppm Fe: 5,2 ppm Ni < 0,5 ppm Zn < 2,0 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 < 3,0 ppm Chloroform < 3,0 ppm Dichloromethane: 132,5 ppm Diethyl ether: 283,3 ppm Dimethylacetamide < 1,5 ppm Heptane < 3,0 ppm
Water content - KF	For information	1,57%
Bromide content - ICP-MS	< 300 ppm	< 100 ppm
Sodium content - ICP-MS	< 300 ppm	< 50 ppm
Elemental analysis - OEA	Δ%C, Δ%N < 0,4	Conform with C ₂₈ H ₅₂ N ₄ O ₈ + 0,7 H ₂ O Fw = 585,35 g/mol



CheMatech SAS
2 rue Pauline Kergomard
21000 Dijon - FRANCE
tel : +33 (0)3 80 44 19 00
fax : +33 (0)3 80 44 19 01
email : quality@chematech-mdt.com
www.chematech-mdt.com

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Biological Analysis		
Bioburden <i>European Pharmacopeia 2.6.12</i>	TAMC < 1000 CFU/g TYMC < 100 CFU/g	TAMC < 66,7 CFU/g TYMC < 66,7 CFU/g
Endotoxins <i>European Pharmacopeia 2.6.14</i>	≤ 10 UI/g	< 10 UI/g

Manufacturing date: 27/12/2024

Retest date: N/A

Head of Quality Control / Quality Assurance <i>Matthieu Bianco, le 27/01/2025</i>	Stamp  CheMatech macrocycle design technologies 2, rue Pauline Kergomard - 21000 Dijon - France SAS au capital de 995 085 Euros RES DIJON 917 877 094 SIRET 917 877 094 00016 - APE 7112 B
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Version	Date	Modification
1	27/01/2025	Creation of the CoA