COA 质量检验报告

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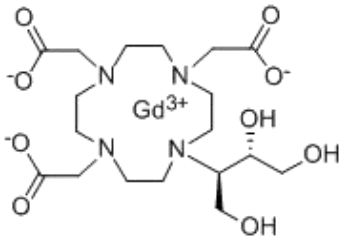
CERTIFICATE OF ANALYSIS

Product Name:	Gadobutrol		
Molecular Formula:	C18H31N4O9.Gd		
Molecular Weigh:	604.712		
Batch No.:	25091705	**CAS No:**	138071-82-6
Mfg. Date:	2025-09-17		
Date of Report:	2025-09-20	**Quantity:**	200kg
Expired Date:	2027-09-17	**Package:**	Drum
Item	Specifications		Results
Appearance	white or off-white powder		white powder
Solubility	Freely soluble in water practically insoluble in anhydrous ethanol and in heptane		Conforms
Identification			
Infrared Spectroscopy	It is consistent with that of the reference standard		Conforms
HPLC Identification	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtain in the Assay		Conforms
Test			
Specific optical rotation (anhydrous substance)	-0.05°~+0.05°		0.00°
Water	2.0%~7.0%		3.0%
Free gadolinium (anhydrous substance)	NMT 0.01%		ND

Related substances	Impurity A NMT 0.05%	ND
	Impurity B NMT 0.05%	ND
	Impurity C NMT 0.05%	ND
	DOTA-Gd NMT 0.05%	ND
	Any Individual Impurity NMT 0.05%	ND
	Total impurities NMT0.3%	ND
Residual Solvent	Benzene NMT0.000157%	ND
	Ethanol NMT 0.3937%	0.07%
Purity	C18H3GdN4O9 :97.5%~102.5% (anhydrous substance)	100.4%
	Gd:98.0%~102.0%(anhydrous substance)	99.6%
Bacterial endotoxin	Less than 1.3EU/g	Conforms
Microorganism		
TAMC	NMT 100 CFU/g	6 CFU/g
TYMC	NMT 10 CFU/g	Less than 1 CFU/g
E.Coli.	Should not be detected in each gram	ND
Storage Conditions	In an airtight container protected from light	
Conclusion	Conforms to the EP 11.0 monograph for Gadobutrol Monohydrate