

COA 质量检验报告



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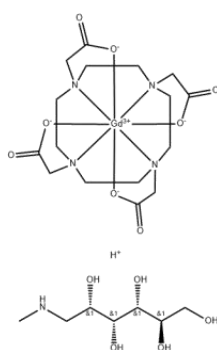
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CERTIFICATE OF ANALYSIS

Product Name:	Gadolinium DOTA meglumine		
Molecular Formula:	C23H42GdN5O13		
Molecular Weigh:	753.86		
Test Reference :	Conforms to the Specification Refer to the USP Gadoterate meglumine injection		
Batch No.:	3431201000	CAS No:	92943-93-6
Mfg. Date:	2025-7-5		
Date of Report:	2025-7-8	Quantity:	255kg
Expired Date:	2027-7-5	Package:	Bag
Item	Specifications		Results
Appearance	White or off-white powder		White powder
Solubility	This product is highly soluble in water, easily soluble in methanol, slightly soluble in 95% ethanol, and almost insoluble in absolute ethanol.		Conforms
Identification			
UV Identification	Maximum absorption at 273nm and 276nm		The maximum absorption wavelength is 274.0nm and 276.3nm
IR Identification	The IR spectrum is consistent with that of the Reference substance		Conforms
HPLC Identification	In the chromatograph recorded under gadoterate dimeglumine content determination, the retention time of the main peak of the test solution should be the same as that of the main peak of the gadoterate dimeglumine control solution.		Conforms

HPLC Identification	In the chromatograph recorded under meglumine content determination, the retention time of the main peak of the test solution should be the same as that of the main peak of the meglumine reference solution.		Conforms
Examination			
Solution clarity and color	It should be clear.The absorption shall be NMT 0.04 at 450 nm and NMT 0.02 at 500 nm		Clarification: the absorbance at 450nm is 0.003; The absorbance at 500nm is 0.001
Water	≤8.0%		3.1%
Heavy metal	No more than ten parts per million		Conforms
PH value	6.5 ~ 8.0		7.5
Free gadolinium	≤0.0025%		Not detected
Free DOTA	≤0.05%		0.02%
Nickel nickel salt	≤1ppm		0.67 ppm
Related substances	Impurity B≤0.05%		Not detected
	Other single impurities ≤0.05%		0.02%
	Total impurity (except impurity B)≤0.45%		0.03%
Microorganism	Total number of aerobic bacteria ≤100 cfu/g		<1 cfu/g
	Total number of molds and yeasts ≤10 cfu/g		<1 cfu/g
	Escherichia coli shall not be detected		Not detected
Bacterial endotoxin	<0.015EU/mg		Conforms
Purity Interms of anhydrous matter	Gadoterate meglumine	98.0%-102.0%	99.9%
	Meglumine	25.4%-26.4%	25.9%
Conclusion	This product is tested according to the Internal Control Quality Standard of gadoterate meglumine (QS-30005-09), and the results are in line with the provisions.		

