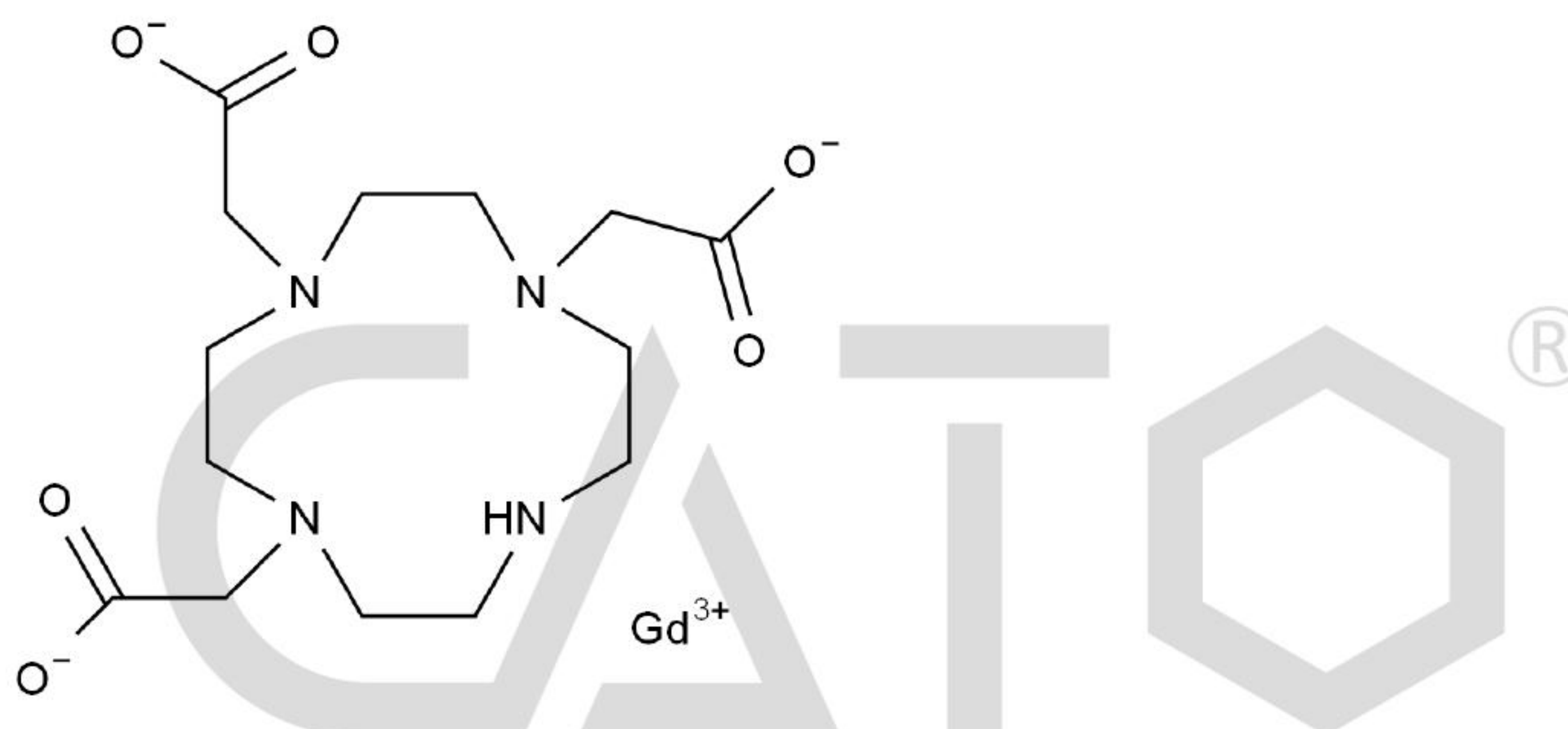


Certificate of Analysis

Reference Material & Standard

Product Name:	Gadobutrol EP Impurity C (Gadoteridol USP Related Compound B)	Catalogue Number:	C4X-2120100
Synonyms:	N/A	Lot Number:	0413-RH-0211
CAS Number:	112188-16-6	Expiry Date:	Apr 16, 2030
Molecular Formula:	C ₁₄ H ₂₃ N ₄ O ₆ Gd	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	343.36 157.25	Shipping Condition:	Shipping at Room Temperature

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS	Confirmed
Purity	ELSD	96.681%
Loss on Drying	TGA	3.7742%
Assay		93.0%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Loss on Drying) * Purity ELSD (%) / 100%

Loss on Drying is considered as absolute effect, ELSD purity is considered as relative effect.

Signature:

Prepared by:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Apr 17, 2026

Date: Apr 20, 2026

Date: Apr 20, 2026



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