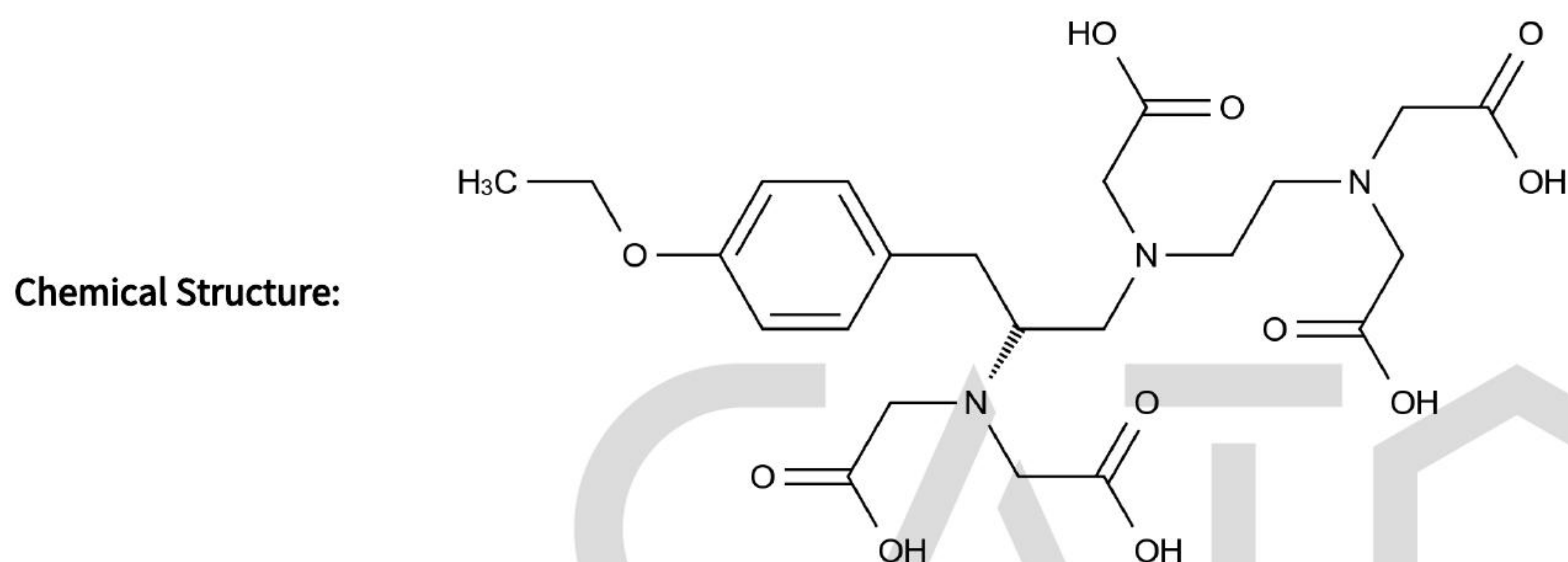


Certificate of Analysis

Reference Material & Standard

Product Name:	Gadoxetate Impurity 7	Catalogue Number:	C4X-26187
Synonyms:	N/A	Lot Number:	0628-RE-0050
CAS Number:	158599-73-6	Expiry Date:	Sep 06, 2025
Molecular Formula:	C23H33N3O11	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	527.52		



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	97.497%
Water Content	Karl Fischer	10.78%
Residual Solvents	NMR	0.21% tertiary butanol
Assay		86.8%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content} - \text{Residual Solvents}) * \text{Purity HPLC (\%)} / 100\%$$

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Aug 27, 2024

Date: Aug 27, 2024

Date: Aug 27, 2024

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