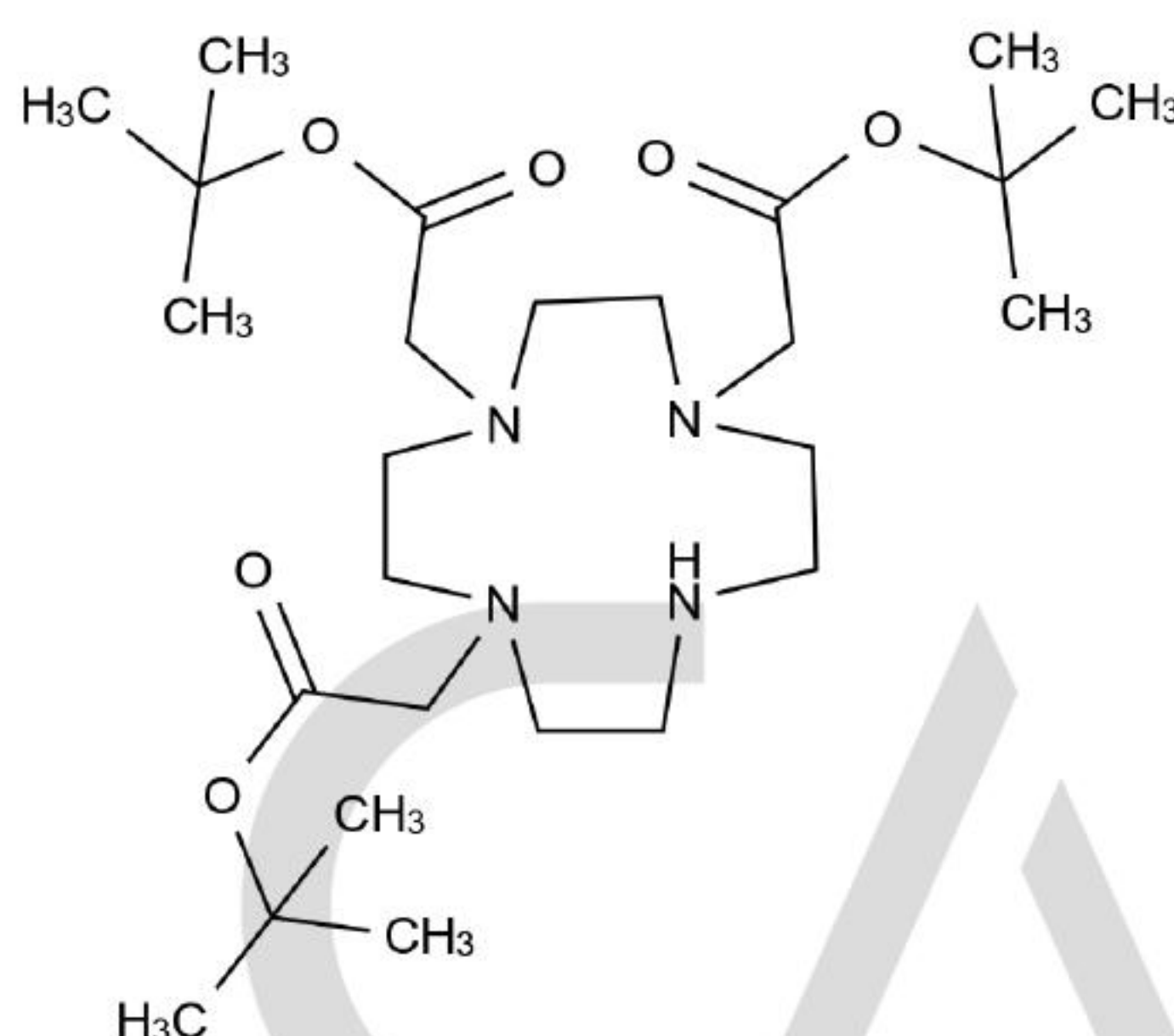


Certificate of Analysis

Reference Material & Standard

Product Name:	Gadobutrol Impurity 121	Catalogue Number:	C4X-2120121
Synonyms:	N/A	Lot Number:	0618-RF-0054
CAS Number:	122555-91-3	Expiry Date:	Jun 20, 2027
Molecular Formula:	C ₂₆ H ₅₀ N ₄ O ₆	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	514.70		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	ELSD	98.650%
Loss On Drying	TGA	2.4987%
Assay		96.2%

Comment:

The calculation of the 100% 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: Jun 21, 2024

Date: Jun 21, 2024

Date: Jun 21, 2024

