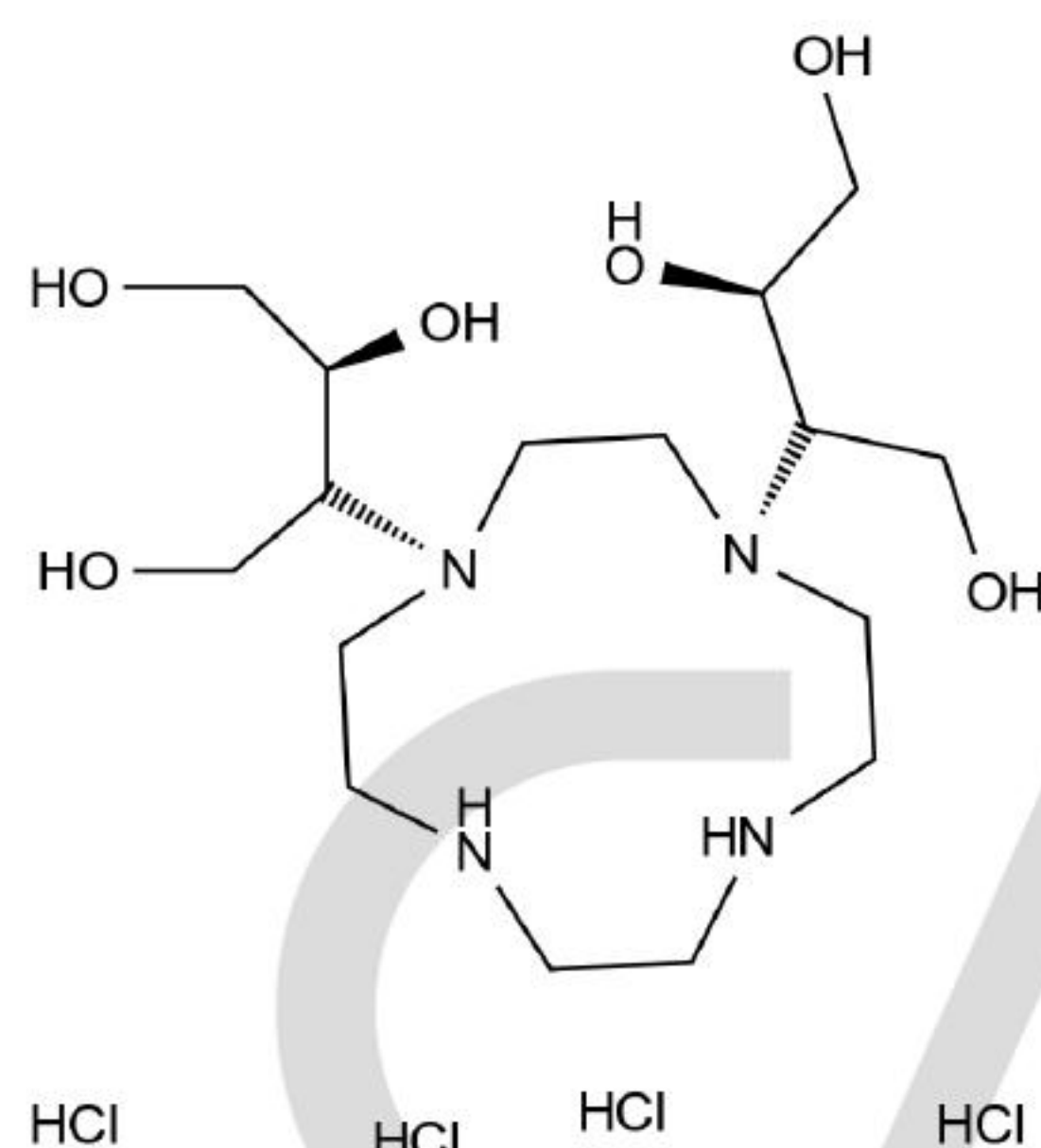


Certificate of Analysis

Reference Material & Standard

Product Name:	Gadobutrol Impurity 143 4HCl	Catalogue Number:	C4X-2120143
Synonyms:	N/A	Lot Number:	0823-RF-0009
CAS Number:	N/A	Expiry Date:	Sep 03, 2027
Molecular Formula:	C ₁₆ H ₃₆ N ₄ O ₆ 4*HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	380.48 4*36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	99.826%
Water Content	Karl Fischer	6.67%
Residual Solvents	NMR	0.62% acetonitrile
Assay		92.5%

Comment:

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

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

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

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Sep 04, 2024

Date: Sep 04, 2024

Date: Sep 04, 2024

