

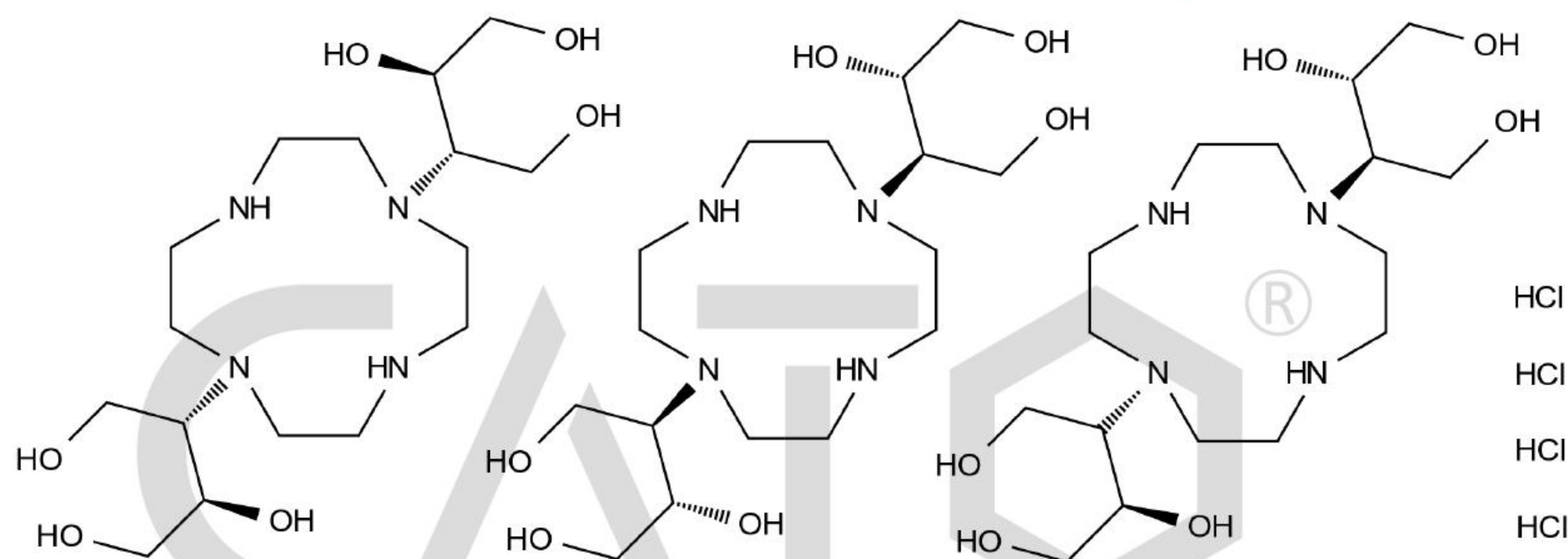
Certificate of Analysis

Reference Material & Standard

Product Name:	Gadobutrol Impurity 38(Mixture)	Catalogue Number:	C4X-2120138
Synonyms:	N/A	Lot Number:	0823-RF-0008
CAS Number:	N/A	Expiry Date:	Aug 25, 2027
Molecular Formula:	3*C16H36N4O6 4*HCl	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	3*380.48 4*36.46	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&HNMR	Confirmed
Purity	HPLC	96.037%
Water Content	Karl Fischer	13.50%
Residual Solvents	NMR	Not detected in NMR
Assay		83.1%

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:

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Reviewed by:

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Approved by General Manager:

David

Date: Sep 09, 2024

Date: Sep 09, 2024

Date: Sep 09, 2024

