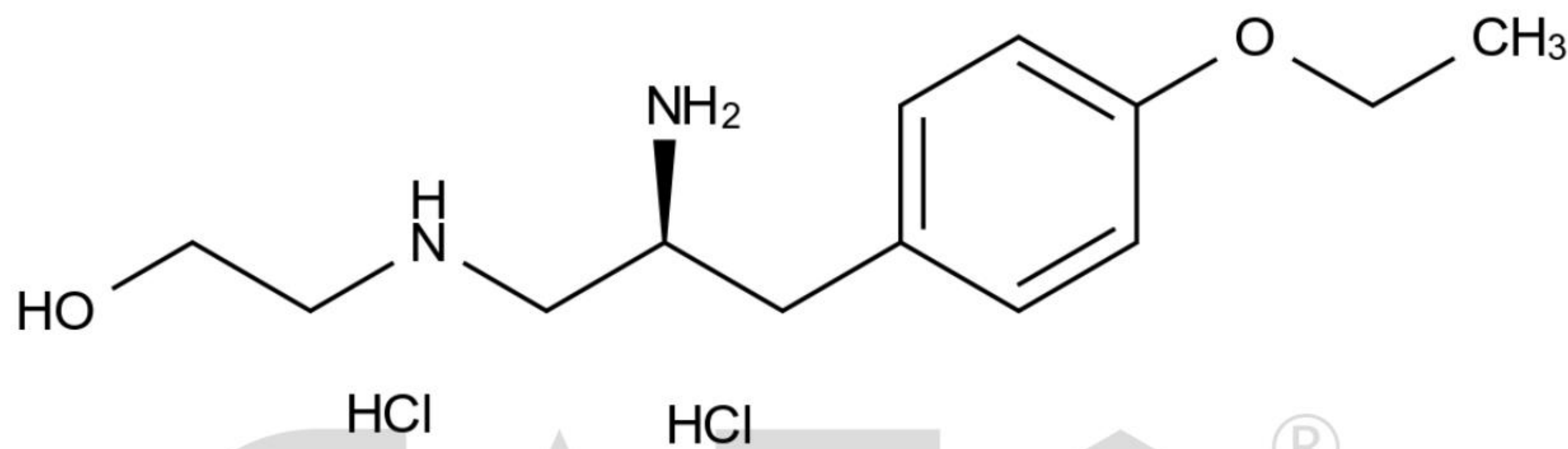


Certificate of Analysis

Reference Material

Product Name:	Gadoxetate Impurity 1	Catalogue Number:	C4X-26181
Chemical Name:	N/A	Lot Number:	0914-RE-0055
CAS Number:	N/A	Expiry Date:	Sep 01, 2026
Molecular Formula:	C ₁₃ H ₂₂ N ₂ O ₂ 2*HCl	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	238.33 2*36.46		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Colourless Gel
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.826%
Water Content	Karl Fischer	10.07%
Assay		89.8%

Comment:

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

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

Water Content is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Aporoved by General manager:

David

Date: Sep 02, 2023

Date: Sep 15, 2023

Date: Sep 15, 2023

