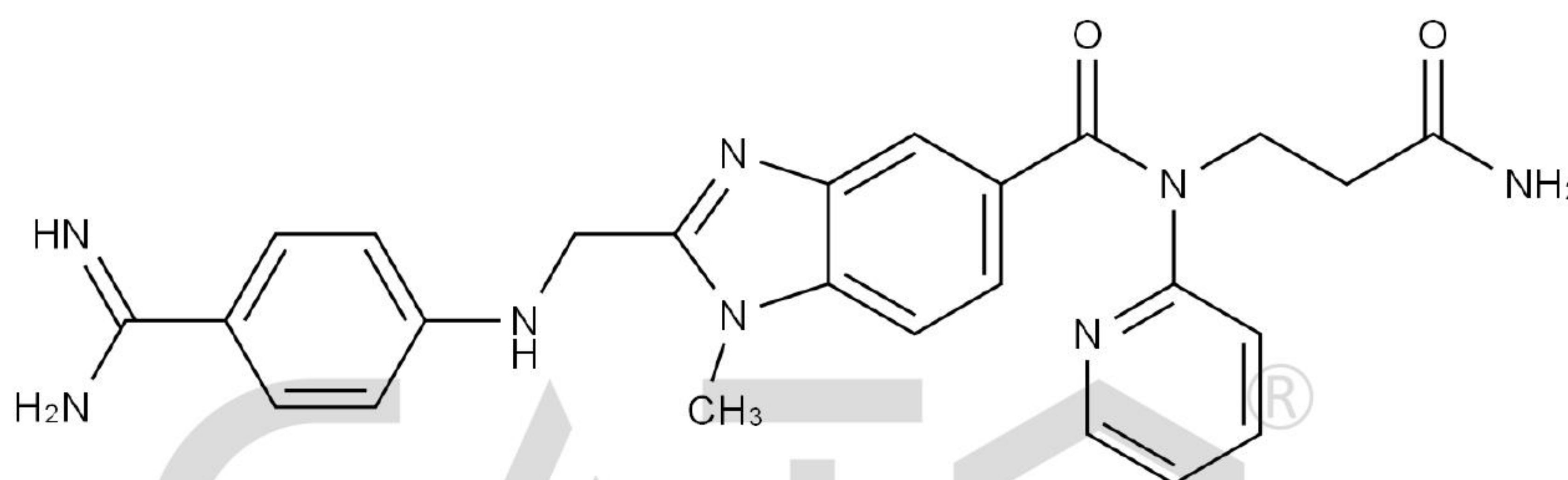


Certificate of Analysis

Reference Material & Standard

Product Name:	Dabigatran Impurity 54	Catalogue Number:	C4X-108954
Synonyms:	N/A	Lot Number:	0901-RG-0116
CAS Number:	1643377-48-3	Expiry Date:	Aug 28, 2029
Molecular Formula:	C ₂₅ H ₂₆ N ₈ O ₂	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	470.53		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&UV&HNMR	Confirmed
Purity	HPLC	98.959%
Water Content	Karl Fischer	0.33%
Residual Solvents	NMR	Not detected in NMR
Assay		98.6%

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:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Sep 02, 2025

Date: Sep 02, 2025

Date: Sep 02, 2025

