

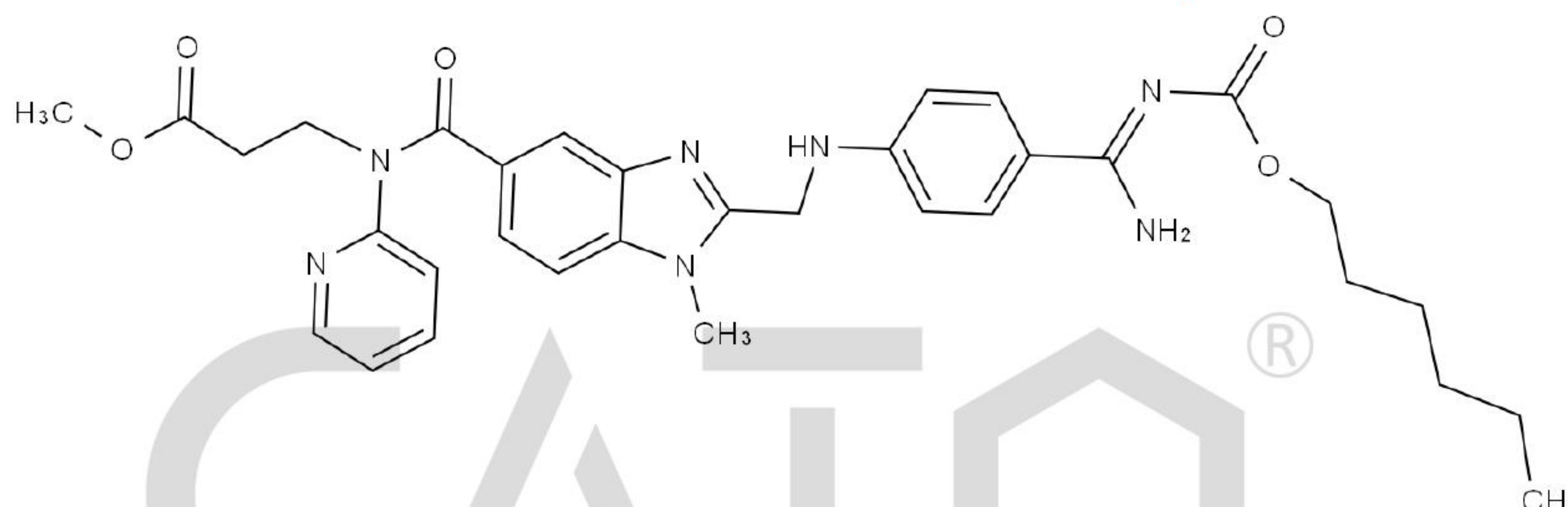
Certificate of Analysis

Reference Material & Standard

Product Name:	Dabigatran Impurity 6	Catalogue Number:	C4X-10896
Synonyms:	N/A	Lot Number:	0526-RG-0060
CAS Number:	211915-00-3	Expiry Date:	Oct 20, 2027
Molecular Formula:	C33H39N7O5	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	613.71	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.029%
Water Content	Karl Fischer	0.37%
Residual Solvents	NMR	Not detected in NMR
Assay		97.7%

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: May 26, 2025

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