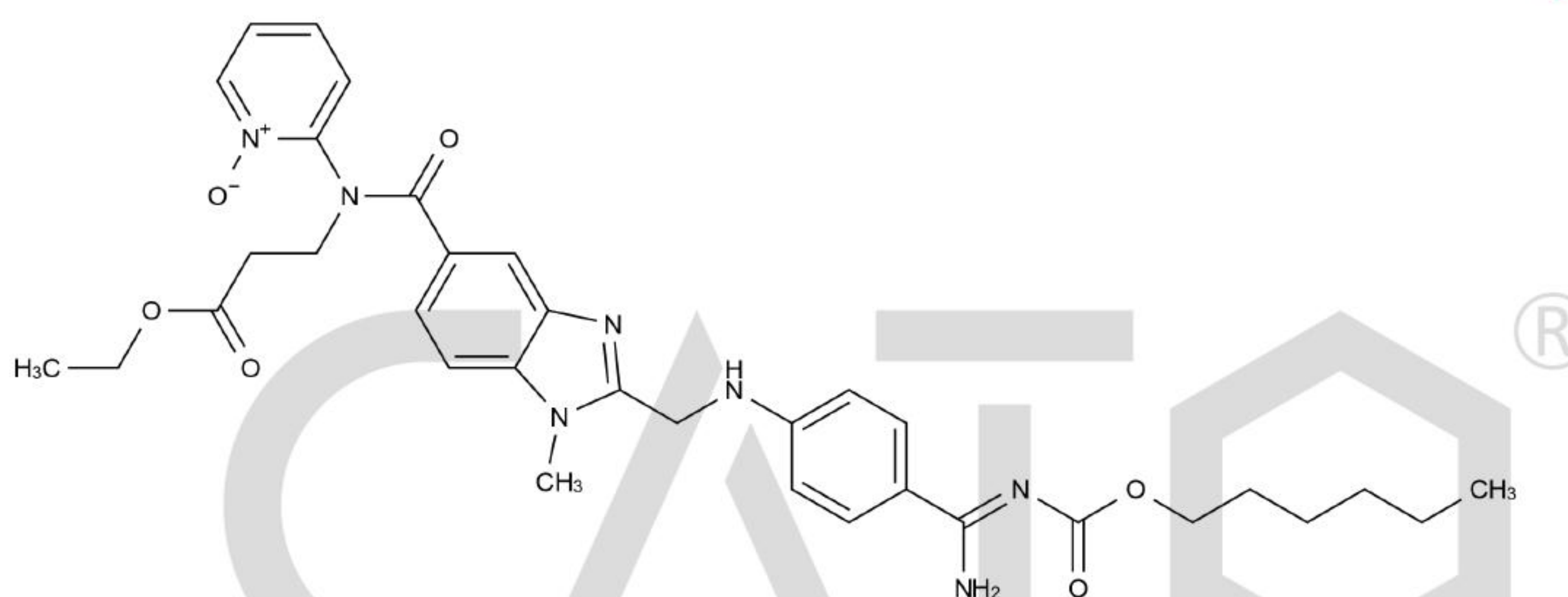


Certificate of Analysis

Reference Material & Standard

Product Name:	Dabigatran Impurity 9	Catalogue Number:	C4X-10899
Synonyms:	2-[N-(3-Ethoxy-3-oxopropyl)-2-[[[4-{N-[(hexyloxy)carbonyl]carbamimidoyl}phenyl]amino]methyl]-1-methyl-1H-benzodimidazole-5-carboxamido]pyridine 1-oxide	Lot Number:	0618-RH-0127
CAS Number:	1381757-44-3	Expiry Date:	Jul 02, 2030
Molecular Formula:	C ₃₄ H ₄₁ N ₇ O ₆	Storage:	2°C ~ 8°C Sealed
Molecular Weight:	643.73	Shipping Condition:	Shipping at Room Temperature
Solubility:	Soluble in Acetonitrile and DMSO	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	98.464%
Residue on Ignition	TGA	0.8993%
Loss on Drying	TGA	0.0189%
Assay	qNMR	97.8%
Assay	Mass Balance	97.6%

Comment:

- The retest date of this product is Jul 02, 2029.
- The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Residue on Ignition} - \text{Loss on Drying}) * \text{Purity HPLC (\%)} / 100\%$$
Residue on Ignition and Loss on Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Alice

Approved by General Manager:

David

Date: Jul 03, 2026

Date: Jul 03, 2026

Date: Jul 03, 2026



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