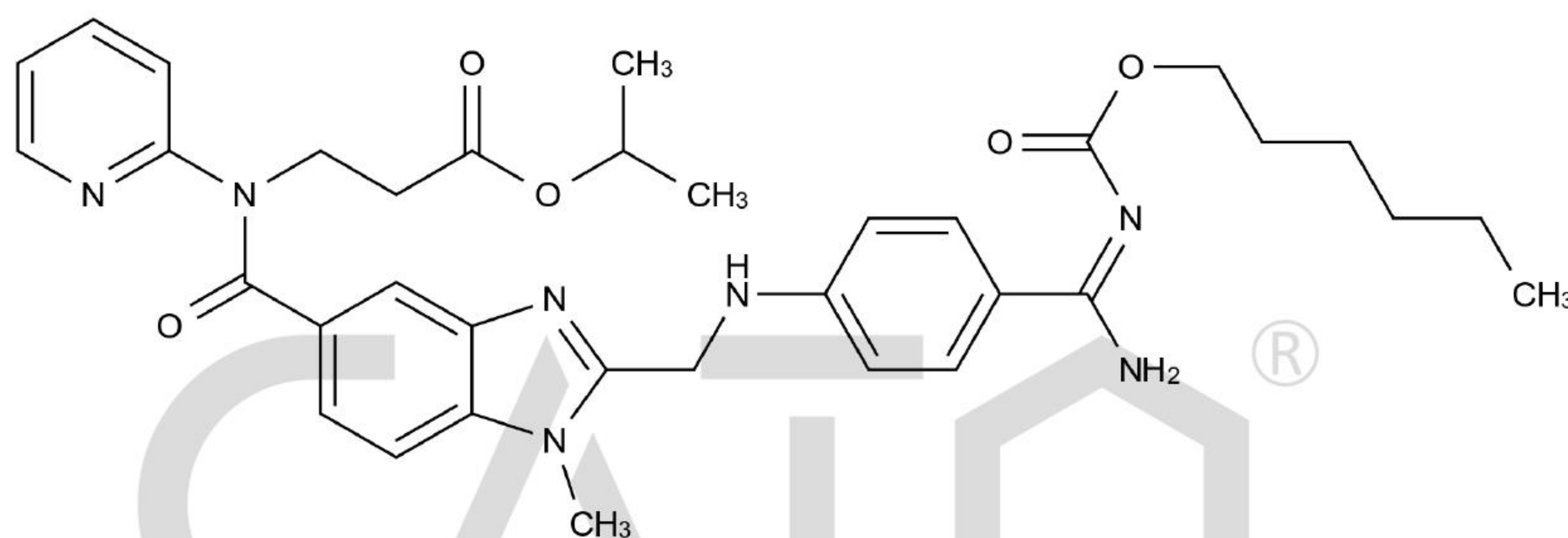


Certificate of Analysis

Reference Material & Standard

Product Name:	O-Desethyl O-Isopropyl Dabigatran Etexilate	Catalogue Number:	C4X-1089101
Synonyms:	Dabigatran Etexilate Impurity 101	Lot Number:	0425-RG-0067
CAS Number:	1610758-19-4	Expiry Date:	Apr 29, 2028
Molecular Formula:	C35H43N7O5	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	641.76		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.431%
Residue on Ignition	TGA	0.1633%
Loss On Drying	TGA	0.0163%
Assay		99.3%

Comment:

The calculation of the 100% 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:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Apr 30, 2025

Date: Apr 30, 2025

Date: Apr 30, 2025

