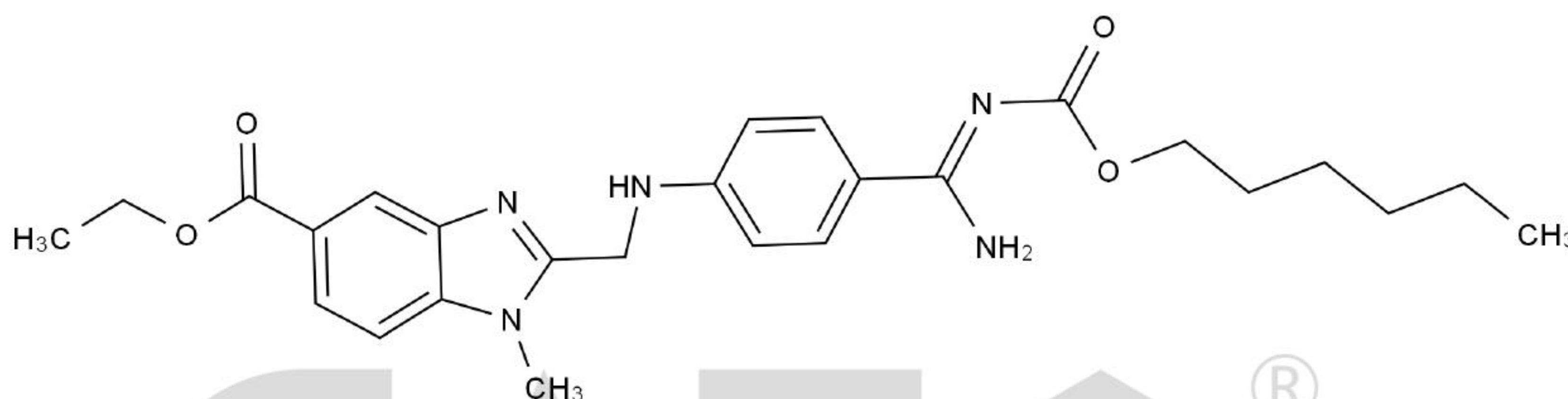


# Certificate of Analysis

## Reference Material & Standard

|                    |                                                               |                   |                                           |
|--------------------|---------------------------------------------------------------|-------------------|-------------------------------------------|
| Product Name:      | Dabigatran Impurity 4                                         | Catalogue Number: | C4X-10894                                 |
| Synonyms:          | N/A                                                           | Lot Number:       | 0403-RE-0022                              |
| CAS Number:        | 1408238-36-7                                                  | Expiry Date:      | Jan 10, 2026                              |
| Molecular Formula: | C <sub>26</sub> H <sub>33</sub> N <sub>5</sub> O <sub>4</sub> | Storage:          | 2°C ~ 8°C Protected from light and Sealed |
| Molecular Weight:  | 479.57                                                        |                   |                                           |

### Chemical Structure:



| Test Items        | Method            | Results             |
|-------------------|-------------------|---------------------|
| Appearance        | Visual inspection | Off-White Solid     |
| Identification    | LCMS&IR&HNMR      | Confirmed           |
| Purity            | HPLC              | 99.598%             |
| Water Content     | Karl Fischer      | 0.16%               |
| Residual Solvents | NMR               | Not detected in NMR |
| Assay             |                   | 99.4%               |

### 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: Aug 22, 2024

Date: Aug 22, 2024

Date: Aug 22, 2024

