

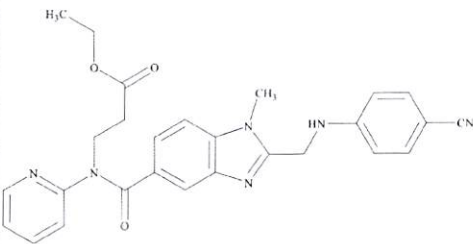
Certificate of Analysis

Certificate No.: 20240112007



Date: January 12, 2024

Retest date: January 12, 2027

Compound Name: Dabigatran Impurity 65	
Synonyms:	ethyl 3-(2-(((4-cyanophenyl)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5-carboxamido)propanoate
TLC Catalogue Number:	D-5915
CAS Number:	211915-84-3
Molecular Weight:	482.54
Molecular Formula:	C ₂₇ H ₂₆ N ₆ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3560-077A1
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, DMF



Test Description	Specifications	Results
Visual Description	Off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.6%
Impurity (HPLC)	RT 1.35, 0.19%	
Water Content (KF)	N/A	0.1%
Residual Solvents (NMR)	0.1% ethanol	
Assay (%)	Not less than 90.0%	99.4%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01/15/2024
Approved by:	Quality Assurance		01/15/2024

Attachments: HPLC, IR, MS and NMR spectra.