

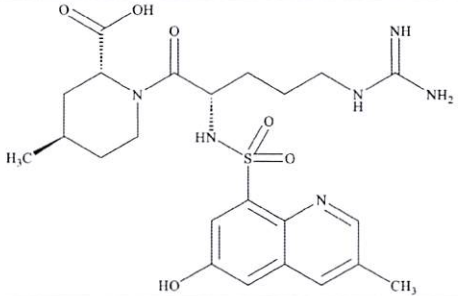


Certificate of Analysis



Certificate No.: 20240705003

Date: July 5, 2024

Retest date: July 3, 2027

Compound Name:	Argatroban Impurity 10	
Synonyms:	(2R,4R)-1-(((6-hydroxy-3-methylquinolin-8-yl)sulfonyl)-L-arginyl)-4-methylpiperidine-2-carboxylic acid	
TLC Catalogue Number:	A-5924	
CAS Number:	N/A	
Molecular Weight:	520.61	
Molecular Formula:	C ₂₃ H ₃₂ N ₆ O ₆ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	6110-069A2	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO	

Test Description	Specifications	Results
Visual Description	White to 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%	97.1%
Impurity (HPLC)	RT 7.03, 0.64%; RT 13.07, 1.47%; RT 15.17, 0.42%	
Water Content (KF)	N/A	2.6%
Optical Rotation	N/A	$[\alpha]_D^{25.0}(c=0.38, \text{DMSO}): +159.3^\circ$
Residual Solvents (NMR)	2.7% methanol	
Assay (%)	Not less than 90.0%	92.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/08/2024
Approved by:	Quality Assurance		07/08/2024

Attachments: HPLC, IR, MS and NMR spectra.