

Certificate of Analysis

Certificate No.: 20230705012

Date: July 5, 2023

Retest date: June 28, 2026

Compound Name: Bedaquiline Impurity 1 (Mixture of Enantiomers)	
Synonyms:	<i>rel</i> -(1R,2R)-4-amino-1-(6-bromo-2-methoxyquinolin-3-yl)-2-(naphthalen-1-yl)-1-phenylbutan-2-ol
TLC Catalogue Number:	B-101007
CAS Number:	N/A
Molecular Weight:	527.46
Molecular Formula:	C ₃₀ H ₂₇ BrN ₂ O ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	5587-084A2
Storage Conditions:	Store at -20 °C
Solubility:	Solution of Methanol and Acetonitrile, DMSO



and enantiomer

Test Description	Specifications	Results
Visual Description	Pale yellow 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%	98.7%
Impurity (HPLC)	RT 11.98, 0.86%; RT 18.04, 0.22%	
Water Content (KF)	N/A	0.3%
Residual Solvents (NMR)	0.8% methanol	
Assay (%)	Not less than 90.0%	97.6%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/06/2023
Approved by:	Quality Assurance		07/06/2023

Attachments: HPLC, IR, MS and NMR spectra.