

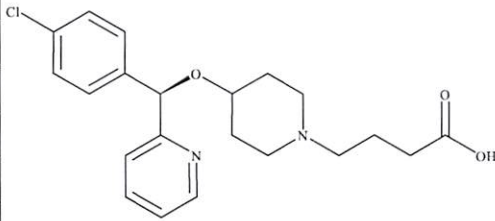
Certificate of Analysis

Certificate No.: 20240627001-2



Date: June 27, 2024

Retest date: June 21, 2027

Compound Name: (R)-Bepotastine	
Synonyms:	(R)-4-(4-((4-chlorophenyl)(pyridin-2-yl)methoxy)piperidin-1-yl)butanoic acid
TLC Catalogue Number:	B-502
CAS Number:	190730-41-7
Alternate CAS Number:	190730-42-8 (Besylate salt)
Molecular Weight:	388.89
Molecular Formula:	C ₂₁ H ₂₅ ClN ₂ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	6253-059A3
Storage Conditions:	Hygroscopic, store at 2-8 °C
Solubility:	DMSO, Water, Ethanol



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%	99.8%
Impurity (HPLC)	RT 5.97, 0.18%	
Purity (Chiral HPLC)	Not less than 95.0%	98.2%
Water Content (KF)	N/A	1.6%
Optical Rotation	[α] _D ^{25.0} (c=5.00, CH ₃ OH): -3.4°	[α] _D ^{25.0} (c=0.39, DMSO): -6.7°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	96.4%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		02/27/2025
Approved by:	Quality Assurance		02/27/2025

Attachments: Peak Attribution Table, HPLC, IR, MS and NMR spectra.