

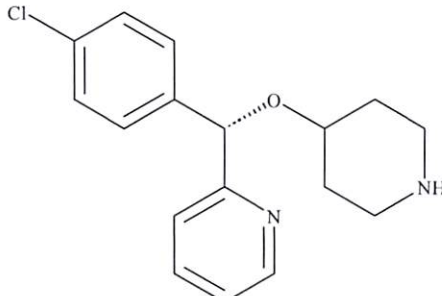
Certificate of Analysis

Certificate No.: **20240527002**



Date: May 27, 2024

Retest date: May 16, 2027

Compound Name: Bepotastine Impurity 5	
Synonyms:	(S)-2-((4-chlorophenyl)(piperidin-4-yloxy)methyl)pyridine
TLC Catalogue Number:	B-5012
CAS Number:	201594-84-5
Molecular Weight:	302.80
Molecular Formula:	C ₁₇ H ₁₉ ClN ₂ O
Source:	TLC Pharmaceutical Standards
Source Lot No.:	5773-078A2
Storage Conditions:	Store at 2-8 °C
Solubility:	DMSO, Ethanol, solution of Methanol and Acetonitrile



Test Description	Specifications	Results
Visual Description	Yellow semi-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%	99.0%
Impurity (HPLC)	RT 2.05, 0.42%; RT 4.86, 0.12%; RT 6.71, 0.45%	
Purity (Chiral HPLC)	Not less than 98.0%	99.3%
Optical Rotation	[α] _D ^{N/A} (c=0.05, CH ₃ OH): -11.0°	[α] _D ^{20.0} (c=0.31, CH ₃ OH): -9.0°
Residual Solvents (NMR)	1.9% methanol	
Assay (qNMR)	Not less than 90.0%	92.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/28/2024
Approved by:	Quality Assurance		05/28/2024

Attachments: HPLC, IR, MS and NMR spectra.