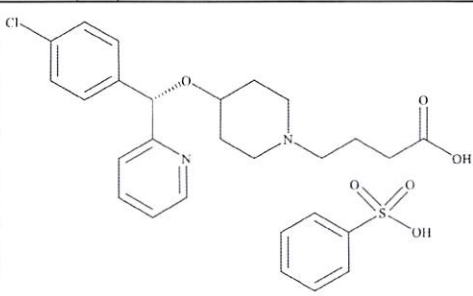


Certificate of Analysis

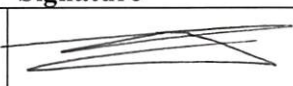

Certificate No.: **20230913506**

Date: September 13, 2023

Retest date: September 12, 2026

Compound Name:	Bepotastine Besylate	
Synonyms:	(S)-4-(4-((4-chlorophenyl)(pyridin-2-yl)methoxy)piperidin-1-yl)butanoic acid, benzenesulfonic acid (1:1)	
TLC Catalogue Number:	B-503	
CAS Number:	190786-44-8	
Molecular Weight:	388.90 158.18	
Molecular Formula:	C ₂₁ H ₂₅ ClN ₂ O ₃ · C ₆ H ₆ O ₃ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	1683-035A1	
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
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.9%
Impurity (HPLC)	N/A	
Purity (Chiral HPLC)	Not less than 98.0%	100.0%
Water Content (KF)	N/A	0.4%
Residue (TGA at 800 °C)	N/A	0.0%
Optical Rotation	[α] _D ^{20.0} (c=5.00, CH ₃ OH): +6.0°	[α] _D ^{25.0} (c=0.27, CH ₃ OH): +2.5°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		09 114 12023
Approved by:	Quality Assurance		09 114 12023

Attachments: HPLC, IR, MS, NMR and TGA spectra.