



Certificate of Analysis

Certificate No.: 20240627022

Date: June 27, 2024

Retest date: June 21, 2027

Compound Name:	Bepotastine-d₆	
Synonyms:	(S)-4-(4-((4-chlorophenyl)(pyridin-2-yl)methoxy)piperidin-1-yl)butanoic-2,2,3,3,4,4-d ₆ acid	
TLC Catalogue Number:	B-5016	
CAS Number:	2469626-70-6	
Molecular Weight:	394.93	
Molecular Formula:	C ₂₁ H ₁₉ D ₆ ClN ₂ O ₃	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	6268-043A3	
Storage Conditions:	Hygroscopic, store at 2-8 °C	
Solubility:	Methanol, DMSO, Water, Acetonitrile, 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%	99.3%
Impurity (HPLC)	RT 3.56, 0.17%; RT 14.95, 0.32%	
Purity (Chiral HPLC)	Not less than 98.0%	99.6%
Isotopic Enrichment	Not less than 98.0%	99.2%
Water Content (KF)	N/A	0.7%
Optical Rotation	$[\alpha]_D^{25.0}(c=5.10, CH_3OH): +3.5^\circ$	$[\alpha]_D^{25.0}(c=0.41 CH_3OH): +6.3^\circ$
Residual Solvents (NMR)	0.1% dichloromethane and 0.3% acetonitrile	
Assay (%)	Not less than 90.0%	97.8%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/28/2024
Approved by:	Quality Assurance		06/28/2024

Attachments: HPLC, IR, MS and NMR spectra.