

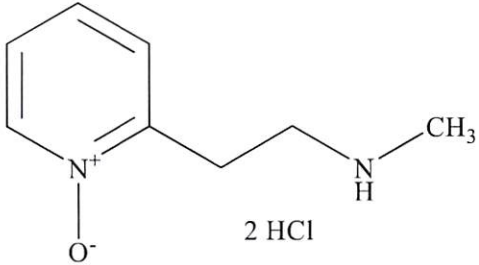
Certificate of Analysis

Certificate No.: 20240328506



Date: March 28, 2024

Retest date: March 26, 2027

Compound Name: Betahistine Impurity 4 DiHCl	
Synonyms:	2-(2-(methylamino)ethyl)pyridine 1-oxide, hydrochloride (1:2)
TLC Catalogue Number:	B-3610
CAS Number:	88796-99-0 (free base)
Molecular Weight:	152.20 2*36.46
Molecular Formula:	C ₈ H ₁₂ N ₂ O · 2 HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3896-066A1
Storage Conditions:	Hygroscopic, store at 2-8 °C
Solubility:	Methanol, DMSO, Water



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%	99.4%
Impurity (HPLC)	RT 7.33, 0.49%	
Water Content (KF)	N/A	0.3%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.1%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		04 / 01 / 2024
Approved by:	Quality Assurance		04 / 01 / 2024

Attachments: HPLC, IR, MS and NMR spectra.