



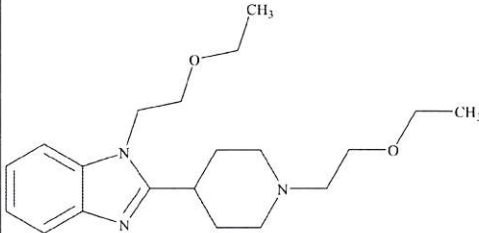
Certificate of Analysis

Certificate No.: 20231113009


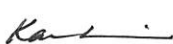
Date: November 13, 2023

Retest date: November 10, 2026

Compound Name: Bilastine Impurity 5	
Synonyms:	1-(2-ethoxyethyl)-2-(1-(2-ethoxyethyl)piperidin-4-yl)-1H-benzo[d]imidazole
TLC Catalogue Number:	B-1710
CAS Number:	N/A
Molecular Weight:	345.49
Molecular Formula:	C ₂₀ H ₃₁ N ₃ O ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	C0013-074A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol



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%	100.0%
Impurity (HPLC)	N/A	
Residual Solvents (NMR)	No residual solvent	
Assay (qNMR)	Not less than 90.0%	98.7%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		11 / 16 / 2023
Approved by:	Quality Assurance		11/16/2023

Attachments: HPLC, IR, MS and NMR spectra.