

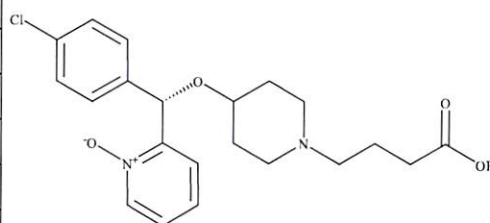
## Certificate of Analysis

Certificate No.: **20250303502**



Date: March 3, 2025

Retest date: February 27, 2028

<b>Compound Name:</b> Bepotastine N-Oxide Impurity	
<b>Synonyms:</b>	(S)-2-(((1-(3-carboxypropyl)piperidin-4-yl)oxy)(4-chlorophenyl)methyl)pyridine 1-oxide
<b>TLC Catalogue Number:</b>	B-504
<b>CAS Number:</b>	N/A
<b>Alternate CAS Number:</b>	N/A
<b>Molecular Weight:</b>	404.89
<b>Molecular Formula:</b>	C <sub>21</sub> H <sub>25</sub> ClN <sub>2</sub> O <sub>4</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	1921-009A3
<b>Storage Conditions:</b>	Hygroscopic, store at 2-8 °C
<b>Solubility:</b>	Methanol



Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>99.4%</b>
<b>Impurity (HPLC)</b>	RT 0.97, 0.26%; RT 10.40, 0.19%	
<b>Water Content (KF)</b>	N/A	<b>1.4%</b>
<b>Optical Rotation</b>	N/A	[α] <sub>D</sub> <sup>25.0</sup> (c=0.22, CH <sub>3</sub> OH): <b>+19.6°</b>
<b>Residual Solvents (NMR)</b>	2.2% methanol	
<b>Assay (%)</b>	Not less than 90.0%	<b>95.8%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03/03/2025
Approved by:	Quality Assurance		03/03/2025

**Attachments:** Peak Attribution Table, HPLC, IR, MS and NMR spectra.