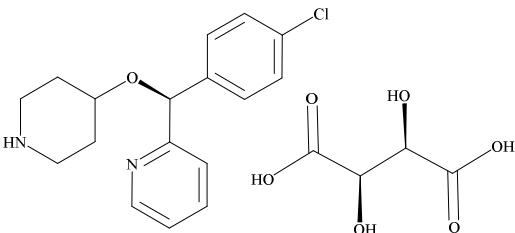


# Certificate of Analysis

 Certificate No.: **20191031008**

Date: October 31, 2019

Retest date: October 30, 2022

<b>Compound Name:</b>	<b>Bepotastine Impurity A Tartrate</b>	
<b>Synonyms:</b>	(S)-2-((4-chlorophenyl)(piperidin-4-yloxy)methyl)pyridine, tartrate (1:1)	
<b>TLC Catalogue Number:</b>	B-505	
<b>CAS Number:</b>	210095-58-2	
<b>Molecular Weight:</b>	302.80 150.09	
<b>Molecular Formula:</b>	C <sub>17</sub> H <sub>19</sub> ClN <sub>2</sub> O · C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	2415-002A4	
<b>Storage Conditions:</b>	Store at 2-8 °C	
<b>Solubility:</b>	Methanol, DMSO	

Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
<b>IR</b>	Conforms to structure	<b>Conforms</b>
<b>MS</b>	Conforms to structure	<b>Conforms</b>
<b><sup>1</sup>H NMR</b>	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>99.9%</b>
<b>Impurity (HPLC)</b>	N/A	
<b>Purity (Chiral HPLC)</b>	Not less than 98.0%	<b>99.9%</b>
<b>Water Content (KF)</b>	N/A	<b>0.4%</b>
<b>Optical Rotation</b>	N/A	$[\alpha]_D^{25.0}$ (c=0.52, CH <sub>3</sub> OH): <b>+9.8°</b>
<b>Residual Solvents (NMR)</b>	No residual solvent	
<b>Assay (%)</b>	Not less than 90.0%	<b>99.4%</b>
<b>Recommendation:</b>	<b>Released.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		
Approved by:	Quality Assurance		

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