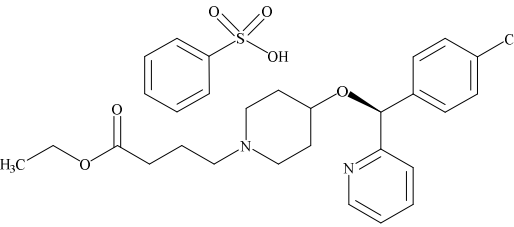


Certificate of Analysis

Certificate No.: **20180913008**

Date: September 13, 2018

Retest date: September 6, 2021

Compound Name:	Bepotastine Ethyl Ester Besylate	
Synonyms:	Ethyl (S)-4-(4-((4-chlorophenyl)(pyridin-2-yl)methoxy)piperidin-1-yl)butanoate, benzenesulfonate (1:1)	
TLC Catalogue Number:	B-506	
CAS Number:	190730-39-3 (free base)	
Molecular Weight:	416.95 158.18	
Molecular Formula:	C ₂₃ H ₂₉ ClN ₂ O ₃ · C ₆ H ₆ O ₃ S	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3166-005A5	
Storage Conditions:	Store at 2-8 °C.	
Solubility:	Methanol, DMSO, DMF	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 98.0%	98.9%
Impurity (HPLC)	RT 2.43, 0.1%; RT 5.76, 0.2%; RT 10.39, 0.2%	
Water Content (KF)	N/A	1.8%
[α]_D^{25.0} (c=0.54, CH₃OH)	No reference	+0.5°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 95.0%	97.1%
Recommendation:	Released.	

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

Attachments: HPLC, MS and NMR spectra.