

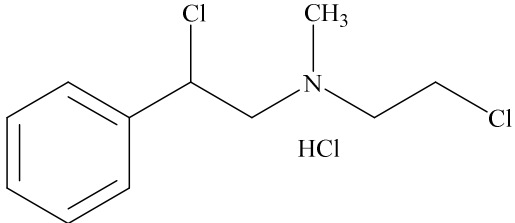
Certificate of Analysis

Certificate No.: **20190929039**

Date: September 29, 2019

Retest date: September 20, 2022

Compound Name: Mirtazapine Impurity 5 HCl	
Synonyms:	2-chloro- <i>N</i> -(2-chloroethyl)- <i>N</i> -methyl-2-phenylethan-1-amine, hydrochloride (1:1)
TLC Catalogue Number:	M-1025
CAS Number:	6407-19-8
Molecular Weight:	232.15 36.46
Molecular Formula:	C ₁₁ H ₁₅ Cl ₂ N. HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	3566-052A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Acetonitrile



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%	99.0%
Impurity (HPLC)	RT 5.69, 0.25%; RT 8.68, 0.41%; RT 9.17, 0.26%	
Water Content (KF)	N/A	0.4%
Residual Solvents (NMR)	0.2% dichloromethane and 0.3% ethyl acetate	
Assay (%)	Not less than 90.0%	98.1%
Recommendation:	Released. The compound deteriorates in water and alcohol.	

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

Attachments: HPLC, IR, MS and NMR spectra.