

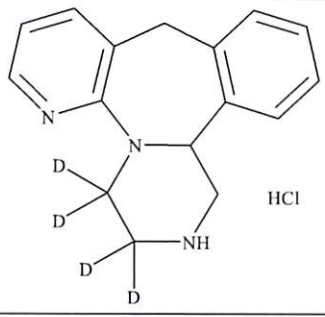
Certificate of Analysis

Certificate No.: **20230414008-2**



Date: April 14, 2023

Retest date: April 4, 2026

Compound Name: Mirtazapine EP Impurity D-d ₄ HCl (Mirtazapine USP Related Compound A-d ₄ HCl, N-Desmethyl Mirtazapine-d ₄ HCl)	
Synonyms:	1,2,3,4,10,14b-hexahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepine-3,3,4,4-d ₄ , hydrochloride (1:1)
TLC Catalogue Number:	M-103
CAS Number:	1188266-12-7
Molecular Weight:	255.36 36.46
Molecular Formula:	C ₁₆ H ₁₃ D ₄ N ₃ . HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	1809-016A5
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO



Test Description	Specifications	Results
Visual Description	Pale brown 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%	99.6%
Impurity (HPLC)	RT 2.34, 0.20%	
Isotopic Enrichment	Not less than 98.0%	99.7%
Residual Solvents (NMR)	0.1% methanol	
Assay (qNMR)	Not less than 90.0%	91.7%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/23/2024
Approved by:	Quality Assurance		07/23/2024

Attachments: HPLC, IR, MS and NMR spectra.