

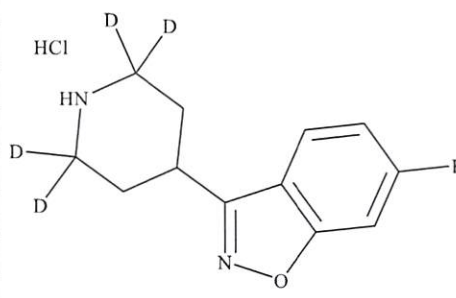
Certificate of Analysis

Certificate No.: 20251230028



Date: December 30, 2025

Retest date: December 29, 2028

Compound Name: Risperidone EP Impurity M-d ₄ HCl (Paliperidone USP Related Compound B-d ₄ HCl)	
Synonyms:	6-fluoro-3-(piperidin-4-yl-2,2,6,6-d ₄)benzo[d]isoxazole, hydrochloride (1:1)
TLC Catalogue Number:	R-0649
CAS Number:	N/A
Alternate CAS Number:	84163-13-3 (non-labelled)
Molecular Weight:	224.27 36.46
Molecular Formula:	C ₁₂ H ₉ D ₄ FN ₂ O. HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	7231-042A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, DMF



Test Description	Specifications	Results
Visual Description	Off-white 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%	99.9%
Impurity (HPLC)	N/A	
Isotopic Enrichment	Not less than 98.0%	99.4%
Water Content (KF)	N/A	0.1%
Residual Solvents (NMR)	0.2% methanol and 0.2% dichloromethane	
Assay (%)	Not less than 90.0%	99.4%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01/06/2026
Approved by:	Quality Assurance		01/06/2026

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