

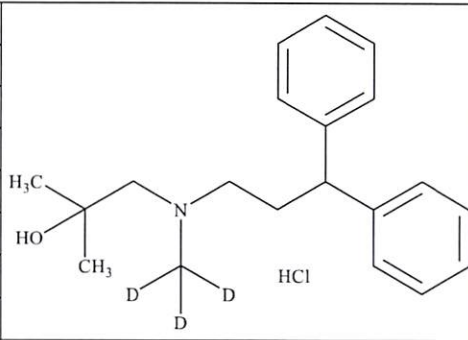
Certificate of Analysis

Certificate No.: **20260625022**

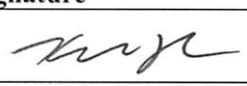

Date: June 25, 2026

Retest date: June 23, 2029

Compound Name: Lercanidipine EP Impurity E-d ₃ HCl	
Synonyms:	1-((3,3-diphenylpropyl)(methyl-d ₃)amino)-2-methylpropan-2-ol, hydrochloride (1:1)
TLC Catalogue Number:	L-17104
CAS Number:	N/A
Alternate CAS Number:	1189689-16-4 (free base)
Molecular Weight:	300.46 36.46
Molecular Formula:	C ₂₀ H ₂₄ D ₃ NO. HCl
Source:	TLC Pharmaceutical Standards
Source Lot No.:	7468-081A4
Storage Conditions:	Hygroscopic, 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%	99.5%
Impurity (HPLC)	RT 10.73, 0.11%; RT 11.49, 0.30%	
Isotopic Enrichment	Not less than 98.0%	99.5%
Water Content (KF)	N/A	0.9%
Residual Solvents (NMR)	0.8% acetonitrile	
Assay (%)	Not less than 90.0%	97.8%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/25/2026
Approved by:	Quality Assurance		06/25/2026

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