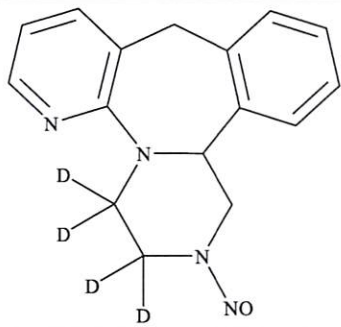


Certificate of Analysis



Certificate No.: 20260320009

Date: March 20, 2026

Retest date: March 18, 2029

Compound Name:	<i>N</i> -Nitroso Mirtazapine EP Impurity D-d ₄ (<i>N</i> -Nitroso Mirtazapine USP Related Compound A-d ₄ , <i>N</i> -Nitroso <i>N</i> -Desmethyl Mirtazapine-d ₄)	
Synonyms:	2-nitroso-1,2,3,4,10,14b-hexahydrobenzo[<i>c</i>]pyrazino[1,2- <i>a</i>]pyrido[3,2- <i>f</i>]azepine-3,3,4,4- <i>d</i> ₄	
TLC Catalogue Number:	M-1030	
CAS Number:	N/A	
Alternate CAS Number:	N/A	
Molecular Weight:	284.36	
Molecular Formula:	C ₁₆ H ₁₂ D ₄ N ₄ O	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	7315-081A4	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Acetonitrile, DMSO	

Test Description	Specifications	Results
Visual Description	Pale yellow solid	Conforms
Identification		
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.1%
Impurity (HPLC)	RT 0.83, 0.34%; RT 11.39, 0.33%; RT 16.38, 0.13%	
Isotopic Enrichment	Not less than 98.0%	99.9%
Residual Solvents (NMR)	0.2% methanol and 0.3% dichloromethane	
Assay (qNMR)	Not less than 90.0%	97.8%
Recommendation:	Release. The compound is a <i>N</i> -Nitroso product. Avoid using metal spatula and applying pressure. Wear proper personal protective equipment when handling.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		03/20/2026
Approved by:	Quality Assurance		03/20/2026

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