

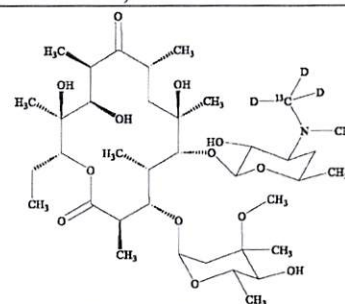
Certificate of Analysis

Certificate No.: 20241220015


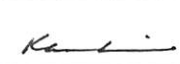
Date: December 20, 2024

Retest date: December 19, 2025

Compound Name: Erythromycin- ¹³ C-d ₃	
Synonyms:	(3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-14-ethyl-7,12,13-trihydroxy-4-(((2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyltetrahydro-2H-pyran-2-yl)oxy)-6-(((2S,3R,4S,6R)-3-hydroxy-6-methyl-4-(methyl(methyl- ¹³ C-d ₃)amino)tetrahydro-2H-pyran-2-yl)oxy)-3,5,7,9,11,13-hexamethyloxacyclotetradecane-2,10-dione
TLC Catalogue Number:	E-201
CAS Number:	2378755-50-9
Molecular Weight:	737.95
Molecular Formula:	C ₃₆ ¹³ CH ₆₄ D ₃ NO ₁₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	5965-093A3
Storage Conditions:	Store at -20 °C
Solubility:	Methanol, DMSO, DMF, Acetonitrile, Ethanol



Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	100.0%
Impurity (HPLC)	N/A	
Isotopic Enrichment	Not less than 98.0%	99.5% D; 99.0% ¹³C
Optical Rotation	[α] _D ^{N/A} (c=0.99, CH ₃ OH): -75.4°	[α] _D ^{25.0} (c=0.40, CH ₃ OH): -70.2°
Residual Solvents (NMR)	0.1% dichloromethane, 0.3% methanol and 1.8% diethyl ether	
Assay (qNMR)	Not less than 90.0%	91.5%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		12/23/2024
Approved by:	Quality Assurance		12/23/2024

Attachments: HPLC, IR, MS and NMR spectra.