CERTIFICATE OF ANALYSIS

(Certificate No. KMR088004-01)

Release Date: 25/02/2025 **Re-test Date:** 24/02/2028

N-Nitroso -N-Demethyl Roxithromycin

Identification

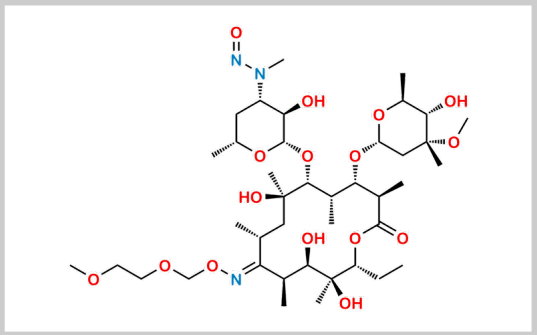
Chemical Name :
N-((2S,3R,4S,6R)-2-(((3R,4S,5S,6R,7R,9R,11S,12R,13S,14R,E)-14-ethyl-7,12,13-trihydroxy-4-(((2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyltetrahydro-2H-pyran-2-yl)oxy)-10-(((2-methoxyethoxy)methoxy)imino)-3,5,7,9,11,13-hexamethyl-2-oxooxacyclotetradecan-6-yl)oxy)-3-hydroxy-6-methyltetrahydro-2H-pyran-4-yl)-N-methylnitrous amide

CAT No. : KMR088004

CAS No. : NA

Molecular Formula : C40H73N3O16

Molecular Weight : 852.0



Analytical Information

Batch No.	: R088004-093	**Solubility**	: Acetonitrile
Description	: Off white solid	**Mass**	: Confirm
HPLC Purity	: NLT 95.1 %	**IR**	: Confirm
Weight Loss By TGA	: NLT 0.1 %	**1H NMR**	: Confirm
% Potency	: 95 %	**13C NMR**	: Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.1(Weight Loss By TGA)] x [95.1(HPLC Purity)]/100 = 95 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		25/02/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA