

# CERTIFICATE OF ANALYSIS

(Certificate No. KMR088004-01)

Release Date: 25/02/2025

Re-test Date: 24/02/2028

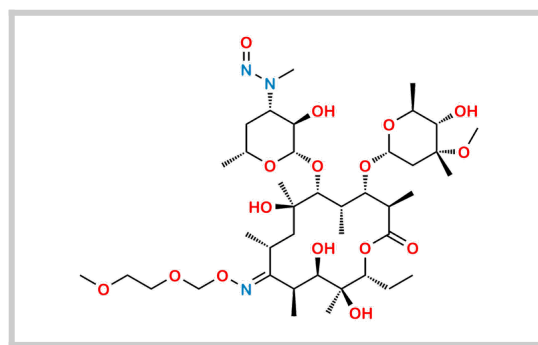
## N-Nitroso -N-Demethyl Roxithromycin

### 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** : C<sub>40</sub>H<sub>73</sub>N<sub>3</sub>O<sub>16</sub>  
**Molecular Weight** : 852.0



### Analytical Information

<b>Batch No.</b>	: R088004-093	<b>Solubility</b>	: Acetonitrile
<b>Description</b>	: Off white solid	<b>Mass</b>	: Confirm
<b>HPLC Purity</b>	: NLT 95.1 %	<b>IR</b>	: Confirm
<b>Weight Loss By TGA</b>	: NLT 0.1 %	<b><sup>1</sup>H NMR</b>	: Confirm
<b>% Potency</b>	: 95 %	<b><sup>13</sup>C NMR</b>	: 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
<b>Prepared By</b>	Analytical	Jignesh Patel		25/02/2025
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		25/02/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA