

# CERTIFICATE OF ANALYSIS

(Certificate No. KME001001-01)

Release Date: 01/01/2024

Re-test Date: 31/12/2026

## N-NITROSO DESMETHYL ERYTHROMYCIN

### Identification

**Chemical Name :**

N-((2S,3R,4S,6R)-2-(((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)-3,5,7,9,11,13-hexamethyl-2,10-dioxooxacyclotetradecan-6-yl)oxy)-3-hydroxy-6-methyltetrahydro-2H-pyran-4-yl)-N-methylnitrous amide

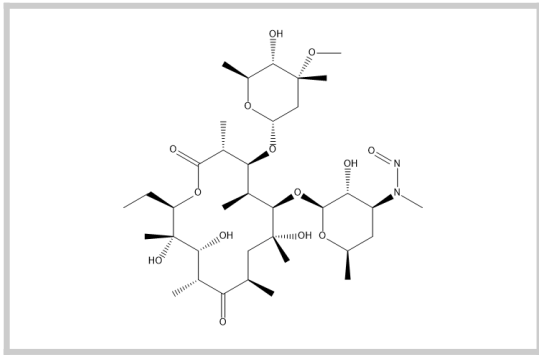
**Alt. Name** : N-Nitroso Erythromycin EP Impurity B

**CAT No.** : KME001001

**CAS No.** : Not Available

**Molecular Formula** : C<sub>36</sub>H<sub>64</sub>N<sub>2</sub>O<sub>14</sub>

**Molecular Weight** : 748.9



### Analytical Information

**Batch No.** : ERY-N-NO-045-348

**Description** : White Solid

**HPLC Purity** : 98.17 %

**Weight Loss By TGA** : 3.29 %

**% Potency** : 94.94 %

**Solubility** : Methanol

**Mass** : Confirm as Na adduct

**IR** : Confirm

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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 - 3.29(Weight Loss By TGA)] x [98.17(HPLC Purity)]/100 = 94.94 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		16/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		16/10/2024

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