

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

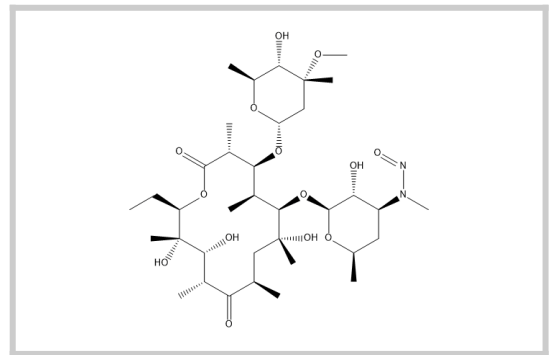
Alt. Name : N-Nitroso Erythromycin EP Impurity B

CAT No. : KME001001

CAS No. : Not Available

Molecular Formula : C₃₆H₆₄N₂O₁₄

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

¹H NMR : Confirm

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 - 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, ¹HNMR, ¹³CNMR, IR and TGA