# **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

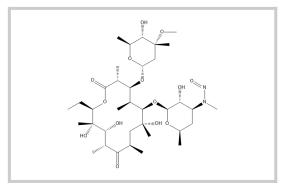
**Alt. Name** : N-Nitroso Erythromycin EP Impurity

В

CAT No. : KME001001
CAS No. : Not Available

Molecular Formula : C36H64N2O14

**Molecular Weight** : 748.9



# **Analytical Information**

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

**Description** : White Solid **Mass** : Confirm as Na

adduct

**HPLC Purity** : 98.17 %

Weight Loss By TGA : 3.29 % IR : Confirm

**% Potency** : 94.94 % : 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		21/11/2025
Reviewed & Approved By	Quality Control	Jatin Patel		21/11/2025

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