CERTIFICATE OF ANALYSIS

(Certificate No. KME001001-02)

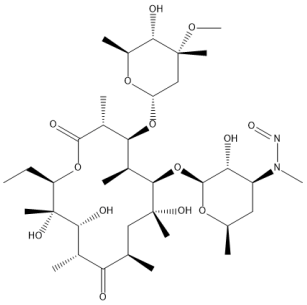
Release Date: 17/09/2026 **Re-test Date:** 16/09/2029

N-NITROSO OF N-DEMETHYL ERYTHROMYCIN A

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-045-262	**Solubility**	: Methanol
Description	: White Soild	**Mass**	: Confirm as Na adduct
HPLC Purity	: 95.74 %	**IR**	: Confirm
Weight Loss By TGA	: 3.48 %	**1H NMR**	: Confirm
% Potency	: 92.41 %	**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 - 3.48(Weight Loss By TGA)] x [95.74(HPLC Purity)]/100 = 92.41 %
-Re-tested on 17.09.2026

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		17/09/2026
Reviewed & Approved By	Quality Control	Jatin Patel		17/09/2026

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