

CERTIFICATE OF ANALYSIS

(Certificate No. KMA001001-02)

Release Date: 02/01/2026

Re-test Date: 01/01/2029

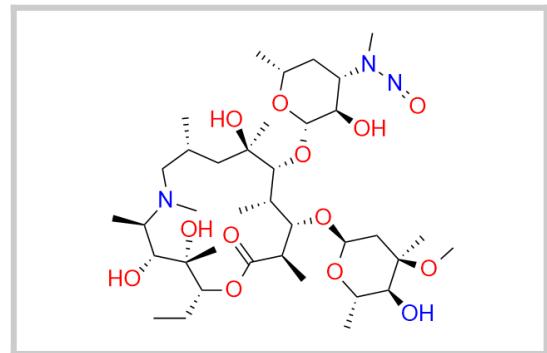
N-NITROSO OF AZITHROMYCIN IMPURITY-I

Identification

Chemical Name :

N-((2S,3R,4S,6R)-2-(((2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10-trihydroxy-13-(((2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyltetrahydro-2H-pyran-2-yl)oxy)-3,5,6,8,10,12,14-heptamethyl-15-oxo-1-oxa-6-azacyclopentadecan-11-yl)oxy)-3-hydroxy-6-methyltetrahydro-2H-pyran-4-yl)-N-methylnitrous amide (E-isomer)

Alt. Name : N-Nitroso Desmethyl Azithromycin
CAT No. : KMA001001
CAS No. : Not Available
Molecular Formula : C37H69N3O13
Molecular Weight : 763.9



Analytical Information

Batch No.	: A001001-114-085	Solubility	: Water
Description	: White Solid	Mass	: Confirm
HPLC Purity	: 96.71 %	IR	: Confirm
Weight Loss By TGA	: 5.19 %	1H NMR	: Confirm
% Potency	: 91.69 %		

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 - 5.19(Weight Loss By TGA)] x [96.71(HPLC Purity)]/100 = 91.69 %
Recommendation : Released

Department	Name	Signature	Date
Prepared By	Analytical	Parag Vekariya	02/01/2026
Reviewed & Approved By	Quality Control	Jatin Patel	02/01/2026

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