

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)

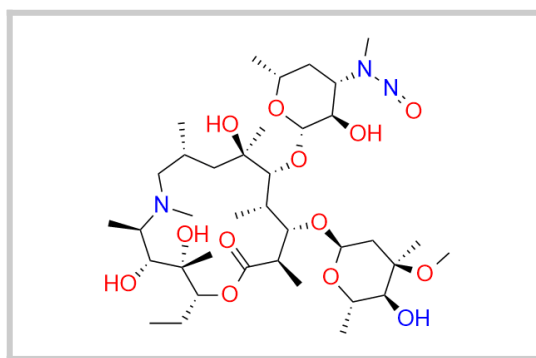
Alt. Name : N-Nitroso Desmethyl Azithromycin

CAT No. : KMA001001

CAS No. : Not Available

Molecular Formula : C37H69N3O13

Molecular Weight : 763.9



Analytical Information

Batch No. : A001001-114-085

Description : White Solid

HPLC Purity : 96.71 %

Weight Loss By TGA : 5.19 %

% Potency : 91.69 %

Solubility : *Refer in Additional information

Mass : Confirm

IR : Confirm

1H 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 = $[100 - 5.19(\text{Weight Loss By TGA})] \times [96.71(\text{HPLC Purity})]/100 = 91.69 \%$

*Solubility: Soluble in 1mg/1.0 ml Water and Freely Soluble in 5mg/1.0 ml methanol

-Solubility changed on 30.03.2026

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Vekariya		30/03/2026
Reviewed & Approved By	Quality Control	Jatin Patel		30/03/2026

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