

CERTIFICATE OF ANALYSIS

(Certificate No. KMA001038-01)

Release Date: 26/09/2025

Re-test Date: 25/09/2028

NITROSO 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 (Mixture of E/Z Isomer)

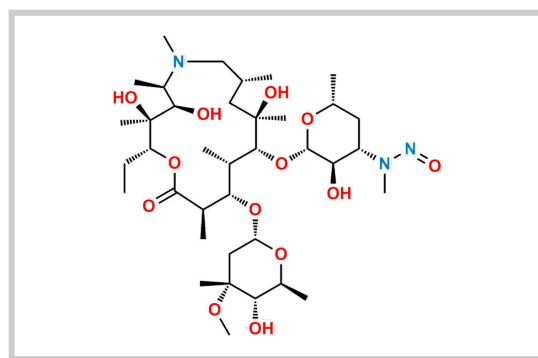
Alt. Name : N-Nitroso Desmethyl Azithromycin

CAT No. : KMA001038

CAS No. : Not Available

Molecular Formula : C37H69N3O13

Molecular Weight : 764.0



Analytical Information

Batch No. : AZI-N-NO-045-264

Description : Off White Solid

HPLC Purity : 93.97 %

Weight Loss By TGA : 3.79 %

% Potency : 90.41 %

Solubility : Methanol

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 = $[100 - 3.79(\text{Weight Loss By TGA})] \times [93.97(\text{HPLC Purity})]/100 = 90.41 \%$

-Mixture of Isomer

-Re-tested on 26.09.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		13/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		13/10/2025

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