

CERTIFICATE OF ANALYSIS

(Certificate No. KMA001001-01)

Release Date: 28/08/2023

Re-test Date: 27/08/2026

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 (Mixture of E-Z Isomers)

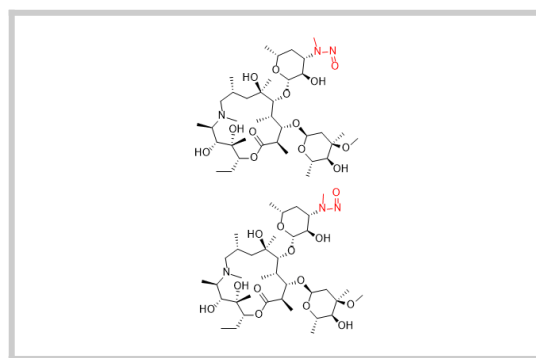
Alt. Name : N-Nitroso Desmethyl Azithromycin

CAT No. : KMA001001

CAS No. : Not Available

Molecular Formula : C37H69N3O13

Molecular Weight : 763.9



Analytical Information

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

Description : Off White Solid

HPLC Purity : 99.64 %

Weight Loss By TGA : 3.69 %

% Potency : 95.96 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

1H NMR : Confirm

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 = $[100 - 3.69(\text{Weight Loss By TGA})] \times [99.64(\text{HPLC Purity})]/100 = 95.96 \%$

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------|
| Prepared By | Analytical | Jignesh patel | | |
| Reviewed & Approved By | Quality Control | Jatin patel | | |

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