# **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)

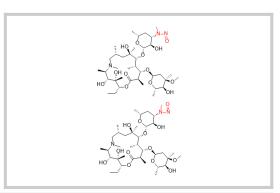
**Alt. Name** : N-Nitroso Desmethyl Azithromycin

**CAT No.** : KMA001001

CAS No. : Not Available

**Molecular Formula** : C37H69N3O13

**Molecular Weight** : 763.9



## **Analytical Information**

Batch No. : AZI-N-NO-045-264 **Solubility** : Methanol **Description** : Off White Solid Mass : Confirm **HPLC Purity** : 99.64 % IR : Confirm Weight Loss By TGA : 3.69 % 1H NMR : Confirm % Potency : 95.96 % **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(Weight Loss By TGA)] x [99.64(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