CERTIFICATE OF ANALYSIS

(Certificate No. KMA001038-01)

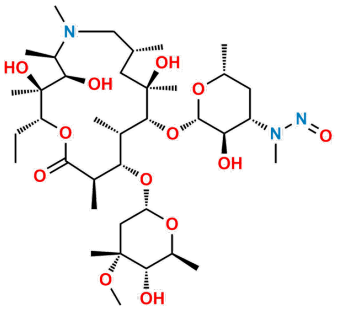
Release Date: 26/09/2025 **Re-test Date:** 25/09/2028

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	**Solubility**	: Methanol
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 93.97 %	**IR**	: Confirm
Weight Loss By TGA	: 3.79 %	**1H NMR**	: Confirm
% Potency	: 90.41 %		

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(Weight Loss By TGA)] x [93.97(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