CERTIFICATE OF ANALYSIS

(Certificate No. KMA001021-01)

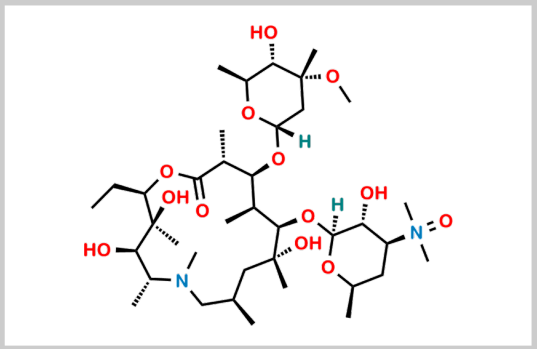
Release Date: 26/07/2025 **Re-test Date:** 25/07/2028

Azithromycin N-Oxide

Identification

Chemical Name :
Azithromycin 3'-N-Oxide (as per EP) ; (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-l-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylazinoyl)-β-d-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one (as per USP)

Alt. Name	: Azithromycin N-Oxide (USP)
CAT No.	: KMA001021
CAS No.	: 90503-06-3
Molecular Formula	: C38H72N2O13
Molecular Weight	: 765.0



Analytical Information

Batch No.	: A001021-102-139	**Solubility**	: ACN : Water (1:1)
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 92.05 %	**IR**	: Confirm
Weight Loss By TGA	: 2.08 %	**1H NMR**	: Confirm
% Potency	: 90.14 %		

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 - 2.08(Weight Loss By TGA)] x [92.05(HPLC Purity)]/100 = 90.14 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		26/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		26/07/2025

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