

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)

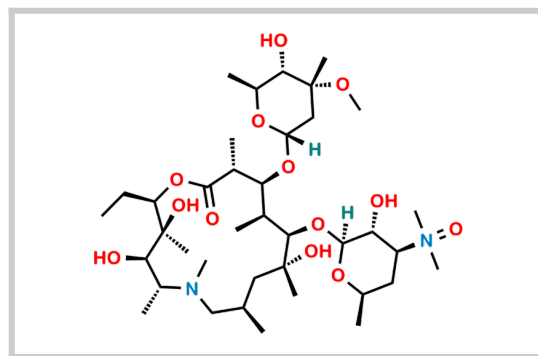
Alt. Name : Azithromycin N-Oxide (USP)

CAT No. : KMA001021

CAS No. : 90503-06-3

Molecular Formula : C₃₈H₇₂N₂O₁₃

Molecular Weight : 765.0



Analytical Information

Batch No. : A001021-102-139

Description : White Solid

HPLC Purity : 92.05 %

Weight Loss By TGA : 2.08 %

% Potency : 90.14 %

Solubility : ACN : Water (1:1)

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 - 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