

CERTIFICATE OF ANALYSIS

(Certificate No. KMA001019-01)

Release Date: 26/07/2025

Re-test Date: 25/07/2028

Desosaminylazithromycin

Identification

Chemical Name :

13-O-Decladinosylazithromycin (as per EP) ; (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-Ethyl-3,4,10,13-tetrahydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[[3,4,6-trideoxy-3-dimethylamino-Beta-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one (as per USP)

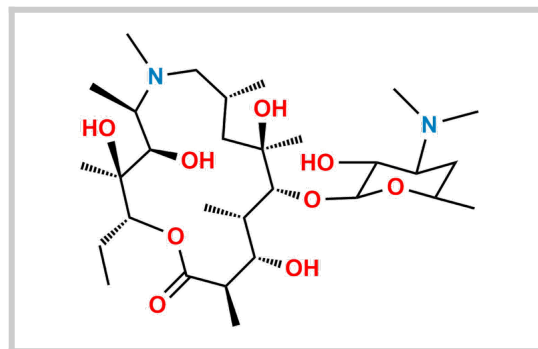
Alt. Name : Desosaminylazithromycin (USP) ;
Descladinose Azithromycin

CAT No. : KMA001019

CAS No. : 117693-41-1

Molecular Formula : C₃₀H₅₈N₂O₉

Molecular Weight : 590.8



Analytical Information

Batch No. : A001019-102-140

Description : White Solid

HPLC Purity : 99.31 %

Weight Loss By TGA : 1.21 %

% Potency : 98.11 %

Solubility : Methanol

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 - 1.21(Weight Loss By TGA)] x [99.31(HPLC Purity)]/100 = 98.11 %

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