CERTIFICATE OF ANALYSIS

(Certificate No. KMA001015-03)

Release Date: 28/03/2026 **Re-test Date:** 27/03/2029

AZITHROMYCIN IMPURITY F

Identification

Chemical Name :
3′-N-demethyl-3′-N-formylazithromycin (as per EP & USP)

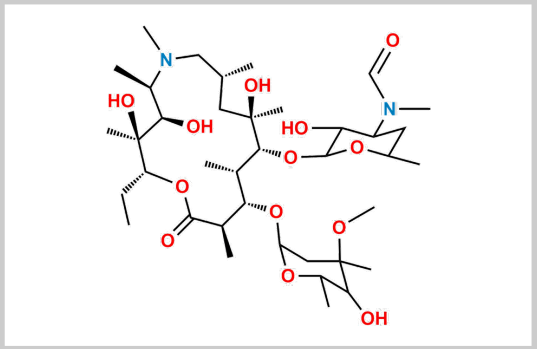
Alt. Name : Azithromycin USP Related Compound F ; Azithromycin Mycinmethylformamido Analog (USP)

CAT No. : KMA001015

CAS No. : 612069-28-0

Molecular Formula : C38H70N2O13

Molecular Weight : 763.0



Analytical Information

Batch No. : A001015-114-229

Description : White Solid

HPLC Purity : 92.07 %

Weight Loss By TGA : 0.96 %

% Potency : 91.19 %

Solubility : ACN : Water

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 - 0.96(Weight Loss By TGA)] x [92.07(HPLC Purity)]/100 = 91.19 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/03/2026
Reviewed & Approved By	Quality Control	Jatin Patel		28/03/2026

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