

CERTIFICATE OF ANALYSIS

(Certificate No. KMA001015-01)

Release Date: 22/05/2025

Re-test Date: 21/05/2028

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.

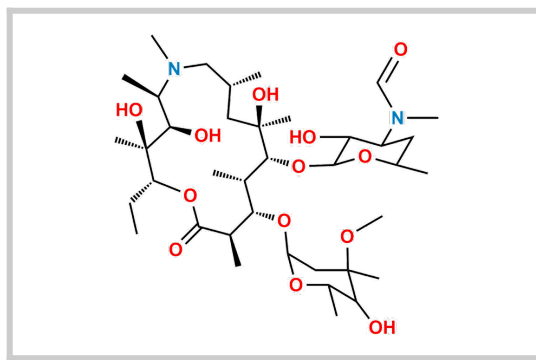
: 612069-28-0

Molecular Formula

: C38H70N2O13

Molecular Weight

: 763.0



Analytical Information

Batch No.

: A001015-102-026

Solubility

: ACN : Water (1:1)

Description

: White Solid

Mass

: Confirm

HPLC Purity

: 98.35 %

IR

: Confirm

Weight Loss By TGA

: 2.15 %

¹H NMR

: Confirm

% Potency

: 96.24 %

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 - 2.15(Weight Loss By TGA)] x [98.35(HPLC Purity)]/100 = 96.24 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		22/05/2025

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