

CERTIFICATE OF ANALYSIS

(Certificate No. KMC181003-01)

Release Date: 10/02/2025

Re-test Date: 09/02/2028

Clarithromycin EP Impurity A

Identification

Chemical Name :

2-Demethyl-2-(hydroxymethyl)-6-O-methylerythromycin A (as per EP)

Alt. Name

: Clarithromycin F (EP) ; 2-Demethyl-2-(hydroxymethyl)-6-O-methylerythromycin A

CAT No.

: KMC181003

CAS No.

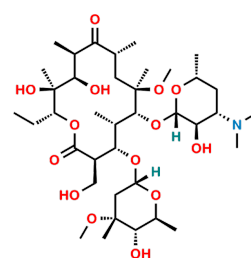
: 124412-58-4

Molecular Formula

: C₃₈H₆₉NO₁₄

Molecular Weight

: 764.0



Analytical Information

Batch No.

: CLA-A-21

Solubility

: DMSO

Description

: Off white solid

Mass

: Confirm

HPLC Purity

: 98.66 %

IR

: Confirm

Weight Loss By TGA

: 2.56 %

¹H NMR

: Confirm

% Potency

: 96.13 %

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 - 2.56(Weight Loss By TGA)] x [98.66(HPLC Purity)]/100 = 96.13 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		10/02/2025

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