

# 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)

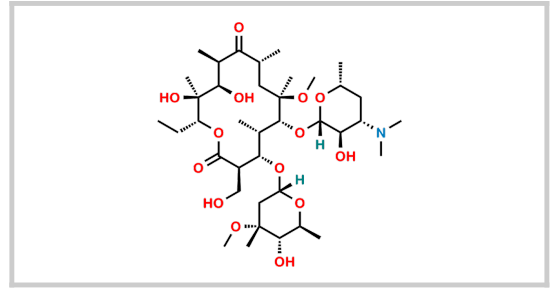
**Alt. Name** : Clarithromycin F (EP) ; 2-Demethyl-2-(hydroxymethyl)-6-O-methylerythromycin A

**CAT No.** : KMC181003

**CAS No.** : 124412-58-4

**Molecular Formula** : C<sub>38</sub>H<sub>69</sub>NO<sub>14</sub>

**Molecular Weight** : 764.0



### Analytical Information

**Batch No.** : CLA-A-21

**Description** : Off white solid

**HPLC Purity** : 98.66 %

**Weight Loss By TGA** : 2.56 %

**% Potency** : 96.13 %

**Solubility** : DMSO

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 2.56(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, <sup>1</sup>HNMR, IR and TGA