CERTIFICATE OF ANALYSIS

(Certificate No. KMC181003-01)

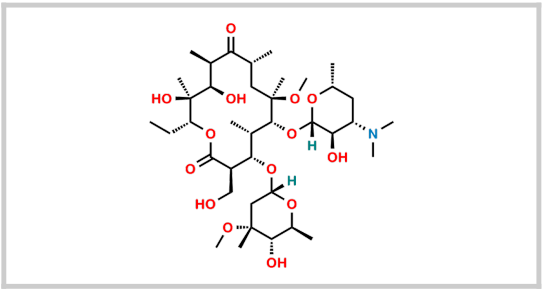
Release Date: 10/02/2025 **Re-test Date:** 09/02/2028

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