CERTIFICATE OF ANALYSIS

(Certificate No. KMA001010-01)

Release Date: 27/07/2025 **Re-test Date:** 26/07/2028

Azithromycin Impurity A

Identification

Chemical Name :
6-Demethyl Azithromycin (as per EP) ; 9-Deoxo-9a-aza-9a-homoerythromycin A (as per USP)

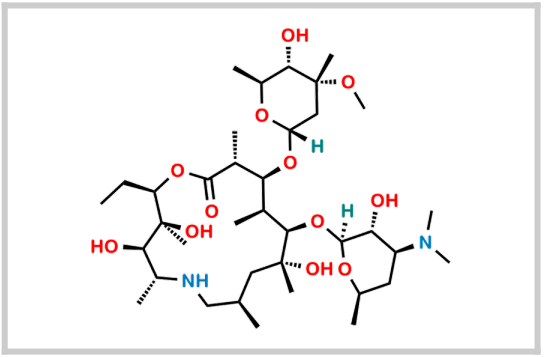
Alt. Name : Azaerythromycin A (USP)

CAT No. : KMA001010

CAS No. : 76801-85-9

Molecular Formula : C37H70N2O12

Molecular Weight : 735.0



Analytical Information

Batch No. : AZA-EPA-073-097

Description : White Solid

HPLC Purity : 94.22 %

Weight Loss By TGA : 2.57 %

% Potency : 91.8 %

Solubility : ACN : WATER (1 : 1)

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 - 2.57(Weight Loss By TGA)] x [94.22(HPLC Purity)]/100 = 91.8 %
-Re-tested on 27.07.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/07/2025

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