

CERTIFICATE OF ANALYSIS

(Certificate No. KME001025-01)

Release Date: 11/03/2025

Re-test Date: 10/03/2028

Pseudoerythromycin A Enol Ether

Identification

Chemical Name :

(15R,2R,3R,6R,7S,8S,9R)-7-[(2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-3-[(2R,3R)-2,3-dihydroxypentan-2-yl]-13,15,2,6,8-pentamethyl-9-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-14,15-dihydro-4-oxa-1(2,5)-furanacyclononaphan-5-one (as per EP)

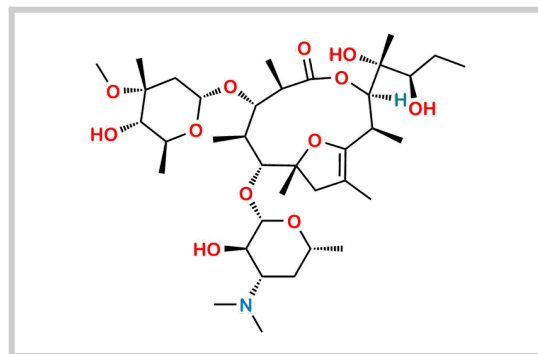
Alt. Name : pseudoerythromycin A enol ether (EP)

CAT No. : KME001025

CAS No. : 105882-69-7

Molecular Formula : C₃₇H₆₅N₀O₁₂

Molecular Weight : 715.9



Analytical Information

Batch No. : E001025-091-257

Description : Off White Solid

HPLC Purity : 98.66 %

Weight Loss By TGA : 0.76 %

% Potency : 97.91 %

Solubility : Water

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 - 0.76(Weight Loss By TGA)] x [98.66(HPLC Purity)]/100 = 97.91 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		11/03/2025

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