

CERTIFICATE OF ANALYSIS

(Certificate No. KME001023-01)

Release Date: 05/09/2024

Re-test Date: 04/09/2027

Erythromycin EP Impurity E

Identification

Chemical Name :

(2R,3R,4S,5R,8R,9S,10S,11R,12R)-9-[(2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-5-ethyl-3,4-dihydroxy-2,4,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-6,15-dioxabicyclo[10.2.1]pentadec-1(14)-en-7-one (as per EP)

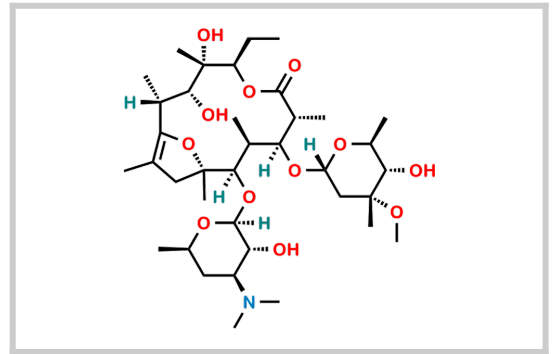
Alt. Name : Erythromycin A Enol ether (EP)

CAT No. : KME001023

CAS No. : 33396-29-1

Molecular Formula : C₃₇H₆₅NO₁₂

Molecular Weight : 715.9



Analytical Information

Batch No. : E001023-073-358

Description : White Solid

HPLC Purity : 98.19 %

Weight Loss By TGA : 2.01 %

% Potency : 96.22 %

Solubility : Acetonitrile

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 = $[100 - 2.01(\text{Weight Loss By TGA})] \times [98.19(\text{HPLC Purity})]/100 = 96.22 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		07/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		07/09/2024

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA