

CERTIFICATE OF ANALYSIS

(Certificate No. KME001019-01)

Release Date: 30/09/2024

Re-test Date: 29/09/2027

Erythromycin EP Impurity B

Identification

Chemical Name :

(3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-4-[(2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(methylamino)- β -D-xylo-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione (as per EP);
(3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-14-Ethyl-7,12,13-trihydroxy-4-[[[(2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyltetrahydro-2H-pyran-2-yl]oxy]-6-[[[(2S,3R,4S,6R)-3-hydroxy-6-methyl-4-(methylamino)tetrahydro-2H-pyran-2-yl]oxy]-3,5,7,9,11,13-hexamethyloxacyclotetradecane-2,10-dione (as per USP)

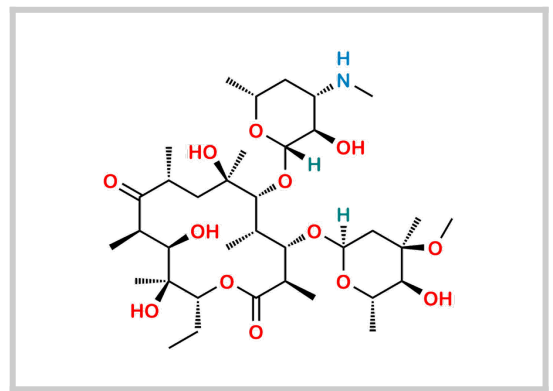
Alt. Name : Erythromycin USP Related Compound N ; 3"-N-Desmethylerythromycin A (EP) ; N-Demethylerythromycin A

CAT No. : KME001019

CAS No. : 992-62-1

Molecular Formula : C₃₆H₆₅N₁O₁₃

Molecular Weight : 719.9



Analytical Information

Batch No. : E001019-073-398

Description : Off White Solid

HPLC Purity : 99.88 %

Weight Loss By TGA : 2.74 %

% Potency : 97.14 %

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 - 2.74(Weight Loss By TGA)] x [99.88(HPLC Purity)]/100 = 97.14 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		30/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		30/09/2024

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