CERTIFICATE OF ANALYSIS

(Certificate No. KME001019-01)

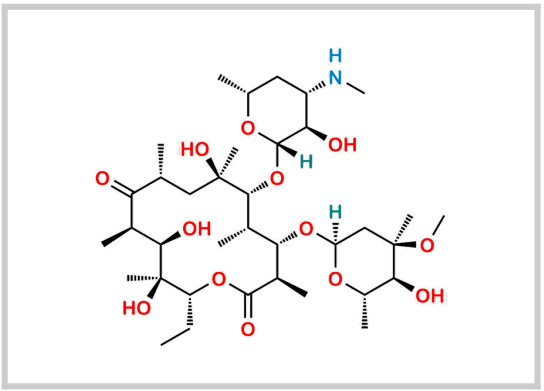
Release Date: 30/09/2024 **Re-test Date:** 29/09/2027

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	: C36H65NO13
Molecular Weight	: 719.9



Analytical Information

Batch No.	: E001019-073-398	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.88 %	**IR**	: Confirm
Weight Loss By TGA	: 2.74 %	**1H NMR**	: Confirm
% Potency	: 97.14 %		

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, 1HNMR, IR and TGA