

CERTIFICATE OF ANALYSIS

(Certificate No. KMA001002-01)

Release Date: 25/05/2024

Re-test Date: 24/05/2027

Azithromycin Impurity I

Identification

Chemical Name :

(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10-trihydroxy-13-(((2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyltetrahydro-2H-pyran-2-yl)oxy)-11-(((2S,3R,4S,6R)-3-hydroxy-6-methyl-4-(methylamino)tetrahydro-2H-pyran-2-yl)oxy)-3,5,6,8,10,12,14-heptamethyl-1-oxa-6-azacyclopentadecan-15-one

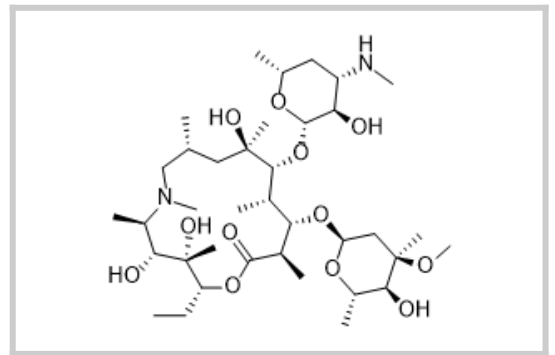
Alt. Name : N'-Desmethyl Azithromycin; N-Demethylazithromycin (USP)

CAT No. : KMA001002

CAS No. : 172617-84-4

Molecular Formula : C37H70N2O12

Molecular Weight : 734.96



Analytical Information

Batch No. : AZI-I-073-220

Description : Off White Solid

HPLC Purity : 95.94 %

Weight Loss By TGA : 1.01 %

% Potency : 94.97 %

Solubility : ACN

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 = $[100 - 1.01(\text{Weight Loss By TGA})] \times [95.94(\text{HPLC Purity})]/100 = 94.97 \%$

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/05/2024
Reviewed & Approved By	Quality Control	Jatin Patel		25/05/2024

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