CERTIFICATE OF ANALYSIS

(Certificate No. KMA001009-01)

Release Date: 25/07/2025 **Re-test Date:** 24/07/2028

Azithromycin Dihydrate

Identification

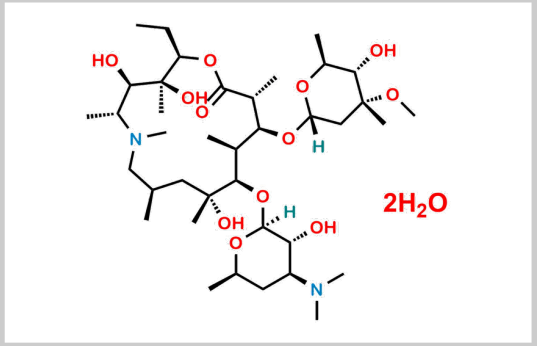
Chemical Name :
(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one dihydrate (as per EP) ;
(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-l-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-d-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one dihydrate

CAT No. : KMA001009

CAS No. : 117772-70-0

Molecular Formula : C38H72N2O12 : 2H2O

Molecular Weight : 749.0 : 2(18.0)



Analytical Information

Batch No.	: A001009-102-141	**Solubility**	: ACN : Water (1:1)
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 98.63 %	**IR**	: Confirm
Weight Loss By TGA	: 0.91 %	**1H NMR**	: Confirm
% Potency	: 97.73 %	**13C 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 - 0.91(Weight Loss By TGA)] x [98.63(HPLC Purity)]/100 = 97.73 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		26/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		26/07/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA