

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA001009-01)

Release Date: 25/07/2025

Re-test Date: 24/07/2028

## Azithromycin Dihydrate

### Identification

**Chemical Name :**

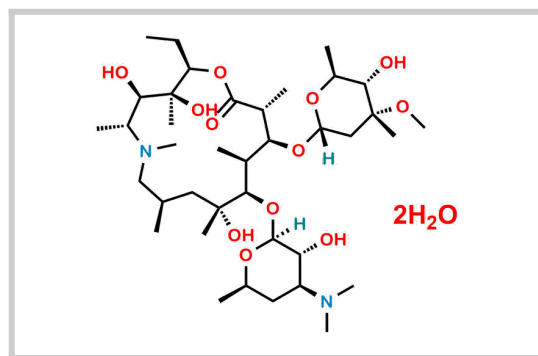
(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl- $\alpha$ -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[[3,4,6-trideoxy-3-(dimethylamino)- $\beta$ -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one dihydrate (as per EP) ;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

CAT No. : KMA001009

CAS No. : 117772-70-0

Molecular Formula : C<sub>38</sub>H<sub>72</sub>N<sub>2</sub>O<sub>12</sub> : 2H<sub>2</sub>O

Molecular Weight : 749.0 : 2(18.0)



### Analytical Information

Batch No. : A001009-102-141

Description : White Solid

HPLC Purity : 98.63 %

Weight Loss By TGA : 0.91 %

% Potency : 97.73 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

<sup>1</sup>H NMR : Confirm

<sup>13</sup>C 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA