

Azithromycin Dihydrate

Description	white or almost white powder
Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride
Specific Optical Rotation	-45° to -49°
pH	9.0 to 11.0
Water content	1.8 -6.5%
Assay	96.0 – 102.0 %± 0.5
Reaidual Solvent	OK
Organic Impurities	
Impurity A	Not more than 0.5 %
Impurity B	Not more than 2.0%
Impurity C	Not more than 0.5 %
Sum of impurities D & J & Q	Not more than 0.5 %
Impurity E	Not more than 0.5 %
Impurity F	Not more than 0.5%
Impurity G	Not more than 0.2 %
Impurity H	Not more than 0.5 %
Impurity I	Not more than 0.5 %
Impurity L	Not more than 0.5 %
Impurity M	Not more than 0.5 %
Impurity N	Not more than 0.5 %
Impurity O	Not more than 0.5 %
Impurity P	Not more than 0.5 %
Any other impurity	Not more than 0.2 %
Total impurity	Not more than 3.0%
Packaging	20 kg in double polyethylene bags in each carton box
Storage	Preserve in tight container store below 30°C and dry place
Shelf Life	24 months

IUPAC 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.

Molecular Weight: 785.02

Molecular Formula: C₃₈H₇₂N₂O₁₂.2H₂O

Cas registry NO.: [117772-70-0]

Application: Azithromycin is a semi-synthetic macrolide antibiotic of the azalide class for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions

Structure:

