

Specification

Formula Hill: $C_{38}H_{72}N_2O_{12} \cdot 2H_2O$
Molar Mass: 785,02 g/mol
CAS N°: 117772-70-0

Print Date: 01 July 2021

101421 Azithromycin dihydrate, Ph. Eur.

	Specifications
Assay	96 - 102 %
Infrared Absorption	conforms
Appearance	
- White or almost white	conforms
- Powder	conforms
Appearance of solution	conforms
pH	9,0 - 11,0
Solubility	conforms
Specific rotation	-49 - -45 °
Related substances	
- Impurity A	≤ 0,5 %
- Impurity B	≤ 2,0 %
- Impurity C	≤ 0,5 %
- Impurity E	≤ 0,5 %
- Impurity F	≤ 0,2 %
- Impurity G	≤ 0,5 %
- Impurity H	≤ 0,5 %
- Impurity I	≤ 0,5 %
- Impurity L	≤ 0,5 %
- Impurity M	≤ 0,5 %
- Impurity N	≤ 0,5 %
- Impurity O	≤ 0,5 %
- Impurity P	≤ 0,5 %
- Any other impurity	≤ 0,2 %
- Sum of impurities D, J and Q	≤ 0,5 %
- Total impurities	≤ 3,0 %
Sulfated ash	≤ 0,2 %
Water by KF	1,8 - 6,5 %

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Conforms to: Ph. Eur. 9.3 specification
Storage: +2 - +8°C
Transport Conditions: no special conditions required