



**DC FINE  
CHEMICALS**

# Specification

**Formula Hill:**  $C_{38}H_{72}N_2O_{12} \cdot 2H_2O$   
**Molar Mass:** 785.02 g/mol  
**CAS N°:** 117772-70-0

## 101421 Azithromycin dihydrate, Ph.Eur.

	Specification
Assay (HPLC) (anhydrous substances)	96 - 102 %
Infrared absorption	conforms
Appearance	white or almost white powder
Appearance of solution	conforms
pH	9.0 - 11.0
Solubility	conforms
Specific rotation	-45 - -49 °
Related substances	
- Impurity A	≤ 0.5 %
- Impurity B	≤ 2.0 %
- Impurity C	≤ 0.5 %
- Impurity E	≤ 0.5 %
- Impurity F	≤ 0.5 %
- Impurity G	≤ 0.2 %
- 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	1.8 - 6.5 %

Conforms to

Ph. Eur. 9.3 specification