

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: 17 January 2023

101420 Azithromycin dihydrate, USP

	Specifications	Method
Assay (dried subs)	945 - 1.030 microg/mg	USP
Identity	conforms	USP
Appearance		
- White or almost white	conforms	USP
- Powder	conforms	USP
Crystallinity	conforms	USP
pH	9,0 - 11,0	USP
Solubility	conforms	USP
Specific rotation	-49 - -45 °	USP
Organic impurities		
- Impurity RT 0.29	≤ 0,5 %	USP
- Impurity RT 0.37	≤ 0,5 %	USP
- Impurity RT 0.42	≤ 0,5 %	USP
- Impurity RT 0.43	≤ 0,5 %	USP
- Impurity RT 0.51	≤ 0,5 %	USP
- Impurity RT 0.54	≤ 0,3 %	USP
- Impurity RT 0.55	≤ 0,2 %	USP
- Impurity RT 0.61	≤ 0,7 %	USP
- Impurity RT 0.64	≤ 0,5 %	USP
- Impurity RT 0.73	≤ 0,5 %	USP
- Impurity RT 0.76	≤ 0,5 %	USP
- Impurity RT 0.79	≤ 0,5 %	USP
- Impurity RT 0.83	≤ 0,5 %	USP
- Impurity RT 0.92	≤ 0,2 %	USP
- Impurity RT 1.23	≤ 0,5 %	USP
- Impurity RT 1.26	≤ 0,5 %	USP
- Impurity RT 1.31	≤ 1,0	USP
- Any individual, unidentified impurity	≤ 0,2	USP
- Total impurities	≤ 3,0	USP
Residue after ignition	≤ 0,3 %	USP
Water by KF	4,0 - 5,0 %	USP

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The product cannot be considered as an Active Pharmaceutical Ingredient (API)

Conforms to: USP specification
Storage: +2 - +8°C
Transport Conditions: no special conditions required