



Certificate of Analysis

Report No. CU60920002

Product Name	Azithromycin Dihydrate	Quantity	743.920Kg
Batch No.	2001-6091-PP002	Testing Date	January 06, 2020
Manu. Date	January 05, 2020	Report Date	January 13, 2020
Retest Date	January 04, 2025	Testing Basis	USP42
Items	Requirements	Results	
Appearance	White or almost white crystalline powder	White crystalline powder	
Identification IR	Conforms to Azithromycin RS	Complies	
HPLC	Conforms to Azithromycin RS	Complies	
Specific optical rotation	Between -45° and -49°	-48°	
Crystallinity	Meets the requirements	Complies	
pH	Between 9.0 and 11.0	10.2	
Water	Between 4.0% and 5.0%	4.6%	
Residue on ignition	Not more than 0.3%	0.03%	
Heavy metals	Not more than 25ppm	<10ppm	
Related substances (Procedure 2)			
Azithromycin-N-oxide	Not more than 0.5%	UDL	
3'-(N-N-Didemethyl-3'-N-formylazithromycin	Not more than 0.5%	UDL	
Erythromycin A iminoether	Not more than 0.5%	UDL	
Aminoazithromycin	Not more than 0.5%	UDL	
Azithromycin related compound F	Not more than 0.5%	UDL	
Desosaminylazithromycin	Not more than 0.3%	0.20%	
3'-N-{[4-(Acetylamino)phenyl]sulfonyl}-3'-didemethylazithromycin	Not more than 0.15%	UDL	
N-Demethylazithromycin	Not more than 0.7%	UDL	
Erythromycin A oxime	Not more than 0.5%	UDL	
Azithromycin C(3''-o-demethylazithromycin)	Not more than 0.5%	0.04%	
3'-De(dimethylamino)-3'-oxoazithromycin	Not more than 0.5%	0.02%	
3'-N-{[4-(Acetylamino)phenyl]sulfonyl}-3'-demthylazithromycin	Not more than 0.5%	UDL	
Azaerythromycin A	Not more than 0.5%	0.01%	
Azithromycin impurity P	Not more than 0.2%	0.01%	
2-Desethyl-2-propylazithromycin	Not more than 0.5%	0.10%	
3'-N-Demethyl-3'-N-[(4-methylphenyl)sulfonyl]azithromycin	Not more than 0.5%	UDL	
3-Deoxyazithromycin(azithromycin B)	Not more than 1.0%	0.45%	
Any individual, unidentified impurity	Not more than 0.2%	0.09%	
Total impurities	Not more than 3.0%	1.1%	
Assay On the anhydrous basis	Not less than 945 µg/mg and not more than 1030 µg/mg	991 µg/mg	
Residual solvents Acetone	Not more than 3200 ppm	1000ppm	
Methanol	Not more than 3000ppm	UDL	
Dichloromethane	Not more than 600ppm	UDL	
Bulk density	Between 0.35 and 0.65 g/ml	0.60g/ml	
Tapped density	Between 0.65 and 0.85 g/ml	0.75g/ml	
Particle Size Distribution	Not less than 80% passes through 40mesh	Complies	
Conclusion	The material complies as per USP42		

Storage conditions: Preserve in tight containers

Chief of QC:

[Signature]

2020.01.13

Checker:

[Signature]

Prepared:

[Signature]

2020.01.13

