

SHANDONG ZESHENG CHEMICAL CO., LTD

CERTIFICATE OF ANALYSIS



Name of product: Azithromycin	Batch No.: 210125-1111
Quantity: 1600 Kg	Packing: 25kg/DRUM
Report Date: 2021-01-27	Expiry Date: 2025-01-24
Manufacturing Date: 2021-01-25	Analysis No.: 0009

Specification: Base on USP 43 / IP2018

Test Items	Specification USP	Specification IP	Results
Characters	White or almost white powder		White powder
Solubility	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride		Corresponds
Identification	A)IR: Conforms to azithromycin RS B)Rt HPLC: Conforms to azithromycin RS		Corresponds Corresponds
Crystallinity	Exhibit birefringence and extinction positions		Meets the requirements
PH	9.0~11.0	9.0~11.0	10.12
Optical Rotation	-45° ~ -49°	-45° ~ -49°	-47°
Appearance of solution:	—	Solution A is clear and colourless	Corresponds
Heavy metals	—	≤25ppm	<25ppm
Water	4.0%~5.0%	1.8%~6.5%	4.42%
Residue on ignition/Sulphated ash:	≤0.3%	≤0.2%	0.04%
Limit of related substances			
Azithromycin-N-oxide	≤0.5%	—	0.02%
3'-(N,N-didemethyl)-3'-N-formylazithromycin	≤0.5%	—	<0.006%
Erythromycin A iminoether	≤0.5%	—	<0.01%
3'-(N,N-didemethyl)azithromycin (aminoazithromycin)	≤0.5%	—	<0.01%
Azithromycin related compound F	≤0.5%	—	0.02%
Desosaminylazithromycin	≤0.3%	—	0.02%
3'-N-{[4-(Acetylamino)phenyl]sulfonyl}-3',3'-didemethylazithromycin	≤0.15%	—	0.01%
N-Demethylazithromycin	≤0.7%	—	<0.01%
Erythromycin A oxime	≤0.5%	—	<0.01%
Azithromycin C (3''-o-demethylazithromycin)	≤0.5%	—	0.01%
3'-De(dimethylamino)-3'-oxoazithromycin	≤0.5%	—	<0.007%
3'-N-{[4-(Acetylamino)phenyl]sulfonyl}-3'-demethylazithromycin	≤0.5%	—	<0.001%
Azaerythromycin A	≤0.5%	—	0.06%
Azithromycin impurity P	≤0.2%	—	0.03%
2-Desethyl-2-propylazithromycin	≤0.5%	—	0.11%
3'-N-Demethyl-3'-N-[(4-methylphenyl)sulfonyl]azithromycin	≤0.5%	—	0.01%
3-Deoxyazithromycin (azithromycin B)	≤1.0%	≤2.0%	0.39%
Any individual, unidentified impurity	≤0.2%	—	ND
Total impurities	≤3.0%	—	0.68%
The sum of all the other secondary peaks:	—	≤3.0%	0.42%
Assay	945~1030 μg/mg	96.0%~102.0%	986 μg/mg
Residue solvents			
Acetone	≤3000ppm		977 ppm
Ethanol	≤2000ppm		21 ppm
Chloroform	≤60ppm		<3 ppm
Bulk density			0.60 g/ml
Tapped density			0.70 g/ml
Malvern Test			
d(0.1)			52 um
d(0.5)			152 um
d(0.7)			210 um
d(0.9)			313 um
D[4, 3]			169 um

Conclusion: The product conforms to the standard of USP43/ IP2018

Person in charge: 王少海 2021.1.27

Check: 杨丙彦 2021.1.27

Analyst: 杨丙彦 2021.1.27