

1604000301

NEXCHEM PHARMACEUTICAL CO., LTD

Certificate of Analysis

Report No. CT160916004

Product Name		Azithromycin Dihydrate	Quantity	530.300Kg
Batch No.		1604-609-FP001	Testing Date	April 04,2016
Manu.Date		April 04,2016	Report Date	May 10,2016
Retest Date		March,2021	Testing Basis	USP38
Items		Requirements	Results	
Appearance		White or almost white crystalline powder	White crystalline powder	
Solubility		Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride	Complies	
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	10.0	
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	<25ppm	
Related substances (Procedure 2)				
Azithromycin-N-oxide		Not more than 0.5%	UDL	
3'-N,N'-Dimethyl-3'-N'-formylazithromycin		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%	0.11%	
3'-N-[[4-(Acetylamino)phenyl]sulfonyl]-3'-dimethylazithromycin		Not more than 0.15%	UDL	
N-Demethylazithromycin		Not more than 0.7%	UDL	
Azithromycin C(3'-O-demethylazithromycin)		Not more than 0.5%	UDL	
3'-De(dimethylamino)-3'-oxoazithromycin		Not more than 0.5%	0.01%	
3'-N-[[4-(Acetylamino)phenyl]sulfonyl]-3'-demethylazithromycin		Not more than 0.5%	UDL	
Azierythromycin A		Not more than 0.5%	UDL	
Azithromycin impurity P		Not more than 0.2%	0.04%	
2-Desethyl-2-propylazithromycin		Not more than 0.5%	0.13%	
3'-N'-Demethyl-3'-N'-[(4-methylphenyl)sulfonyl]azithromycin		Not more than 0.5%	UDL	
3-Deoxyazithromycin (azithromycin B)		Not more than 1.0%	0.27%	
Any individual unidentified impurity		Not more than 0.2%	0.09%	
Total impurities		Not more than 3.0%	0.74%	
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	975ppm	
Methanol		Not more than 3000ppm	UDL	
Dichloromethane		Not more than 600ppm	UDL	
Bulk density		Between 0.35 and 0.65 g/ml	0.56g/ml	
Tapped density		Between 0.65 and 0.85 g/ml	0.70g/ml	
Particle Size Distribution		Not less than 80% passes through 40 mesh	Complies	
Microbiological Count				
Bacteria		Less than 1000CFU/g	Complies	
Yeast and Mould		Less than 100 CFU/g	Complies	
Pathogens and Endobacterias		Absent	Complies	
Conclusion		The material complies as per USP38		

Storage conditions: Preserve in tight containers

Chief of QC: 章平 2016.05.10

Checker: 2016.05.10

Prepared: 潘美利

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