

Certificate of Analysis

Name of Product:	Azithromycin(injection)		
Batch No.	20190717	Manufacture date	2019/07/17
Analysis date	2019/07/30	Retest date	2021/06
Quantity	275Kg	Standard	CP2015/YBH006 82010(Residual solvent)

Item	Specification	Results
Appearance	White or almost white crystalline powder;Odorless, slightly hygroscopic	Complies
Solubility	Soluble in methanol, acetone, absolute ethanol or dilute hydrochloric acid, soluble in acetonitrile, almost insoluble in water	Complies
Specific rotation	-45° ~-49°	-48°
Identification	The retention time of the main peak of the reference solution of the test solution is consistent with the retention time of the main peak of the reference solution.	Complies
	The infrared absorption spectrum of this product is consistent with the reference spectrum (spectral chart 772) or the reference spectrum	Complies
Crystallinity	Birefringence	Complies
PH	9.0~11.0	9.4
Water	NMT5.0%	4.1%
Residue on ignition	NMT0.2%	0.07%
Heavy metals	NMT10ppm	Complies
Related substances	ImpurityB NMT1.0%	0.2%
	ImpurityR NMT0.5%	ND
	ImpurityQ NMT0.5%	ND
	ImpurityJ NMT0.5%	ND
	ImpurityI NMT0.5%	ND
	ImpurityS NMT0.5%	ND

	ImpurityA NMT0.5%	ND
	ImpurityH NMT0.5%	ND
	Other single impurity NMT0.5%	0.1%
	Total impurities NMT2.0%	0.6%
Residual solvent	Acetone NMT0.5%	0.04%
	Methanol NMT0.3%	ND
	Dichloromethane NMT0.06%	0.01%
	Triethylamine NMT0.016%	ND
	Formaldehyde NMT0.05%	0.0003%
Assay	96.0%~102.0%(Calculated on the dried basis)	98.6%
Bacterial endomycin	NMT 0.2EU/mg	Complies
Aerobic Bacteria	NMT1000cfu/g	<10cfu/g
Total mold and yeast	NMT 100cfu/g	<10cfu/g
Conclusion	The test results conform to above standard.	

Tested by: Anna

Checked by: Alice

Approved by: Mich

