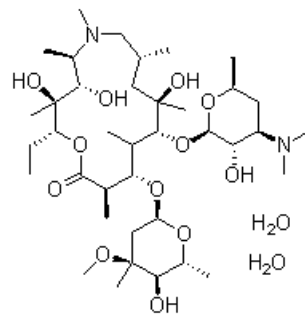


RACERTIFICATE OF ANALYSIS

Product name: Azithromycin

CAS: 117772-70-0



BATCH NO.: HF141104		QUANTITY: 1500kg
MFG. DATE : Nov.,4, 2014		PACKAGE: 25kg/drum
REP. DATE : Nov. 7, 2014		EXP. DATE : Nov, 2017
ITEMS	STANDARDS	RESULTS
APPEARANCE	White or almost white powder	White powder
SOLUBILITY	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride	Complies
IDENTIFICATION	IR: Conforms to Azithromycin RS	Complies
	HPLC: The retention time of the Azithromycin peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	Complies
SPECIFIC ROTATION	-45°~ -49°	-47.5°
CRYSTALLINITY	Exhibit birefringence and extinction positions	Complies
PH	9.0~11.0 (2mg/ml methanol-water(1:1))	10.31
WATER	4.0%~5.0%	4.26%
RESIDUE ON IGNITION	≤0.3%	0.03%
HEAVY METALS	≤25ppm	Complies
RELATED SUBSTANCES	Azaerythromycin A (Impurity A) ≤0.5%	0.13%
	Azithromycin B (Impurity B) ≤1.0%	0.29%
	Azithromycin C (Impurity C) ≤0.5%	0.07%
	Desosamylazithromycin (Impurity J) ≤0.3%	0.09%
	3'-(N,N-didemethyl)azithromycin (Impurity E) ≤0.5%	Not detected
	Azithromycin related compound F (Impurity F) ≤0.5%	0.11%
	3'-N-demethyl-3'-N-[(4-methylphenyl)sulfonyl] azithromycin (Impurity G) ≤0.5%	0.06%
	N-demethylazithromycin (Impurity I) ≤0.7%	Not detected
	Azithromycin N-oxide (Impurity L) ≤0.5%	0.09%
	3'-(N,N-didemethyl)-3'-N-formylazithromycin (Impurity M) ≤0.5%	0.04%
	3'-De(dimethylamino)-3'-oxoazithromycin (Impurity N) ≤0.5%	Not detected
	2-Desethyl-2-propylazithromycin (Impurity O) ≤0.5%	0.19%
	Azithromycin impurity P (Impurity P) ≤0.2%	Not detected
	Any other impurity ≤0.2%	0.16%
Total Impurities: ≤3.0 %	1.23%	
RESIDUAL SOLVENTS	Methylene Chloride ≤600ppm	Not detected
	Acetone ≤5000ppm	410ppm
ASSAY	945~1030 ug/mg (Anhydrous substance)	991ug/mg
Conclusion: It complies to USP37 specification.		