

Certificate Of Analysis

Product name : Clarithromycin
 Batch number : 10-09-FP0271
 Batch quantity : 400KGS
 Manufacturing date : SEP. 07, 2010
 Expiry date : AUG. 2015

TESTS	STANDARDS	RESULTS
Appearance	A white or almost white crystalline powder	White crystalline powder
Solubility	Practically insoluble in water, soluble in methylene chloride and in acetone; slightly soluble in methanol. Slightly soluble in phosphate buffer at pH value of 2 to 5.	Complies
Identification	Complies with Clarithromycin RS	Complies
Specific rotation	-89° to -95°	-93°
Crystallinity	Meets the requirements	Complies
pH	7.5 to 10.0	8.9
Water	Not more than 2.0%	0.39%
Residue on ignition	Not more than 0.3%	0.05%
Heavy metals	Not more than 0.002%	Complies
Assay	960 to 1040ug/mg	967ug/mg
Residual solvent		
Ethanol	Not more than 3000ppm	170ppm
Bulk density	0.30 to 0.55g/ml	0.53g/ml
Tagged density	0.55 to 0.80 g/ml	0.69g/ml
Particle size	90% passes through 40 mesh	Complies

Conclusion : Conform to the standard USP28.