

Certificate of Analysis for Tulathromycin

Report No: D-20180521-004

File encoding: WL-QS-FP004-R02 (06)

Batch No: D180503		Mfg Date: 2018.05.12	Retest Date: 2020.05.11
Report Date: 2018.05.21		Bach Size: 35.50kg	Standard: WL-QS-FP004
Items	Specification		Result
Characters	White or almost white crystalline powder		White crystalline powder
Solubility	Freely soluble in methanol, acetone, ethyl acetate; Soluble in ethanol.		Comply
Identification	HPLC: The retention time of the major peak corresponds to that of the reference substance solution, as obtained in the Assay.		Comply
	IR spectrum of sample corresponds to that of reference.		Comply
Water	≤0.5%		0.46%
Residual solvents	Methylene chloride	≤600 ppm	Not detected
	Ethyl acetate	≤5000 ppm	10ppm
	Heptane	≤5000 ppm	769ppm
Specific rotation	-22° ~-26°		-25°
Residue on ignition	≤0.20%		0.07%
Heavy metals	≤20ppm		<20ppm
Assay	Tulathromycin A should be at 96.0%~102.0% (on the dried substance)		97.4%
Related substances	Tulathromycin B	≤1.0%	0.24%
	Impurity C	≤0.5%	Not detected
	Impurity D	≤0.5%	Not detected
	Impurity E	≤0.5%	Not detected
	Any single impurity	≤0.2%	0.13%
	Total impurities	≤3.0%	0.36%
Conclusion	The product complies with the in-house standards.		
Storage Condition	Preserve in well-closed, protect from light, store at cool and dry place.		

Reported by/Date: Xu Fan 2018.05.21 QC manager/Date: Zheng Jian Huang 2018.05.21 Reviewed by QA/Date: Lin Yunchang 2018.05.21