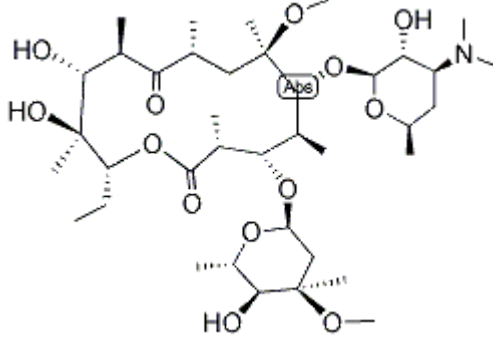


**HANGZHOU DINGYAN CHEM CO.,LTD**

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E-Mail:sales@dingyanchem.com,Web: www.dingyanchem.com

CERTIFICATE OF ANALYSIS**NO: DYC1116071453**

Product Name	Clarithromycin
CAS Number	81103-11-9
Molecule Structure	
Molecule Formula	C38H69N013
Batch Number	20160403
Mfg. Date	2016-05-08
Retest Date	2019-05-07
Report Date	2016-05-11

Items	Standard	Result
Appearance	White or almost white crystalline powder	white crystalline powder
Solubility	Soluble in acetone;slightly soluble in anhydrous ethanol, in methanol, and in acetonitrile, and in phosphate buffer at PH values of 2 to 5;practically insoluble in water	Complies
Identification	IR:Conforms to the spectrum of Clarithromycin RS	Complies
Appearance of Solution	Clear or not more opalescent than reference suspension II and not more intensely coloured than reference solution Y7	Complies
Specific Optical Rotation	-94 ° ~-102 ° (Anhydrous substance, 10mg/ml	-97°

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	methylene chloride)	
Water	$\leq 2\%$	0.28%
Sulphated Ash	$\leq 0.2\%$	0.02%
PH	8~10	8.6
Impurity	A $\leq 1.0\%$ B $\leq 1.0\%$ C $\leq 1.0\%$ D $\leq 1.0\%$ E $\leq 1.0\%$ F $\leq 1.0\%$ G $\leq 1.0\%$ H $\leq 1.0\%$ I $\leq 1.0\%$ J $\leq 1.0\%$ K $\leq 1.0\%$ L $\leq 1.0\%$ M $\leq 1.0\%$ N $\leq 1.0\%$ O $\leq 1.0\%$ P $\leq 1.0\%$	0.2% Not detected <0.1% 0.29% 0.8% 0.38% <0.1% <0.1% Not detected Not detected Not detected Not detected Not detected Not detected Not detected Not detected Not detected
Any Impuritized Greater Than 0.4%	4 max	1
Total Impuritized	$\leq 3.5\%$	1.7%
Assay (HPLC)	96%~102% (Anhydrous substance)	98.2%
Residual Solvents (GC)	Ethanol $\leq 5000\text{ppm}$ Pyridine $\leq 200\text{ppm}$	Not detected Not detected
Conclusion	Conforms to USP39 specification for Clarithromycin	

Hangzhou Dingyan Chem Co., Ltd.
Quality Control
QUALITY CONTROL: *Park* CHECK: 姚仙娟 INSPECTOR: 刘清风

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