



Certificate of analysis

Productname: Roxithromycin

Cas number: 80214-83-1

Molecular Formula: C₄₁H₇₆N₂O₁₅

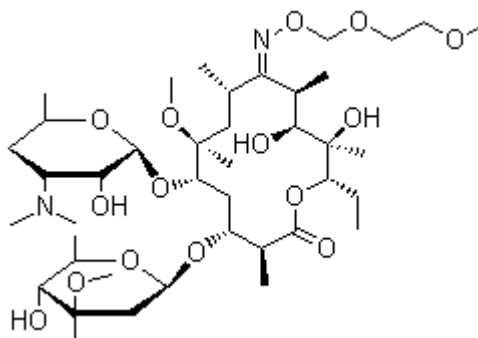
Molecular Weight: 837.05

Batch No. : 20170724

Date of production: 24th, Jul, 2017

Date of Expiry: 23th, Jul, 2019

Chemical structure:



Items	Specifications	Test results
Description	White or off-white crystalline powder	off -white crystalline powder
Identification	IR HPLC	Conform
Specific Rotation	-82°~-87°	-85°
Solution	Soluble in Ethanol or Propanol	Soluble in Ethanol or Propanol
Alkalinity	8.0~10.0	8.8
Related substances	Individual impurity ≤1.0%	0.6%
water	≤3.0%	2.2%
Heavy mental	≤10ppm	conform
Residual solvent	Methanol≤0.3% Triethylamine≤0.032% N,N-Diethylformamide≤0.088%	0.048% 0 0.017%
Residue on ignition	0.1%	0.06%
Bacterial endotoxins	conform	conform
Assay	≥ 96%	96.6%

Conclusion: It complies with the Enterprise Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang