



# Certificate of analysis

Product name: Rifabutin

Cas number: 72559-06-9

Molecular Formula: C<sub>46</sub>H<sub>62</sub>N<sub>4</sub>O<sub>11</sub>

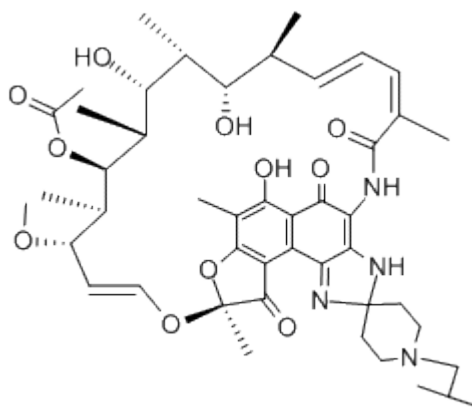
Molecular Weight: 847

Date of production: Aug. 07, 2019

Batch No: 20190807

Exp Date: Aug. 06, 2021

Chemical structure:



Items	Specifications	Results
Appearance	Purple red to purple black powder	Conforms
Identification	NMR HPLC	Conforms
Solubility	Soluble in methanol and chloroform Slightly soluble in ethanol Meet the test Practically insoluble in water	Conforms
water	≤2.5%	1.6%
Limit of N-Iso Butylpiperidone	≤0.5%	0.3%
Residual solvents	(A)Tetrahydrofuran ≤0.072%	0.02%
	(B)Dichloromethane ≤0.06%	N.D
	(C)Hexane ≤0.029%	0.001%
	(D)2-Methoxyethanol ≤0.005%	N.D
Chromatographic Purity	(A)Each individual impurity at about RRT 0.5,0.6,0.8 and 1.4 with respect to Rifabutin (A) ≤1%	(A) 0.02%, 0.13% 0.47%, 0.17
	(B)Each other individual impurity (B) ≤ 0.5%	(B) 0.32%
	(C)Total Impurity (C) ≤ 3.0%	(C) 2.7%
Assay (C <sub>46</sub> H <sub>62</sub> N <sub>4</sub> O <sub>11</sub> ) On anhydrous basis	95.0% to 102.0%	95.9%

**Conclusion: It complies with the USP36 Standard.**

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F