

Certificate of Analysis

Rifabutin

CAS No.	72559-06-9	Code	BIOJRIF001
Batch No	240701	Manufacture Date	Jun.28, 2024
Retest Date	Jun.27, 2028	Quantity	1Kg

Testing Items	Specifications	Results
Appearance	Reddish-violet amorphous powder.	Reddish-violet amorphous powder.
Identification	The infrared absorption spectrum of test sample corresponds to that of Rifabutin CRS.	Complies
	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation obtained as directed in the assay.	Complies
Solubility	Soluble in chloroform and in methanol, sparingly soluble in alcohol, very slightly soluble in water	Complies
Assay	950µg/mg~1020µg/mg (Calculated on the anhydrous basis)	971.7µg/mg
Limit of N-isobutylpiperidone	No spot in the chromatogram of the test solution at an RF value corresponding to that of N-isobutylpiperidone is more intense than that of the principal spot observed in the chromatogram obtained from the standard solution containing 0.05 mg of N-isobutylpiperidone per mL(0.5%)	Complies
Organic Impurities	Impurity A(16-Desacetyl-rifa-butin) $\leq 1.0\%$	0.06%
	Impurity B(Rifabutin 14R epi-mer) $\leq 0.75\%$	0.31%
	Impurity C(Rifabutin N-ox-ide) $\leq 0.50\%$	0.07%
	Impurity D(Rifabutin 21R epimer) $\leq 0.75\%$	Not detected
	Impurity E(Didehydrorifabutin) $\leq 1.0\%$	0.14%
	Impurity F(Rifabutin N-oxide open ring) $\leq 0.25\%$	0.07%
	Specified unknown impurity $\leq 0.50\%$	Not detected
	Any unspecified impurity $\leq 0.5\%$	0.19%
	Total impurities $\leq 3.0\%$	1.9%

Water	≤2.5%	0.70%
Residual solvents	Ethanol ≤5000ppm Acetone ≤5000ppm Dichloromethane ≤600ppm Ethyl acetate ≤5000ppm Tetrahydrofuran ≤720ppm Cyclohexane ≤3880ppm Ethylene glycol monomethyl ether ≤50ppm Pyridine ≤200ppm Dimethylformamide ≤880ppm Benzene ≤2ppm	57ppm Not detected Not detected Not detected Not detected Not detected Not detected Not detected Not detected Not detected
Microbial limits	TAMC ≤10 ³ cfu/g TYMC ≤10 ² cfu/g E. coli(in 1g): Absence	Complies Complies Not detected
Conclusion	This product conforms to USP2022 standard	

***Storage condition: Store below 25°C, Protect from moisture and light.**