

Certificate of Analysis

Rifaximin

CAS No.	80621-81-4	Code	BIOJRI001
Batch No	F011-260323	Manufacture Date	Mar.23, 2026
Retest Date	Mar.22, 2029	Quantity	25Kgs

Testing Items	Specifications	Results
Appearance	Red-orange, hygroscopic, crystalline powder.	Red-orange, hygroscopic, crystalline powder.
Solubility	Practically insoluble in water, soluble in acetone and in methanol.	Complies
Identification (IR)	The infrared absorption spectrum of test sample corresponds to that of Rifaximin CRS.	Complies
Related Substances (HPLC)	Sum of impurities D and H: not more than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution(a) (0.5 percent).	0.28%
	Unspecified impurities: for each impurity, not more than 0.5% times the area of the principal peak in the chromatogram obtained with reference solution(a) (0.1 percent).	0.07%
	Total impurities: not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution(a) (1.0 percent).	0.4%
Water	≤4.5%	1.6%
Sulphated ash	≤0.1%	0.08%
Assay (HPLC)	97.0%~102.0% (Calculated on the anhydrous basis)	100.7%
Residual solvents (GC)	Methanol ≤3000ppm	1317ppm
	Benzene ≤2ppm	Not detected
Conclusion	This product conforms to EP11 standard	

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