

Certificate of analysis

Rifaximin

CAS No.	80621-81-4	Code	BIOJRI001
Batch No	20231207	Manufacture Date	Dec.29, 2023
Expiry Date	Dec.28, 2025	Quantity	30Kgs

Testing Items	Specifications	Results
Appearance	Red-orange or dark-red, crystalline powder, odourless	Red-orange, crystalline powder, odourless
Identification	HPLC: The retention time of major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of standard preparation.	Complies
	IR: The infrared absorption of the sample should correspond to that of standard	Complies
Solubility	Freely soluble in methanol and acetonitrile, soluble in ethanol, practically insoluble in 0.1mol/L solution of hydrochloric acid or water	Complies
Crystallinity	Meet the requirements	Complies
pH	4.5~7.5	6.3
Related Substances	Single impurity \leq 1.0% Total impurities \leq 3.0%	0.4% 0.6%
Loss on Drying	\leq 4.5%	0.5%
Residue on Ignition	\leq 0.1%	0.07%
Heavy Metals	\leq 20ppm	<20ppm
Assay	\geq 95% (on dried basis)	99.5%
Conclusion	This product conforms to CP2020 standard	

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