

Certificate of analysis

Rifaximin

CAS No.	80621-81-4	Code	BIOJRI001
Batch No	20230910	Manufacture Date	Sep.10, 2023
Expiry Date	Sep.09, 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	6.5
Related Substances	Single impurity $\leq 1.0\%$ Total impurities $\leq 3.0\%$	0.27% 0.5%
Loss on Drying	$\leq 4.5\%$	2.9%
Residue on Ignition	$\leq 0.1\%$	0.03%
Heavy Metals	$\leq 20\text{ppm}$	$< 20\text{ppm}$
Assay	$\geq 95\%$ (on dried basis)	97.2%
Conclusion	This product conforms to CP2015 standard	

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