

Certificate of Analysis

Rifaximin

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|-------------|--------------|------------------|--------------|
| CAS No. | 80621-81-4 | Code | BIOJRI001 |
| Batch No | F011-250416 | Manufacture Date | Apr.28, 2025 |
| Retest Date | Apr.27, 2027 | 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). | 0.35% |
| | 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). | 0.09% |
| | Total impurities: not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution(a) (1.0 percent). | 0.62% |
| Water | ≤4.5% | 2.4% |
| Sulphated ash | ≤0.1% | 0.02% |
| Assay (HPLC) | 97.0%~102.0% (Calculated on the anhydrous basis) | 100.5% |
| Residual solvents (GC) | Methanol ≤3000ppm | 1721ppm |
| | Benzene ≤2ppm | Not detected |
| Conclusion | This product conforms to EP11 standard | |

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