



INDOFINE Chemical Company, Inc.

121 Stryker Lane, Bldg. 30, Suite 1 • Hillsborough, NJ 08844 • U.S.A.

Phone: (908) 359-6778 • FAX: (908) 359-1179

website: www.indofinechemical.com

e-mail: chemical@indofinechemical.com

Certificate of Analysis

Catalogue Number	BIO-346
Lot Number	002943-1903041
Product	Rifampicin 3-(4-Methylpiperazinyloxyethyl)rifamycin SV
CAS Number	13292-46-1
Molecular Formula	C ₄₃ H ₅₈ N ₄ O ₁₂
Molecular Weight	823

Appearance	Red-brown crystalline powder
Solubility	Very slightly soluble in water Freely soluble in chloroform Soluble in ethylacetate and in methanol
Crystallinity	Meets the requirement
pH	5.9
Mould and Yeast	< 100 cfu/g
Infrared Spectrum	Conforms to structure
Loss on Drying	0.3%
Residual Solvents	Acetone : < 5000 ppm 1-Butanol : < 5000 ppm Ethyl acetate : < 5000 ppm Butyl acetate : < 5000 ppm N,N-Dimethylformamide : < 880 ppm
E. Coli	Absent
Microbial Count	< 1000 cfu/g (TAMC)
Related Substances	Rifampin quinone : 0.1% Any other individual related substance : 0.5% Total impurities other than Rifampin quinone : 1.6%
Assay by titration	98.32%
Grade	USP
Storage	Store at 0 - 8 °C

Prepared by:
Ramesh Mandadi
Ramesh Mandadi
Director of Operations

Reviewed and approved by:
Sujata Moton
S. Moton
VP