

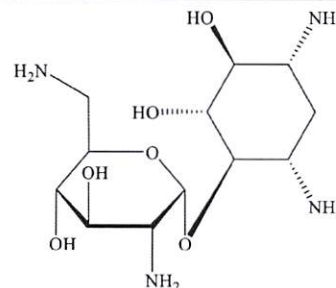
## Certificate of Analysis

Certificate No.: 20241121502



Date: November 21, 2024

Retest date: November 15, 2027

|  |  |
|--|--|
| <b>Compound Name:</b> Neomycin Sulfate EP Impurity A (Neamine) |  |
| <b>Synonyms:</b>   | (2R,3S,4R,5R,6R)-5-amino-2-(aminomethyl)-6-(((1R,2R,3S,4R,6S)-4,6-diamino-2,3-dihydroxycyclohexyl)oxy)tetrahydro-2H-pyran-3,4-diol |
| <b>TLC Catalogue Number:</b>                                   | N-080003   |
| <b>CAS Number:</b>   | 3947-65-7  |
| <b>Molecular Weight:</b>                                       | 322.36   |
| <b>Molecular Formula:</b>                                      | C <sub>12</sub> H <sub>26</sub> N <sub>4</sub> O <sub>6</sub>  |
| <b>Source:</b>   | TLC Pharmaceutical Standards   |
| <b>Source Lot No.:</b>   | C0031-009A2  |
| <b>Storage Conditions:</b>                                     | Store at 2-8 °C  |
| <b>Solubility:</b>   | Methanol, DMSO, DMF, Water   |



| Test Description               | Specifications                                 | Results  |
|--------------------------------|--|--|
| <b>Visual Description</b>      | White to off-white solid                       | <b>Conforms</b>                                |
| <b>Identification</b>          |  |  |
| <b>IR</b>                      | Conforms to structure                          | <b>Conforms</b>                                |
| <b>MS</b>                      | Conforms to structure                          | <b>Conforms</b>                                |
| <b><sup>1</sup>H NMR</b>       | Conforms to structure                          | <b>Conforms</b>                                |
| <b>Elemental Analysis</b>      | Conforms to structure                          | <b>Conforms</b>                                |
| <b>Purity (HPLC)</b>           | Not less than 95.0%                            | <b>99.4%</b>                                   |
| <b>Impurity (HPLC)</b>         | RT 3.69, 0.51%                                 |  |
| <b>Optical Rotation</b>        | $[\alpha]_D^{21.0}(c=1.00, H_2O): +86.2^\circ$ | $[\alpha]_D^{25.0}(c=0.33, H_2O): +89.4^\circ$ |
| <b>Residual Solvents (NMR)</b> | No residual solvent                            |  |
| <b>Assay (qNMR)</b>            | Not less than 80.0%                            | <b>84.4%</b>                                   |
| <b>Recommendation:</b>         | <b>Release.</b>                                |  |

| Name                      | Department        | Signature  | Date       |
|---------------------------|-------------------|--|------------|
| Reviewed and approved by: | Quality Control   |  | 11/22/2024 |
| Approved by:              | Quality Assurance |  | 11/22/2024 |

**Attachments:** HPLC, IR, MS and NMR spectra.