

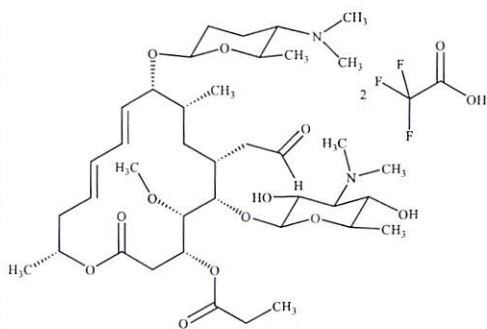
## Certificate of Analysis

Certificate No.: **20250604019**



Date: June 4, 2025

Retest date: May 27, 2028

<b>Compound Name:</b> Spiramycin EP Impurity H Ditrifluoroacetate	
<b>Synonyms:</b>	(4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-(((2S,3R,4S,5S,6R)-4-(dimethylamino)-3,5-dihydroxy-6-methyltetrahydro-2H-pyran-2-yl)oxy)-10-(((2R,5S,6R)-5-(dimethylamino)-6-methyltetrahydro-2H-pyran-2-yl)oxy)-5-methoxy-9,16-dimethyl-2-oxo-7-(2-oxoethyl)oxacyclohexadeca-11,13-dien-4-yl propionate, 2,2,2-trifluoroacetic acid (1:2)
<b>TLC Catalogue Number:</b>	S-439
<b>CAS Number:</b>	N/A
<b>Alternate CAS Number:</b>	N/A
<b>Molecular Weight:</b>	754.96 2*114.02
<b>Molecular Formula:</b>	C <sub>39</sub> H <sub>66</sub> N <sub>2</sub> O <sub>12</sub> . 2 C <sub>2</sub> HF <sub>3</sub> O <sub>2</sub>
<b>Source:</b>	TLC Pharmaceutical Standards
<b>Source Lot No.:</b>	6868-049A3
<b>Storage Conditions:</b>	Store at 2-8 °C
<b>Solubility:</b>	Methanol, DMSO, Water, Acetonitrile



Test Description	Specifications	Results
<b>Visual Description</b>	Off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<sup>19</sup> F NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 95.0%	<b>98.0%</b>
<b>Impurity (HPLC)</b>	RT 2.76, 0.53%; RT 8.30, 0.17%; RT 11.53, 0.45%	
<b>Residual Solvents (NMR)</b>	0.1% dichloromethane	
<b>Assay (qNMR)</b>	Not less than 90.0%	<b>92.7%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/04/2025
Approved by:	Quality Assurance		06/04/2025

**Attachments:** Peak Attribution Table, HPLC, IR, MS and NMR spectra.