

Analysis Date: 10-11-2025

Re-test Date: 10-11-2028

## SPIRAMYCIN EP IMPURITY G

### Identification

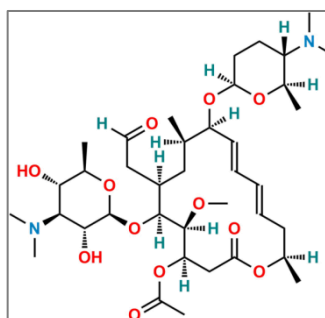
**Chemical Name** : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-[[3,6-dideoxy-3-(dimethylamino)-β-d-glucopyranosyl]oxy]-5-methoxy-9,16-dimethyl-2-oxo-7-(2-oxoethyl)-10-[[2,3,4,6-tetradeoxy-4-(dimethylamino)-β-d-erythro-hexopyranosyl]oxy]oxacyclohexadeca-11,13-dien-4-yl acetate (as per EP)

**CAT No** : ALL-S09304

**CAS No** : N.A.

**Molecular Formula** : C<sub>38</sub>H<sub>64</sub>N<sub>2</sub>O<sub>12</sub>

**Molecular Weight** : 740.9



### Analytical Information

<b>Batch Code</b>	: ALL-S09304	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 95.56%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 1.096%	<b><sup>1</sup>H NMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 1.392%		

### Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (1.096+1.392) × 98.00]/100 = 95.56%

**Recommendation** : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul khadase Jr. Executive	
Approved By	QA&QC	Dr. Ashish Keche Director QA&QC	

**Attachment** : HPLC, Mass, <sup>1</sup>H NMR, IR, TGA

**Shipping Condition** : All Product are stable to be shipped at room temperature, unless otherwise specified

#### Corporate Office