

Analysis Date: 10-11-2025

Re-test Date: 10-11-2028

## SPIRAMYCIN EP IMPURITY D

### Identification

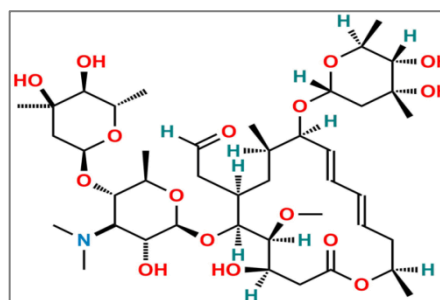
**Chemical Name** : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-[[3,6-dideoxy-4-O-(2,6-dideoxy-3-C-methyl- $\alpha$ -l-ribo-hexopyranosyl)-3-(dimethylamino)- $\beta$ -d-glucopyranosyl]oxy]-10-[(2,6-dideoxy-3-C-methyl- $\alpha$ -l-ribo-hexopyranosyl)oxy]-4-hydroxy-5-methoxy-9,16-dimethyl-7-(2-oxoethyl)oxacyclohexadeca-11,13-dien-2-one (as per EP)

**CAT No** : ALL-S09301

**CAS No** : 87708-39-2

**Molecular Formula** : C<sub>42</sub>H<sub>71</sub>NO<sub>16</sub>

**Molecular Weight** : 846.0



### Analytical Information

<b>Batch No.</b>	: ALL-S09301	<b>HPLC Purity</b>	: 98.00 %
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 97.29%
<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>	: 0.245 %	<b><sup>1</sup>HNMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 0.477%		

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (0.245 + 0.477) × 98.00]/100 = 97.29%

**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