

Analysis Date: 10-11-2025

Re-test Date: 10-11-2028

SPIRAMYCIN EP IMPURITY B

Identification

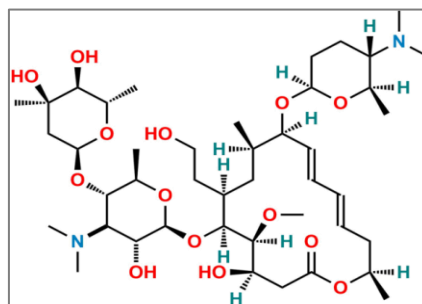
Chemical Name : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-[[3,6-dideoxy-4-O-(2,6-dideoxy-3-C-methyl- α -l-ribo-hexopyranosyl)-3-(dimethylamino)- β -d-glucopyranosyl]oxy]-4-hydroxy-7-(2-hydroxyethyl)-5-methoxy-9,16-dimethyl-10-[[2,3,4,6-tetradeoxy-4-(dimethylamino)- β -d-erythro-hexopyranosyl]oxy]oxacyclohexadeca-11,13-dien-2-one

CAT No : ALL-S09298

CAS No : 249930-66-3

Molecular Formula : C₄₃H₇₆N₂O₁₄

Molecular Weight : 845.1



Analytical Information

Batch Number	: ALL-S09298	HPLC Purity	: 98.00 %
Solubility	: MeOH: ACN	Potency	: 96.30 %
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: 2-8 °C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.199 %	¹H NMR	: Confirm
Residue Of Ignition	: 0.534 %		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.199+0.534) × 98.00]/100 = 96.30 %

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, 1H NMR, IR, TGA

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

Corporate Office