Certificate Of Analysis

Analysis Date: 10-11-2025 **Re-test Date:** 10-11-2028

SPIRAMYCIN EP IMPURITY A

Identification

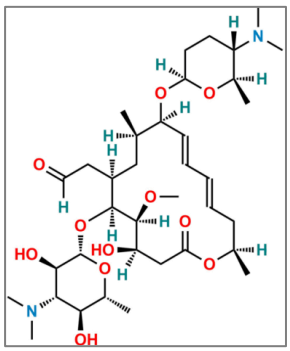
Chemical Name : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-[[3,6-dideoxy-3-(dimethylamino)-β-d-glucopyranosyl]oxy]-4-hydroxy-5-methoxy-9,16-dimethyl-7-(2-oxoethyl)-10-[[2,3,4,6-tetradeoxy-4-(dimethylamino)-β-d-erythro-hexopyranosyl]oxy]oxacyclohexadeca-11,13-dien-2-one (as per EP)

CAT No : ALL-S09299

CAS No : 70253-62-2

Molecular Formula : C36H62N2O11

Molecular Weight : 698.9



Analytical Information

Batch Number	: ALL-S09299	**HPLC Purity**	: 98.00 %
Solubility	: MeOH: ACN	**Potency**	: 96.51 %
Appearance of Product	: Off White Solid	**Mass**	: Confirm
Long Term Storage	: 2-8 ^{0}C	**IR Analysis**	: Confirm
Weight Loss By TGA	: 0.364 %	**1HNMR**	: Confirm
Residue Of Ignition	: 0.745 %		

Additional Information

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

[100 – (0.364 +0.745) × 98.00]/100 = 96.51 %

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

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