

Analysis Date: 10-11-2025

Re-test Date: 10-11-2028

SPIRAMYCIN EP IMPURITY H

Identification

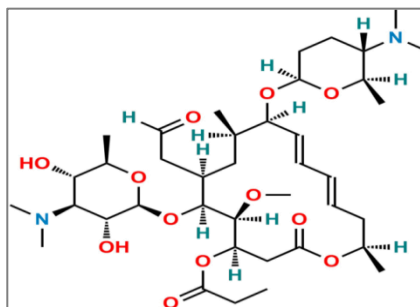
Chemical Name : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-[[3,6-dideoxy-3-(dimethylamino)-β-d-glucopyranosyl]oxy]-5-methoxy-9,16-dimethyl-2-oxo-7-(2-oxoethyl)-10-[[2,3,4,6-tetra-deoxy-4-(dimethylamino)-β-d-erythro-hexopyranosyl]oxy]oxacyclohexadeca-11,13-dien-4-yl propanoate (as per EP)

CAT No : ALL-S09305

CAS No : 4617-99-6

Molecular Formula : C₃₉H₆₆N₂O₁₂

Molecular Weight : 755.0



Analytical Information

Batch Code	: ALL-S09305	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 97.87%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.024%	¹H NMR	: Confirm
Residue Of Ignition	: 0.108%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (0.024+0.108) × 98.00]/100 = 97.87%

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