

Analysis Date: 16-12-2025

Re-test Date: 16-12-2028

JOSAMYCIN EP IMPURITY H

Identification

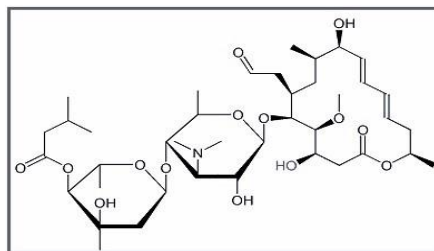
Chemical Name : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-6-[[[3,6-Dideoxy-4-O-[2,6-dideoxy-3-C-methyl-4-O-(3-methylbutanoyl)-α-L-ribo-hexopyranosyl]-3-(dimethylamino)-β-D-glucopyranosyl] oxy]-4,10-dihydroxy-5-methoxy-9,16-dimethyl-7-(2-oxoethyl)oxacyclohexadeca-11,13-dien-2-one

CAT No : ALL-JOS-347

CAS No : 16846-34-7

Molecular Formula : C₄₀H₆₇NO₁₄

Molecular Weight : 785.96



Analytical Information

Batch Code	: ALL-JOS-347	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 96.19%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20 ^o C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.215%	¹H NMR	: Confirm
Residue Of Ignition	: 0.622%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.215+0.622) × 98.00]/100 = 96.19%

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