

Analysis Date: 16-12-2025

Re-test Date: 16-12-2028

JOSAMYCIN EP IMPURITY B

Identification

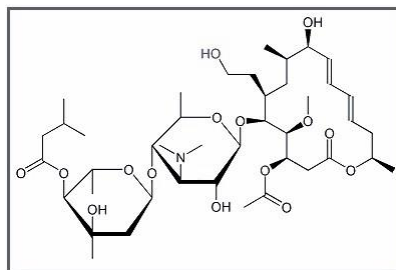
Chemical Name : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-4-(Acetyloxy)-6-[[[3,6-dideoxy-4-O-[2,6-dideoxy-3-C-methyl-4-O-(3-methylbutanoyl)-α-L-ribo-hexopyranosyl]-3-(dimethylamino)-β-D-glucoopyranosyl]oxy]-10-hydroxy-7-(2-hydroxyethyl)-5-methoxy-9,16-dimethyloxacyclohexadeca-11,13-dien-2-one

CAT No : ALL-JOS-419

CAS No : 40361-41-9

Molecular Formula : C₄₂H₇₁NO₁₅

Molecular Weight : 830.01



Analytical Information

Batch Code	: ALL-JOS-419	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 95.93%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20 ^o C	IR Analysis	: Confirm
Weight Loss By TGA	: 1.633%	¹H NMR	: Confirm
Residue Of Ignition	: 0.472%		

Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =
 [100 - (1.633+0.472) × 98.00]/100 = 95.93%

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