

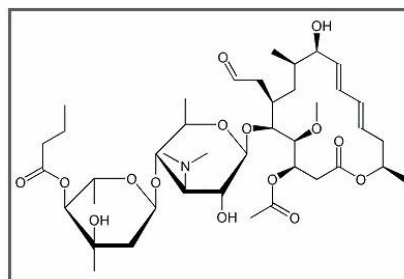
Analysis Date: 16-12-2025

Re-test Date: 16-12-2028

JOSAMYCIN EP IMPURITY A

Identification

Chemical Name	: (4R,5S,6S,7R,9R,10R,11E,13E,16R)-4-(Acetyloxy)-6-[[[3,6-dideoxy-4-O-(2,6-dideoxy-4-O-butanoyl-3-C-methyl-α-L-ribo-hexopyranosyl)-3-(dimethylamino)-β-D-glucopyranosyloxy]-10-hydroxy-5-methoxy-9,16-dimethyl-7-(2-oxoethyl)oxacyclohexadeca-11,13-dien-2-one
CAT No	: ALL-JOS-001
CAS No	: 18361-46-1
Molecular Formula	: C ₄₁ H ₆₇ NO ₁₅
Molecular Weight	: 813.97



Analytical Information

Batch Code	: ALL-JOS-001	HPLC Purity	: 98.00%
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 97.02%
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20 ^o C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.257%	¹H NMR	: Confirm
Residue Of Ignition	: 0.741%		

Additional Information

$$\% \text{Potency} = [100 - (\text{Weight Loss By TGA \%} + \text{Residue Of Ignition \%}) \times \text{Chromatographic Purity\%}] / 100 =$$

$$[100 - (0.257 + 0.741) \times 98.00] / 100 = 97.02\%$$

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