

Analysis Date: 16-12-2025

Re-test Date: 16-12-2028

## JOSAMYCIN EP IMPURITY J

### Identification

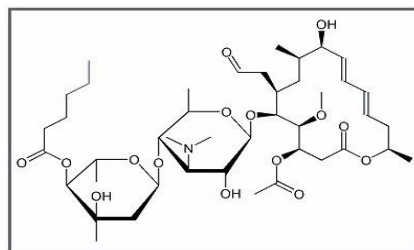
**Chemical Name** : (4R,5S,6S,7R,9R,10R,11E,13E,16R)-4-(Acetyloxy)-6-[[[3,6-dideoxy-4-O-(2,6-dideoxy-4-O-hexanoyl-3-C-methyl-α-L-ribo-hexopyranosyl)-3-(dimethylamino)-β-D-glucopyranosyl]oxy]-10-hydroxy-5-methoxy-9,16-dimethyl-7-(2-oxoethyl)oxacyclohexadeca-11,13-dien-2-one

**CAT No** : ALL-JOS-003

**CAS No** : 851759-08-5

**Molecular Formula** : C<sub>43</sub>H<sub>71</sub>NO<sub>15</sub>

**Molecular Weight** : 842.02



### Analytical Information

<b>Batch Code</b>	: ALL-JOS-003	<b>HPLC Purity</b>	: 98.00%
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 96.59%
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20 <sup>o</sup> C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.784%	<b><sup>1</sup>H NMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 0.654%		

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (0.784+0.654) × 98.00]/100 = 96.59%

**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, <sup>1</sup>H NMR, IR, TGA

**Shipping Condition** : All Product are stable to be shipped at room temperature, unless otherwise specified

#### Corporate Office