

Analysis Date: 31-05-2025

Re-test Date: 31-05-2028

## CLINDAMYCIN PHOSPHATE EP IMPURITY I

### Identification

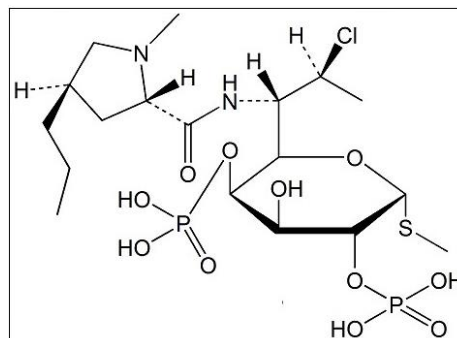
**Chemical Name** : Methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propyl-2-pyrrolidiny] carbonyl]amino]-1-thio-L-threo- $\alpha$ -D-galacto-octopyranoside 2,4-bis(dihydrogen phosphate)

**CAT No** : ALL-C03868

**CAS No** : 1309048-48-3

**Molecular Formula** : C<sub>18</sub>H<sub>35</sub>ClN<sub>2</sub>O<sub>11</sub>P<sub>2</sub>S

**Molecular Weight** : 584.94



### Analytical Information

<b>Batch No</b>	: ALL- C03868	<b>HPLC Purity</b>	: 99.62 %
<b>Solubility</b>	: USP Diluent / EP Diluent (MEOH)	<b>Potency</b>	: 96.95 %
<b>Appearance of Product</b>	: Off White Solid	<b>Mass</b>	: Confirm
<b>Long Term Storage</b>	: -20°C	<b>IR Analysis</b>	: Confirm
<b>Weight Loss By TGA</b>	: 0.276 %	<b><sup>1</sup>HNMR</b>	: Confirm
<b>Residue Of Ignition</b>	: 2.402 %		

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (0.276+2.402) × 99.62]/100 = 96.95 %

**Recommendation** : Released

	Department	Name	Signature
Prepared and Reviewed by	Analytical	Mr. Vipul Khadse 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