

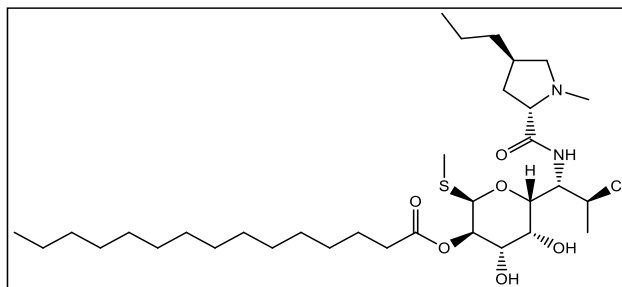
Analysis Date: 05-12-2024

Re-test Date: 05-12-2027

## CLINDAMYCIN PENTADECANOATE IMPURITY

### 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-pentadecanoate |
| CAT No            | : ALL-C03238                                                                                                                                                       |
| CAS No            | : 1123211-67-5                                                                                                                                                     |
| Molecular Formula | : C33H61ClN2O6S                                                                                                                                                    |
| Molecular Weight  | : 649.37                                                                                                                                                           |



### Analytical Information

|                       |                                   |                   |           |
|-----------------------|-----------------------------------|-------------------|-----------|
| Batch Code            | : ALL-C03238                      | HPLC Purity       | : 94.52 % |
| Solubility            | : USP Diluent / EP Diluent (MEOH) | Potency           | : 93.39 % |
| Appearance of Product | : Off White Solid                 | Mass              | : Confirm |
| Long Term Storage     | : -20°C                           | IR Analysis       | : Confirm |
| Weight Loss By TGA    | : 0.381 %                         | <sup>1</sup> HNMR | : Confirm |
| Residue Of Ignition   | : 0.807 %                         |                   |           |

### Additional Information

%Potency = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
[100 - (0.381+0.807) × 94.52]/100 = 93.39 %

Recommendation : Released

|                          | Department | Name                               | Signature |
|--------------------------|------------|------------------------------------|-----------|
| Prepared and Reviewed by | Analytical | Mr. Vipul Khadse<br>Jr. Executive  |           |
| Approved By              | QA&QC      | Dr. Ashish Keche<br>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

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