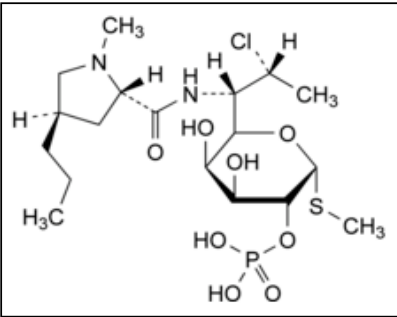


Analysis Date: 13-11-2024

Re-test Date: 13-11-2027

CLINDAMYCIN PHOSPHATE EP IMPURITY L / 7-EPI-CLINDAMYCIN PHOSPHATE

Identification

| | | |
|--------------------------|---|--|
| Chemical Name | : Methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-2-O-phosphono-1-thio-D-erythro- α -D-galacto-octopyranoside |  |
| CAT No | : ALL-C03361 | |
| CAS No | : 620181-05-7 | |
| Molecular Formula | : C ₁₈ H ₃₄ ClN ₂ O ₈ PS | |
| Molecular Weight | : 504.96 | |

Analytical Information

| | | | |
|------------------------------|-----------------------------------|-------------------------|-----------|
| Batch No | : ALL- C03361 | HPLC Purity | : 98.12 % |
| Solubility | : USP Diluent / EP Diluent (MEOH) | Potency | : 95.56 % |
| Appearance of Product | : Off White Solid | Mass | : Confirm |
| Long Term Storage | : -20°C | IR Analysis | : Confirm |
| Weight Loss By TGA | : 1.139 % | ¹HNMR | : Confirm |
| Residue Of Ignition | : 1.464 % | | |

Additional Information

$$\%Potency = [100 - (\text{Weight Loss By TGA \%} + \text{Residue Of Ignition \%}) \times \text{Chromatographic Purity\%}] / 100 = [100 - (1.139 + 1.464) \times 98.12] / 100 = 95.56 \%$$

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, ¹H NMR, IR, TGA

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

Corporate Office