

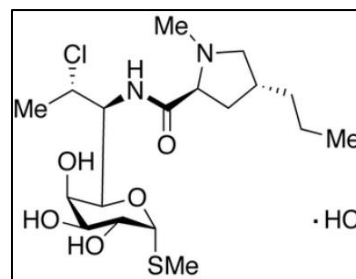
Analysis Date: 06-10-2023

Re-test Date: 06-10-2026

CLINDAMYCIN PHOSPHATE EP IMPURITY E

Identification

Chemical Name	: Methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propylpyrrolidin-2-yl]carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside hydrochloride
CAT No	: ALL-C03695
CAS No	: 21462-39-5(HCl) 18323-44-9 (Base)
Molecular Formula	: C ₁₈ H ₃₃ ClN ₂ O ₅ S : HCl
Molecular Weight	: 461.44



Analytical Information

Batch No	: ALL-C03695	HPLC Purity	: 99.72 %
Solubility	: USP Diluent / EP Diluent (MEOH)	Potency	: 98.95 %
Appearance of Product	: Off White Solid	Mass	: Confirm
Long Term Storage	: -20°C	IR Analysis	: Confirm
Weight Loss By TGA	: 0.619 %	¹H NMR	: Confirm
Residue Of Ignition	: 0.183 %		

Additional Information

$$\% \text{Potency} = [100 - (\text{Weight Loss By TGA \%} + \text{Residue Of Ignition \%}) \times \text{Chromatographic Purity\%}] / 100 = [100 - (0.619 + 0.183) \times 99.72] / 100 = 98.92 \%$$

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