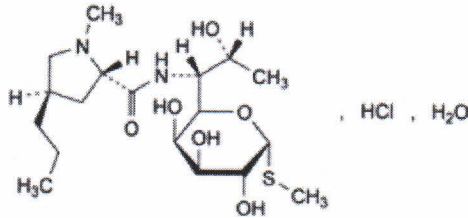




Lincomycin HCl EP8.0

Batch no 2207006  
Mf date Jul 10 2022  
Exp date Jun 2025  
Batch qty 760 bou

Molecular Structure



Molecular Formula C<sub>18</sub>H<sub>35</sub>ClN<sub>2</sub>O<sub>6</sub>S, H<sub>2</sub>O  
Molecular Weight 461.0  
CAS Registry Number 7179-49-9

Mar 10 2023

Tests	Specifications	Results
Appearance	A white or almost white crystalline powder	A white crystalline powder
Identification	IR, test of chlorides	Positive
Appearance of solution	The solution is clear, and not more intensely coloured than reference solution Y <sub>6</sub>	Conforms
Specific optical rotation	+135 ~ +150°	+142°
pH	3.5 ~ 5.5	4.3
Related substances	Impurity A ≤ 0.5% Impurity B ≤ 0.5% Impurity C ≤ 0.2% Any unspecified impurity ≤ 0.10% Total impurities ≤ 2.0%	0.11% 0.12% 0.13% 0.04% 1.1%
Heavy metals	≤ 5 ppm	< 5 ppm
Sulfated ash	≤ 0.5%	< 0.1%
Water	3.1 ~ 4.6%	3.9%
Residual solvents	n-Butanol ≤ 0.5% Acetone ≤ 0.5%	0.02% 0.07%
Bacterial endotoxins	< 0.5 IU/mg	< 0.5 IU/mg
Lincomycin B HCl	≤ 5.0%	2.2%
Assay (oab)	96.0 ~ 102.0% (Lincomycin HCl + Lincomycin B HCl)	99.1%
Packaging & storage	Store in an airtight container at a temperature not exceeding 30°C	
Conclusion	Material complies with EP8.0	

